



IN THE UNITED STATES DISTRICT COURT  
FOR THE CENTRAL DISTRICT OF CALIFORNIA  
EASTERN DIVISION

AMPHASTAR PHARMACEUTICALS INC.	*	
Plaintiff	*	
vs.	*	EDCV-09-0023 MJG
AVENTIS PHARMA SA, et al.	*	
Defendants	*	
* * * * *		

MEMORANDUM AND ORDER RE: MOTION TO DISMISS

The Court has before it Defendants' Motion to Dismiss False Claims Act Qui Tam Complaint [Document 43-1], Defendants' Request for Judicial Notice [Document 44], and the materials submitted relating thereto. The Court has held a hearing and has had the benefit of the arguments of counsel.

I. BACKGROUND

A. The First Suit

At all times relevant hereto, Amphastar Pharmaceuticals, Inc. ("Amphastar") and Sanofi-Aventis S.A. ("Aventis")<sup>1</sup> have been competitors in the pharmaceutical industry.

---

<sup>1</sup> It appears that Defendants, Aventis Pharma S.A. (a French corporation) and Aventis Pharmaceuticals, Inc. (the American subsidiary), merged with and into Sanofi-Aventis S.A., which is the surviving company although it continues to do business under the names of the predecessor companies. For purposes of this

In 1995, Aventis received U.S. Patent No. 5,318,618 ("the '618 Patent") for an anti-coagulant drug, referred to as enoxaparin. Aventis sold the drug under the brand name Lovenox®.<sup>2</sup> The drug can be used to prevent potentially fatal blood clot formation. Aventis lodged a Food and Drug Administration ("FDA") citizen petition in February 2003, arguing that enoxaparin is highly sensitive to Aventis's manufacturing process and that generics should be approved only if shown to be the same as Lovenox.

Later in 2003, Amphastar filed an Abbreviated New Drug Application ("ANDA") with the FDA, requesting the right to commercially manufacture a generic enoxaparin in competition with Aventis, and certifying that Aventis's patents were invalid, unenforceable, or not infringed. Aventis then filed a patent infringement suit against Amphastar (Civil No. 03-0887 MRP filed August 4, 2003) ("the First Suit"). This triggered a 30-month stay on FDA approval of Amphastar's ANDA.<sup>3</sup> In the First Suit, Aventis filed an antitrust counterclaim.

---

memorandum, Defendants are referred to collectively as "Aventis."

<sup>2</sup> A European patent was issued in 1984 on the drug, but it was revoked in October 1990 as a result of a novelty opposition.

<sup>3</sup> When an ANDA applicant makes a certification of invalidity, unenforceability, or noninfringement, this action constitutes a constructive act of infringement, which gives the patent holder standing to sue within 45 days after notice. Filing suit prevents the FDA from approving the ANDA for 30

In the First Suit, Amphastar was granted summary judgment on its affirmative defense and counterclaim of inequitable conduct and the antitrust counterclaim was stayed pending appeal of the infringement claim dismissal. Aventis Pharma S.A. v. Amphastar Pharm., Inc., 390 F. Supp. 2d 952 (C.D. Cal. 2005). On appeal, the Federal Circuit reversed and remanded for the district court to find whether Amphastar could prove intent to deceive by clear and convincing evidence. Aventis Pharma S.A. v. Amphastar Pharm., Inc., 525 F.3d 1334 (Fed. Cir. 2008).

On remand, Judge Pfaelzer of this Court held a bench trial, made the requisite finding, and found the patents unenforceable on the grounds of inequitable conduct. This decision was affirmed by the Federal Circuit. Thereafter, the stay of the antitrust counterclaim was lifted. In January 2009, Aventis filed a motion to dismiss the antitrust counterclaim in the First Suit. In February 2009, Aventis's motion to dismiss the antitrust counterclaim was granted because the antitrust allegations that survived Noerr-Pennington immunity failed to allege antitrust injury, a necessary element. See Mot. Ex. 1, Aventis v. Amphastar, No. 03-cv-0887 (C.D. Cal. May 15, 2009).

---

months from the notice date. Unlike an ordinary infringement suit, this type of infringement suit bars the FDA from approving an ANDA, thereby excluding the would-be entrant from the market. This consequence frequently engenders antitrust claims.

B. The Instant Case

In January 2009,<sup>4</sup> Amphastar commenced the instant litigation by filing the sealed qui tam Complaint under the False Claims Act ("FCA"), 31 U.S.C. § 3729 [Document 1] on behalf of the United States ("the Government") and several states.

In the instant case, Amphastar claims that Aventis:

- (1) made false representations to the U.S. Patent & Trademark Office ("PTO") while prosecuting its U.S. patents;
- (2) improperly listed its '618 patent and another Aventis patent, U.S. Patent No. 4,692,435 ("the '435 patent"), in the FDA's "Orange Book"<sup>5</sup> indicating that both patents covered Lovenox;
- (3) engaged in baseless litigation against Amphastar that triggered the 30-month stay of its ANDA;
- (4) made false representations and material omissions to the FDA; and
- (5) attempted to control the supply of components necessary for market approval or marketing of enoxaparin.

Mot. 10.

Amphastar alleges that Aventis thereby fraudulently inflated the price of enoxaparin, thus overcharging the federal

---

<sup>4</sup> The same month in which Aventis filed its motion to dismiss the antitrust counterclaim in the First Suit.

