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: SUMMARY JUDGMENT (DISCLOSURE)

The Court has before it Defendants' Motion for Summary Judgment for Lack of Jurisdiction Pursuant to 31 U.S.C. § 3730(e)(4)(B)'s Disclosure Requirement [Document 204] and the materials submitted relating thereto. The Court has reviewed the exhibits and considered the materials submitted by the parties. The Court finds a hearing unnecessary.

I. SUMMMARY BACKGROUND[1]

At all times relevant hereto, Amphastar Pharmaceuticals, Inc. ("Amphastar") and Sanofi-Aventis S.A. ("Aventis")[2] have been

[1] For a detailed background, see Memorandum and Order Re: Motion to Dismiss [Document 78].

[2] 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

competitors in the pharmaceutical industry. Extensive litigation between the parties[3] culminated, in 2008, with the invalidation on inequitable conduct grounds of Aventis's U.S. Patent No. 5,318,618 ("the '618 Patent") for "enoxaparin," an anticoagulant drug. See Aventis Pharma S.A. v. Amphastar Pharm., Inc., 525 F.3d 1334 (Fed. Cir. 2008) (affirming the district court's finding of inequitable conduct and holding of unenforceability of patents at issue).

In January 2009, Amphastar filed under seal the instant 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, claiming that Aventis fraudulently inflated the price of enoxaparin charged to the Government and states. The Government and states elected to decline intervention. The Complaint was unsealed on October 28, 2011.

Aventis contends that the Court lacks subject matter jurisdiction because Amphastar is not an "original source of the information" on which the suit is based pursuant to 31 U.S.C. §

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

[3] 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.

3730(e)(4)(A). An "original source" for FCA purposes is defined 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.).

Thus, to be an "original source," Amphastar must have the requisite "direct and independent knowledge" and also must have, prior to filing the case, "provided the [requisite] information to the Government." Id.

Aventis sought dismissal, contending that Amphastar had failed to plead facts establishing a plausible claim that it had the requisite "direct and independent knowledge." Defendants' Motion to Dismiss False Claims Act Qui Tam Complaint [Document 43-1].

In its Memorandum and Order Re: Motion to Dismiss [Document 78], the Court stated:

> [T]he 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.
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> . . . .
>
> [O]n 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.

Id. at 19, 23.

The Court, therefore, determined that it would be appropriate to hold an evidentiary hearing with regard to the jurisdictional "direct and independent knowledge" issue. Decision on Pending Motions [Document 77]; Initial Scheduling Order [Document 89].

At that time, there appeared to be no dispute regarding whether Amphastar voluntarily provided the pertinent information to the Government before filing the qui tam action as required under the FCA. Amphastar alleged that it had provided, on December 31, 2008, a pre-filing disclosure letter to the Government, which was prior to filing the Complaint on January 7, 2009.[4] Aventis now asserts that the letter is insufficient to satisfy the disclosure requirement of 31 U.S.C. § 3730(e)(4)(B).

By the instant motion, Aventis seeks summary judgment, contending that Amphastar failed to provide the requisite information to the Government prior to filing suit. Amphastar contends that it provided the requisite information by the notice letter of December 31, 2008.

[4] The letter has been provided to the Court and Aventis under seal. See, e.g., Documents 174, 186, 187, 194, and 198.

II. LEGAL STANDARD

The motion before the Court is labelled a motion for summary judgment, although it can be viewed as a motion to dismiss for lack of jurisdiction pursuant to Rule 12(b)(1) of the Federal Rules of Civil Procedure.

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 v. Schachter, 804 F. Supp. 53, 57 (N.D. Cal. 1992) (citing Thornhill Pub. Co. v. Gen. Tel. & Elecs. Corp., 594 F.2d 730, 733 (9th Cir. 1979)). The qui tam plaintiff has the burden of proving by a preponderance of the evidence that the court has subject matter jurisdiction. United States v. Alcan Elec. & Eng'g, Inc., 197 F.3d 1014, 1018 (9th Cir. 1999).

The procedural debate – such as there may be – is immaterial. The Court finds that there is no genuine issue of material fact in regard to the adequacy vel non of the notice letter.

III. DISCUSSION

Because this suit is based upon a "public disclosure," the Court has no jurisdiction to hear the claim unless Amphastar can

show that it is an "original source" of the information. 31 U.S.C. § 3730(e)(4)(B).[5]

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.).[6]

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[5] 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.). 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, 559 U.S. 280, 283 n.1 (2010).

[6] The Ninth Circuit has held that the relator also must have "had a hand in the public disclosure of allegations that are a part of . . . [the] suit." United States ex rel. Meyer v. Horizon Health Corp., 565 F.3d 1195, 1201 (9th Cir. 2009)(quoting United States ex rel. Lujan v. Hughes Aircraft Co., 162 F.3d 1027, 1033 (9th Cir. 1998)). See, however, the Supreme Court's decision in Rockwell. See 549 U.S. 457, 471-72 (construing § 3730(e)(4)(A)'s original source exception); see also United States v. Huron Consulting Group, Inc., 843 F. Supp. 2d 464, 471 (S.D.N.Y. 2012)(concluding that the "had a hand" requirement has been abrogated by Rockwell). In any event,

The meaning of "voluntarily provided the information to the Government before filing" a qui tam lawsuit is not settled in case-law or clearly specified in the statute. See, e.g., U.S. ex rel. Duxbury v. Ortho Biotech Prods., L.P., 579 F.3d 13, 22 (1st Cir. 2009) (noting that the "meaning of 'provided the information to the Government before filing an action' under § 3730(e)(4)(B)" is an issue that "has divided the courts"); Glaser v. Wound Care Consultants, Inc., 570 F.3d 907. 915 (7th Cir. 2009); ("§ 3730(e)(4) is hardly a model of careful draftsmanship; the drafting errors throughout § 3730(e)(4) should make us hesitant to attach too much significance to a fine parsing of the syntax." (internal quotation marks omitted)); United States ex rel. Jones v. Horizon Healthcare Corp., 160 F.3d 326, 336 (6th Cir. 1998)("Virtually every court of appeals that has considered the public disclosure bar explicitly or implicitly agrees on one thing, however: the language of the statute is not so plain as to clearly describe which cases Congress intended to bar." (Gilman, CJ, concurring)).

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there is no doubt that Amphastar "had a hand" in the public disclosure in the instant case.

The Ninth Circuit distinguishes between the "government notice provision" and the filing requirement[7] in United States v. Johnson Controls, Inc., 457 F.3d 1009, 1015-16 (9th Cir. 2006), stating:

> Section 3730(e)(4)(B)'s notice provisions apply only to qui tam plaintiffs seeking to avoid the "public disclosure" bar by establishing that they are "original sources," whereas § 3730(b)'s notice provisions apply to all qui tam plaintiffs. Moreover, the provisions differ with respect to what must be turned over to the government: Section