<sup>5</sup> An ANDA must include the patent numbers and the expiration dates of any patents which claim the drug and methods of using the drug. After approval, these patents are listed in a publication commonly known as the "Orange Book." Drugs with ANDA approval are known as "brand-name" drugs.

and various state governments. The Government and the states elected to decline intervention<sup>6</sup> on October 19, 2011. [Documents 30 and 31]. The Complaint was unsealed on October 28, 2011. [Document 32].

By the instant motion, Aventis seeks dismissal of all claims on three grounds:

- (1) lack of subject matter jurisdiction;
- (2) failure to state an FCA claim upon the alleged antitrust violations; and
- (3) failure to meet the minimum standards required for FCA qui tam claims.

## II. DISMISSAL STANDARD

### A. Lack of Subject Matter Jurisdiction, Rule 12(b)(1)<sup>7</sup>

A motion to dismiss filed under Rule 12(b)(1) addresses the court's subject matter jurisdiction. A federal court has federal-question subject matter jurisdiction over an action that arises under federal law and diversity jurisdiction when there is complete diversity of citizenship between the parties and the amount in controversy exceeds \$75,000. See 28 U.S.C. §§ 1331, 1332(a). In the instant case, the existence vel non of

---

<sup>6</sup> Because any rulings in this case could affect the Government's ability to bring future FCA cases, it maintains a continuing interest in this matter and filed an amicus brief [Document 59] in response to the instant motion.

<sup>7</sup> All Rule references herein refer to the Federal Rules of Civil Procedure unless otherwise indicated.

diversity jurisdiction is immaterial. Amphastar can obtain federal-question jurisdiction only if it has a viable case under the FCA.

The plaintiff bears the burden of proving jurisdiction to survive a Rule 12(b)(1) motion to dismiss. Kokkonen v. Guardian Life Ins. Co. of Am., 511 U.S. 375, 377 (1994). The applicable standard depends on the nature of the jurisdictional challenge.

A jurisdictional attack may be either facial or factual. Safe Air for Everyone v. Meyer, 373 F.3d 1035, 1039 (9th Cir. 2004). In a facial attack, the movant "asserts that the allegations contained in a complaint are insufficient on their face to invoke federal jurisdiction." Id. The court considers the complaint's allegations to be true, and "the plaintiff enjoys safeguards akin to those applied when a Rule 12(b)(6) motion is made." Doe v. Schachter, 804 F. Supp. 53, 57 (N.D. Cal. 1992).

A factual attack occurs when the movant "disputes the truth of the allegations that, by themselves, would otherwise invoke federal jurisdiction." Safe Air, 373 F.3d at 1039. The court is not restricted to the face of the pleadings when there is a fact-based challenge to jurisdiction, but may consider evidence outside the four corners of the Complaint and must resolve material issues of fact. See id.

In a Rule 12(b)(1) dismissal context, “where the jurisdictional issue is separable from the merits of the case, the court may hear evidence regarding jurisdiction, resolve existing factual disputes, and rule on that issue.” Doe, 804 F. Supp. at 57 (citing Thornhill Pub. Co. v. General Tel. & Elecs. Corp., 594 F.2d 730, 733 (9th Cir. 1979)). When jurisdictional and substantive issues are intertwined, such that the question of jurisdiction is dependent on resolving factual issues going to the merits, the court should reserve determination of the issue to a motion on the merits or trial. Id. (citing Augustine v. United States, 704 F.2d 1074, 1077 (9th Cir. 1983)).

B. Failure to State a Claim, Rule 12(b)(6)

A motion to dismiss filed under Rule 12(b)(6) tests the legal sufficiency of a complaint. A complaint need only contain “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) (citations omitted).

When evaluating a Rule 12(b)(6) motion to dismiss, a plaintiff’s well-pleaded allegations are accepted as true and the complaint is viewed in the light most favorable to the

plaintiff. Broam v. Bogan, 320 F.3d 1023, 1028 (9th Cir. 2003). However, conclusory statements or a "formulaic recitation of the elements of a cause of action" will not suffice. Twombly, 550 U.S. at 555. A complaint must allege sufficient facts to cross "the line between possibility and plausibility of entitlement to relief." Id. at 557.

Inquiry into whether a complaint states a plausible claim is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." Chavez v. United States, 683 F.3d 1102, 1109 (9th Cir. 2012)(quoting Ashcroft v. Iqbal, 556 U.S. 662, 679 (2009)). Thus, if the well-pleaded facts contained within a complaint "do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged - but it has not shown - that the pleader is entitled to relief." Iqbal, 556 U.S. at 679 (quoting Fed. R. Civ. P. 8(a)(2)) (internal quotation marks omitted).

### III. DISCUSSION

#### A. Judicial Notice

Defendants request the Court to take judicial notice of 16 documents under Fed. R. Evid. 201. The documents in question are publicly available filings, transcripts, and regulatory

submissions associated with four prior legal proceedings between the parties.<sup>8</sup>

Judicial notice may be taken of a fact "not subject to reasonable dispute in that it is capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201.

A court "may take notice of proceedings in other courts, both within and without the federal judicial system, if those proceedings have a direct relation to matters at issue." United States ex rel. Robinson Rancheria Citizens Council v. Borneo, Inc., 971 F.2d 244, 248 (9th Cir. 1992).

Under the judicial notice doctrine, a court may consider matters of public record, such as court filings, but it may not do so for the truth of the facts recited therein. See Lee v. City of Los Angeles, 250 F.3d 668, 690 (9th Cir. 2001). "When a court takes judicial notice of another court's opinion, it may do so 'not for the truth of the facts recited therein, but for the existence of the opinion, which is not subject to reasonable dispute over its authenticity.'" Id. (citation omitted); see also Wright & Graham, Federal Practice and Procedure: Evidence 2d § 5104 ("one of the major abuses of judicial notice, albeit

---

<sup>8</sup> A list of the 16 documents can be found in Appendix A to Defendants' Motion [Document 44].

perhaps unwitting, is courts allowing the use of judicial notice of court records to evade the hearsay rule”).

The Court, therefore, shall take judicial notice of the existence and filing of the documents in question but shall limit the extent of reliance thereon consistent with hearsay considerations.

B. Qui Tam Jurisdiction

A district court’s jurisdiction over qui tam actions is limited by the FCA “public disclosure” provision stating:

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)(A)(2006 ed.);<sup>9</sup> see also Rockwell Int’l Corp. v. United States, 549 U.S. 457, 468 (2007) (“[T]he jurisdictional nature of the original-source requirement is

---

<sup>9</sup> The 2010 amendments to the FCA did not apply retroactively to presentation of false claims occurring before its effective date. Since the Complaint in the instant case was filed in 2009, the pre-amendment text is controlling. See Graham County Soil & Water Conservation District v. United States ex rel. Wilson, 130 S. Ct. 1396, 1400 n.1 (2010).

clear ex visceribus verborum. Indeed, we have already stated that § 3730(e)(4) speaks to 'the power of a particular court' as well as 'the substantive rights of the parties.'" (quoting Hughes Aircraft Co. v. United States ex rel. Schumer, 520 U.S. 939, 951 (1997))).

Aventis contends that the complaint is based on information publicly disclosed in prior litigation and regulatory proceedings. Aventis further argues that Amphastar, a competitor, is not an original source of the information. The FCA defines an "original source" as

an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information.

31 U.S.C. § 3730(e)(4)(B)(2006 ed.).

As discussed herein, the Court finds that:

- (1) The instant case was based on "public disclosures" within the meaning of the FCA.
- (2) On the current state of the record, Aventis is not entitled to dismissal on the basis that Amphastar was not an "original source."

1. Public Disclosure

"The FCA is designed to reward those individuals who provide the government with information regarding fraud which

has not been publicly disclosed.” United States ex rel. Aflatooni v. Kitsap Physicians Servs., 163 F.3d 516, 523 (9th Cir. 1999). If the allegations of fraud are public knowledge prior to informing the government, the government receives no benefit from the allegations being repeated in the relator’s complaint. United States ex rel. Biddle v. Bd. of Trustees of Leland Stanford, Jr. Univ., 161 F.3d 533, 539 (9th Cir. 1998); see also United States ex rel. Springfield Terminal Ry. Co. v. Quinn, 14 F.3d 645, 651 (D.C. Cir. 1994)(explaining the “twin goals of rejecting suits which the government is capable of pursuing itself, while promoting those which the government is not equipped to bring on its own”).

Resolving the public disclosure question requires a court to make two distinct, but related, determinations: (1) whether the public disclosure originated in one of the sources enumerated in the statute, and (2) “whether the content of the disclosure consisted of the ‘allegations or transactions’ giving rise to the relator’s claim, as opposed to ‘mere information.’” United States ex rel. Meyer v. Horizon Health Corp., 565 F.3d 1195, 1199 (9th Cir. 2009)(quoting A-1 Ambulance Serv., Inc. v. California, 202 F.3d 1238, 1243 (9th Cir. 2000)).

a. Was There Public Disclosure?

"Public disclosure may occur in only three categories of fora: (1) in a criminal, civil, or administrative hearing; (2) in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation; or (3) in the news media." Meyer, 565 F.3d at 1200 (citing § 3730(e)(4)(A); A-1 Ambulance, 202 F.3d at 1243 (internal quotation marks omitted)). Thus, documents filed with an agency or court during an administrative proceeding or civil litigation are considered publicly disclosed. A-1 Ambulance, 202 F.3d at 1244.

Aventis contends that the disclosures in the First Suit (in Amphastar's May 21, 2004 antitrust counterclaim, its December 31, 2008 amended counterclaim, its May 13, 2004 response to Aventis's citizen petition) and generally to other FDA submissions, public court filings, and judicial decisions predating the instant complaint were "public disclosures." Except for the sealed 2008 amended counterclaim in the First Suit,<sup>10</sup> the balance of the documents at issue were "public disclosures."

---

<sup>10</sup> This pleading was sealed upon filing and was not public at the time of filing the instant complaint. See United States ex rel. Stinson, Lyons, Gerlin & Bustamante, P.A. v. Prudential Ins. Co., 944 F.2d 1149, 1160 n.9 (3d Cir. 1991)(holding that documents filed under seal are not publicly disclosed for purposes of the False Claims Act).

b. Were the Claims Based on Public Disclosures?

Since there were public disclosures, the Court must determine whether the content of the public disclosures was sufficient to give rise to the relator's claim. See Meyer, 565 F.3d at 1199.

i. Public Disclosure Standard

The parties disagree as to the standard a court should use to decide if the suit is based on the "public disclosures."

Aventis argues that prior disclosures are sufficient to raise the bar as long as they provide notice to enable the government to pursue an investigation. See United States ex rel. Harshman v. Alcan Elec. & Eng'g, Inc., 197 F.3d 1014, 1019 (9th Cir. 1999) (discussing the triggering of the jurisdictional bar when "the prior public disclosures contained enough information to enable the government to pursue an investigation" and when public disclosures "already enable the government to adequately investigate the case and to make a decision whether to prosecute").

Amphastar contends that prior disclosures must be detailed and specific enough to allow the government to go forward on its own with a false claims action.

In Springfield, the D.C. Circuit stated:

[I]f X + Y = Z, Z represents the allegation of fraud and X [true facts] and Y [the misrepresented facts] represent its essential elements. In order to disclose the fraudulent transaction publicly, the combination of X and Y must be revealed, from which readers or listeners may infer Z, i.e., the conclusion that fraud has been committed . . . . Qui tam actions are barred only when enough information exists in the public domain to expose the fraudulent transaction (the combination of X and Y), or the allegation of fraud (Z). When either of these conditions is satisfied, the government itself presumably can bring an action under the FCA . . . .

14 F.3d at 654.

In brief, “[f]raud requires recognition of two elements: a misrepresented state of facts and a true state of facts. The presence of one or the other in the public domain, but not both, cannot be expected to set government investigators on the trail of fraud.” Id. at 655.

“The question, properly, then, is whether the information conveyed [in the public disclosure] could have formed the basis for a governmental decision on prosecution, or could at least have alerted law-enforcement authorities to the likelihood of wrongdoing . . . .” Id. at 654 (citations omitted).

Accordingly, if the elements of the fraudulent transaction were already public, the plaintiff’s additional evidence does not “suffice to surmount the jurisdictional hurdle.” Id. at

655. Moreover, the public disclosure need not present the elements of fraud in a form readily comprehensible to nonexperts. As long as the information is made available, even if not readily understood, the jurisdictional bar is raised.

Id.

The analysis of the Springfield Court was adopted by the Ninth Circuit. See United States ex rel. Found. Aiding the Elderly v. Horizon West, 265 F.3d 1011, 1015 (9th Cir. 2001). The Ninth Circuit, in Horizon West, held that the information the government had in that case was not "sufficient to enable it adequately to investigate the case and to make a decision whether to prosecute." Id. at 1016.

The Court, consistent with the view of the Ninth Circuit, holds that the public disclosures create a potential jurisdictional bar if they present the essential elements of the fraud sufficiently to have permitted the Government to have adequately conducted an investigation so as to decide whether to prosecute. Id.; see also A-1 Ambulance, 202 F.3d at 1243 ("[T]he jurisdictional bar is raised so long as the material elements of the allegedly fraudulent transaction are disclosed in the public domain."); Hagood v. Sonoma County Water Agency, 81 F.3d 1465, 1473 (9th Cir. 1996)("[T]he jurisdictional bar may

be raised by public disclosure unaccompanied by an explicit allegation of fraud." ).

ii. Application of the Standard

The "public disclosure" standard is met if there were either (1) public allegations of fraud "substantially similar"<sup>11</sup> to the one described in the FCA complaint, or (2) enough information publicly disclosed regarding fraudulent transactions so that the government is on notice to either investigate further or to make a decision to proceed with its own claim. It is not necessary for the public disclosures to have specifically named a defendant, to have provided explanatory details, or to have alleged overcharging, false-invoicing, false certification, or any other specific fraud. See Alcan, 197 F.3d at 1018-20 (citing cases); A-1 Ambulance, 202 F.3d at 1245. However, the prior disclosures of a fraudulent transaction must disclose both "a misrepresented state of facts and a true state of facts." Horizon West, 265 F.3d at 1016.

The "public disclosure" standard is not intended to be difficult to meet. Hagood, 81 F.3d at 1476 n. 18 (noting that courts often treat the "based upon public disclosure" step as a

---

<sup>11</sup> See United States ex rel. Lujan v. Hughes Aircraft Co., 162 F.3d 1027, 1033 (9th Cir. 1998).

"quick trigger" to arrive at the more exacting "original source" inquiry).

The FCA prohibits submitting false or fraudulent claims for payment to the United States. U.S.C. § 3729(a)(1)(A),(B). In the instant case, Amphastar alleges that the fraudulent transactions included, in pertinent part, transactions in which Aventis overcharged the United States and its agencies by fraudulently obtaining a patent for Lovenox and by making false representations to the U.S. Food and Drug Administration that delayed approval of generic equivalents to Lovenox, which also resulted in overcharging. As such, the misrepresentation was that the Lovenox patent was valid and deserving of premium pricing when, in actuality, the patent was void so that the government purchasers were overcharged.

The allegations and transactions set forth in the public disclosures<sup>12</sup> are sufficiently definite to give the Government enough information to investigate the claims at issue - they specifically mention the Lovenox patent, the misrepresentations to the PTO including the allegations of missing studies and

---

<sup>12</sup> Primarily, the inequitable conduct lawsuit commencing in 2004 with a counterclaim by Amphastar against Aventis. Aventis sets out a detailed chart of the FCA allegations compared to documents in prior lawsuits between the parties, which demonstrates the prior public disclosure of the fraudulent transactions and allegations of fraud, excluding the 2008 Amended Counterclaim that was filed under seal. See Mot. 7-8.

prior art (although not the details), the improper listing in the FDA Orange Book, and delays to approval of generic equivalents. These material elements of the fraudulent transaction raise a reasonable inference of fraud. It is true that the public disclosure did not state that the government was paying brand-name prices for a non-patented drug, or that false claims were submitted to the government. However, fraud need not be explicitly alleged to constitute public disclosure adequate to raise the jurisdictional bar. A-1 Ambulance, 202 F.3d at 1243; Alcan, 197 F.3d at 1019-20.

Accordingly, the Court finds that Amphastar's FCA claim is based on public disclosures. Hence, the instant case must be dismissed unless Amphastar is an "original source" within the meaning of the FCA.

2. Is Amphastar an Original Source?

To qualify as an "original source," a relator must establish that:

- (1) It has direct and independent knowledge of the information on which the allegations are based,
- (2) It has voluntarily provided the information to the government before filing the qui tam action, and

- (3) It had a hand in the public disclosure of allegations that are a part of the suit.

Meyer, 565 F.3d at 1201 (quoting Lujan, 162 F.3d at 1033).<sup>13</sup>

a. Direct and Independent Knowledge

To have had direct knowledge, Amphastar must have had firsthand knowledge of the alleged fraud and have obtained this knowledge through its own labor unmediated by anything else. Meyer, 565 F.3d at 1202 (citing Alcan, 197 F.3d at 1020); see also United States ex rel. Devlin v. State of California, 84 F.3d 358, 360-61 (9th Cir. 1996)(citing cases); Aflatooni, 163 F.3d at 524-25 (citing cases). Certainly, the knowledge is independent if the relator had evidence on which the allegations were based before the public disclosure of any allegations. Id.; see also Meyer, 565 F.3d at 1202 ("A relator has independent knowledge when he knows about the allegations before that information is publicly disclosed.").

There is no doubt that Amphastar had independent knowledge. However, Aventis argues that Amphastar's knowledge was indirect, second-hand, and mediated. Certainly, Amphastar is not the typical relator - an insider - but a competitor. Nevertheless,

---

<sup>13</sup> As discussed herein, the Court questions the continuing validity of the third requirement in light of the Supreme Court's decision in Rockwell. See 549 U.S. 457, 471-72 (construing § 3730(e)(4)(A)'s original source exception).

Amphastar asserts that it conducted its own investigation to discover the fraud through independent research into enoxaparin and the patents, i.e., it obtained the knowledge through its own labor, unmediated by anything or anyone else.

Amphastar presents a version of the pertinent facts that, if accepted, would suffice to establish that it had direct and independent knowledge sufficient to be an original source. The Court will, for purposes of the instant dismissal motion, accept the facts as asserted by Amphastar. However, the Court does not foreclose Aventis from seeking a factual determination based upon an appropriate evidentiary hearing (or summary judgment).

Thus, the Court accepts the following version of the facts for purposes of the instant motion:

Amphastar's independent research was more than simply using expertise to understand the significance of information acquired through public sources. Nor did it merely assemble existing information. Rather, Amphastar conducted scientific experiments, researched the manufacturing process, and determined that enoxaparin could be manufactured by a process different than disclosed in the Lovenox patent. Amphastar discovered that an Aventis patent example was false based on reproducing the study itself. Through these efforts, Amphastar uncovered the fraud on the PTO. Thus, Amphastar had direct, first-hand, independent knowledge of the alleged fraud and provided additional facts about the alleged fraud that were not available previously. The fact that Amphastar gained additional knowledge through the discovery process in prior civil proceedings does not

preclude it being an original source of the publicly disclosed information.

Aventis contends that, even on these facts, Amphastar still falls short of having direct and independent knowledge. Aventis would have the Court read Rockwell to hold that an original source must have direct and independent knowledge of the information on which all allegations are based. Mot. 9 (citing 549 U.S. at 476). However, the Supreme Court explained in Rockwell that a relator must qualify as an original source for each distinct kind of claim or scheme alleged,<sup>14</sup> and that the original source status hinges on whether the relator has direct and independent knowledge of the information underlying the relator's own allegations in the FCA action, not the information underlying the public disclosure. 549 U.S. at 470-72, 476.

Moreover, as stated by the Springfield Court, "§ 3730(e)(4)(B) does not require that the qui tam relator possess direct and independent knowledge of all of the vital ingredients to a fraudulent transaction . . . . [but] refers to direct and independent knowledge of any essential element of the underlying fraud transaction . . . ." 14 F.3d at 656-57. See also Minnesota Ass'n of Nurse Anesthetists v. Allina Health System Corp., 276 F.3d 1032, 1050 (8th Cir. 2002)("[T]o qualify as an

---

<sup>14</sup> In the instant case, Amphastar alleges only one kind of scheme, although presented in multiple counts due to a multiple of alleged governmental victims.

original source, a relator does not have to have personal knowledge of all elements of a cause of action.”); United States ex rel. Dhawan v. N.Y. Med. Coll., 252 F.3d 118, 121 (2d Cir. 2001)(holding relator must be source of “core information” upon which the complaint is based).

In sum, on the facts accepted as true for purposes of the instant motion, the Court cannot find that Amphastar failed to have direct and independent knowledge of information upon which it based the allegations of fraud presented in the Complaint.

b. Voluntarily Provided to Government

There appears to be no doubt that Amphastar voluntarily provided the pertinent information to the Government before filing the qui tam action. A disclosure is not considered voluntary if the individual is paid to perform the function of reporting fraudulent activity, i.e., “an employee should not receive a windfall for merely doing his job.” Biddle, 161 F.3d at 542. The parties do not dispute that Amphastar provided the information voluntarily and had no pre-existing duty to do so.

c. A Hand in the Disclosure

The Ninth Circuit has held that to be an original source, a relator must have “had a hand in the public disclosure of the

allegations that are a part of his suit." Meyer, 565 F.3d at 1201 (citations and alterations omitted). There is a split among the Circuits regarding the existence of this requirement.<sup>15</sup> However, the issue is moot inasmuch as Amphastar played a part in the public disclosures relating to the allegations made in the Complaint.

C. Failure to State an FCA Claim

Aventis contends that Amphastar has failed to state a viable FCA claim for two main reasons: (1) the underlying conduct that is the basis of Amphastar's allegations is an antitrust violation and, as such, has incurable defects; and (2)

---

<sup>15</sup> See Schindler Elevator Corp. v. United States ex rel. Kirk, 131 S. Ct. 1885, 1895 n. 8 (2011). For example, the Fourth, D.C., and First Circuits require "only that the relator . . . voluntarily provide the information to the government before filing his qui tam action." United States ex rel. Siller v. Becton Dickinson & Co., 21 F.3d 1339, 1351 (4th Cir. 1994); United States ex rel. Duxbury v. Ortho Biotech Prods., L.P., 579 F.3d 13, 22 (1st Cir. 2009); United States ex rel. Davis v. District of Columbia, 679 F.3d 832, 838 (2012). Prior to Rockwell, two circuits (the Second Circuit and the Ninth Circuit) had adopted this third requirement. See United States ex rel. Dick v. Long Island Lighting Co., 912 F.2d 13, 16 (2d Cir.1990); Wang, 975 F.2d at 1418. But in Rockwell, the Supreme Court directly rejected these cases' particular interpretation of the public disclosure bar. 549 U.S. at 471-72. Given that rejection, at least one District Court in the Second Circuit has recently reached the conclusion that the third requirement has been abrogated. United States v. Huron Consulting Group, Inc., 843 F. Supp. 2d 464, 471 (S.D.N.Y. 2012).

Amphastar has failed to plead with particularity and has not sufficiently pleaded materiality or scienter.

1. Antitrust Violations and Immunity

Aventis contends that the FCA claim is based on alleged antitrust violations and, as such, a viable antitrust claim must be pleaded but has not been. Further, Amphastar's antitrust allegations against Aventis in the First Suit were dismissed based on the Noerr-Pennington<sup>16</sup> doctrine. Therefore, Aventis argues that the First Suit precludes using the antitrust claims as a basis for an FCA complaint. See, e.g., United States ex rel. Bunk v. Birkart Globistics GmbH & Co., Nos.

1:02cv1168(AJT/TRJ), 1:07cv1198(AJT/TRJ), 2011 WL 5005313, at \*4

---

<sup>16</sup> Under the Noerr-Pennington doctrine, a party is immune from antitrust liability for petitioning any branch of the government even if there is an improper purpose or motive. Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 135 (1961); United Mine Workers v. Pennington, 381 U.S. 657, 670 (1965). There are two exceptions to this immunity. One exception is a "sham" lawsuit in which a plaintiff uses the judicial process itself, as opposed to the outcome of the process, to harm competition. See Prof. Real Estate Investors, Inc. v. Columbia Pictures Inds., Inc., 508 U.S. 49 (1993)(setting out a two-part test for defining a sham lawsuit). The second exception to the doctrine denies immunity for "conduct in which a party knowingly and willfully makes false representations to the government." In re Busiprone Patent Litig., 185 F. Supp. 2d 363, 369-70 (S.D.N.Y. 2002) (citing Walker Process Equipment, Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172 (1965)). This exception applies narrowly to acts of fraud. Norton v. Curtiss, 433 F.2d 779, 792-93 (C.C.P.A. 1970).

(E.D. Va. Oct. 19, 2011)(ruling that because the underlying conduct "enjoyed . . . immunity" from antitrust liability, "it could not constitute an unlawful conspiracy under the False Claims Act"). Noerr-Pennington issues are also raised by the allegations of fraud on the FDA, a government administrative body.

First, Amphastar is not pleading an antitrust cause of action but rather has pleaded a violation of the False Claims Act under 31 U.S.C. 3729. It is that FCA cause of action that the Court will analyze for viability.

Second, while Noerr-Pennington immunity may, at first glance, appear to broadly protect government petitioning in direct antitrust violations, its applicability to fraudulent patent listings appears to be very limited. See In re Busipirone Patent Litig., 185 F. Supp.2d 363, 372 (S.D.N.Y. 2002)(finding that the request for listing its patent in the FDA's Orange Book was not an example of government petitioning as required by Noerr-Pennington).

Certainly, Noerr-Pennington immunity has been extended to prohibit claims other than for violations of the antitrust laws where the cause of action is based on the defendant's exercise

of its right to petition the government.<sup>17</sup> In the instant case, however, Amphastar is seeking to impose liability for falsely charging the government a higher price than the drug supplied would otherwise render if Aventis had not fraudulently acquired a patent on the drug or delayed the entrance of generic drugs into the marketplace. Amphastar is not seeking to impose liability for the act of petitioning the government.

Even if the conduct at issue could be described as "petitioning," Aventis would not have the right to knowingly and willfully make false representations to the government. See United States ex rel. Wilson v. Maxxam, Inc., No. C 06-7497CW, 2009 WL 322934, \*6 (N.D. Cal. Feb. 9, 2009) ("While citizens have a First Amendment right to petition the government, they do not have a First Amendment right to lie while doing so. Were it otherwise, application of the False Claims Act itself would, in many cases, be unconstitutional.").

Accordingly, the Court finds that Noerr-Pennington immunity does not bar the FCA claims at issue.

---

<sup>17</sup> Petitioning, in this context, is protected by the First Amendment of the United States Constitution, which provides, "Congress shall make no law . . . abridging . . . the right of the people . . . to petition the Government for a redress of grievances." U.S. Const. amend. I.

2. Minimum Pleading Standards

The FCA is "intended to reach all types of fraud, without qualification, that might result in financial loss to the Government." United States ex rel. Hendow v. Univ. of Phoenix, 461 F.3d 1166, 1170 (9th Cir. 2006). To meet the pleading requirements of an FCA claim, the complaint must allege: "(1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due." Id. at 1174, 1177-78.

An action brought under the FCA must also fulfill the particularity requirements of Rule 9(b). Bly-Magee v. California, 236 F.3d 1014, 1018 (9th Cir. 2001). "Rule 9(b) requires a party to 'state with particularity the circumstances constituting fraud or mistake,' including 'the who, what, when, where, and how of the misconduct charged.'" Ebeid ex rel. United States v. Lungwitz, 616 F.3d 993, 998 (9th Cir. 2010)(quoting Vess v. Ciba-Geigy Corp. USA, 317 F.3d 1097, 1106 (9th Cir. 2003)).

In the Ninth Circuit, pleading representative examples of false claims is one way, but not the only way, to meet the Rule 9(b) pleading requirement. See id. at 998-99 ("[I]t is sufficient to allege particular details of a scheme to submit

false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.”).

a. Fraud Enforcement Recovery Act of 2009

The Fraud Enforcement and Recovery Act of 2009 (“FERA”), signed into law on May 20, 2009, expanded the scope of conduct for which persons and organizations can be liable under the FCA. FERA, PL 111-21, 123 Stat. 1617. This enactment potentially impacts the instant case.

FERA amended provisions for liability from any person who “knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government” to any person who “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.” Id. § 4(a). The amendment effectively abrogated the Supreme Court’s decision in Allison Engine Co. v. United States ex rel. Sanders, 553 U.S. 662 (2008), which held that proof of intent to defraud is an element of a false statement claim. Rather, liability now attaches merely so long as a false statement is material to a false or fraudulent claim.

Congress included a retroactive provision for this part of the Act: “subparagraph (B) of section 3729(a)(1) . . . shall

take effect as if enacted on June 7, 2008, and apply to all claims under the False Claims Act (31 U.S.C. 3729 et seq.) that are pending on or after that date." Id. § 4(f)(1). Whether the retroactivity provision applies to the initial case is uncertain. The District Court, in the Allison Engine case, specifically found on remand that the term "claim" was defined in the FCA as a claim made to the government for money or property and that the claims in that case had been submitted a number of years before the lawsuit was filed, so were not pending on June 7, 2008. United States ex rel. Sanders v. Allison Engine Co., Inc., 667 F. Supp. 2d 747, 751-52 (S.D. Ohio 2009).

The Allison Engine court also found that because the FCA is a punitive statute, it could not be applied retroactively because it would violate the ex post facto clause of the Constitution. Id. at 758. But see United States ex rel. Miller v. Bill Harbert Int'l Constr., Inc., 608 F.3d 871, 878 (D.C. Cir. 2010)(holding that the ex post facto clause does not apply to the FCA because it is not penal); United States ex rel. Drake v. NSI, Inc., 736 F. Supp. 2d 489, 502 (D. Ct. 2010)(finding that the FCA is not sufficiently punitive in nature and effect so as to warrant application of the ex post facto clause).

Amphastar alleges, in general terms, that it is seeking recovery for claims filed before and after June 7, 2008. Hence, it appears that some, if not all, of the claims at issue will be subject to FERA.

b. Falsity

The FCA does not limit liability to facially false or fraudulent claims for payment. The term "false or fraudulent claim" has been construed broadly, and "has given rise to two doctrines that attach potential False Claims Act liability to claims for payment that are not explicitly and/or independently false: (1) false certification (either express or implied); and (2) promissory fraud." Hendow, 461 F.3d at 1171. Aventis argues that it is unclear whether Amphastar is alleging "false certification" or "promissory fraud" or both. However, under either theory, the essential elements to be pleaded do not change. Id. at 1174.

Amphastar alleges that Aventis knowingly made false representations to the PTO, made false representations to the FDA, fraudulently concealed from the FDA Aventis's change in manufacturing process, used the illegally-obtained monopoly to overcharge the federal and state governments by as much as five times the amount it charges for the same drug in Europe, and

submitted fraudulent billings, records, and certifications to the governments to secure payments. Compl. ¶¶ 14-21, 24-25, 28-29, 33-34.

Thus, Amphastar's allegations that Aventis engaged in a fraudulent scheme to charge an inflated price for its drug is plausible and specific enough to give Aventis notice of the particular misconduct alleged to constitute the fraud charged.

c. Scienter

Scienter requires knowledge of the falsity with the intent to deceive. United States ex rel. Hopper v. Anton, 91 F.3d 1251, 1265 (9th Cir. 1996).

Amphastar alleges that Aventis knowingly submitted fraudulent billings to secure payments and knowingly presented to the government a false claim, such that the government was billed a higher price than it should have been. Compl. ¶¶ 29, 34. Further, Amphastar alleges that Aventis "set out to obtain patent protection . . . in order to prevent generic competition . . . and thereby knowingly and unlawfully gaining monopoly power . . ." and knowingly included false data in its patent applications in order to misrepresent results. Compl. ¶¶ 13-19. Amphastar also alleges that Aventis concealed the best mode for

manufacturing its drug "in willful violation" of the patent and antitrust laws. Compl. ¶ 19.

Amphastar's allegations that Aventis acted with knowledge and intent to deceive is sufficient to meet Rule 9(b)'s requirement since scienter may be alleged generally.

d. Materiality

Although § 3729 did not expressly contain a materiality requirement before FERA added one in 2009, the Ninth Circuit and at least five other circuit courts have held that the government must also prove that the false statement was material. United States v. Bourseau, 531 F.3d 1159, 1170-71 (9th Cir. 2008). A false statement is material if "it has a natural tendency to influence, or [is] capable of influencing, the decision of the decision-making body to which it was addressed." Id. at 1171. The natural tendency test "focuses on the potential effect of the false statement when it is made rather than on the false statement's actual effect after it is discovered." Id. The Court finds that the Complaint adequately alleges materiality. See, e.g., Compl. ¶ 30, 34.

e. Allegation of Claims

Plaintiff must allege an actual claim, or request to the government for payment. This is self-evident from the statutory language, which requires a "claim paid or approved by the Government." 31 U.S.C. § 3729(a)(2). Amphastar does not, however, allege with particularity that Aventis filed false claims that were paid or approved.

Aventis compares the instant case to an unpublished case, United States ex rel. Promega Corp. v. Hoffman-La Roche, Inc., Civil Action No. 03-1447-A (E.D. Va. Sep 29, 2004)(Mot. Ex. B), in which the plaintiff alleged overpayments by the government due to fraudulently obtained patents. The court found that the complaint was not pleaded with sufficient particularity to satisfy Rule 9(b) because the allegations of higher prices were vague and generalized, failing to specify when and where the false claims were made, and there was a disconnect between the alleged misrepresentations to the PTO and the invoices submitted to the government. Aventis argues the same result is called for in the instant case because Amphastar's allegations are conclusory and speculative, based on "information and belief," without allegations of facts to support the conclusion.

While it is certainly possible that the alleged false statements pleaded would be relevant to, or be capable of

influencing, the government's decision to enter contracts or make payments, Amphastar supplied no representative examples of false claims to support its conclusory allegation of fraudulent billings. Amphastar did not allege facts that would provide any "reliable indicia that would lead to a strong inference that claims were actually submitted." Ebeid, 616 F.3d at 999.

At least in the present context, the allegations, on "information and belief," are insufficient to satisfy the particularity requirements of Rule 9(b) without factual allegations of the information on which the belief is plausibly based. It is not necessary to provide exact dollar amounts, billing numbers, or dates, but at a minimum, Amphastar must allege the particular details of a scheme to submit false claims and details leading to a strong inference that those claims were submitted. See id. It may be sufficient to allege facts establishing that the payments in issue necessarily (or almost certainly) were based on false claims submitted by Aventis.

Accordingly, the Court will dismiss the Complaint but will provide Amphastar with the opportunity to file an Amended Complaint that will cure the problem.

IV. CONCLUSION

For the foregoing reasons:

1. Defendants' Request for Judicial Notice [Document 44] is GRANTED.
2. Defendants' Motion to Dismiss False Claims Act Qui Tam Complaint [Document 43-1] is GRANTED IN PART.
  - a. The False Claims Act Qui Tam Complaint [Document 43-1] is DISMISSED WITH LEAVE TO AMEND.
  - b. Plaintiff may file an Amended Complaint to add allegations pertaining to the filing of false claims<sup>18</sup> by November 30, 2012.
3. Plaintiff shall arrange a telephone conference to be held by November 30, 2012, to discuss the scheduling of further proceedings.

SO ORDERED, on Wednesday, November 14, 2012.

\_\_\_\_\_  
/s/ \_\_\_\_\_  
Marvin J. Garbis  
United States District Judge

---

<sup>18</sup> Amphastar is hereby given leave to amend the Complaint only to the limited extent necessary to include allegations sufficient to create a plausible contention that Aventis filed claims in violation of the FCA.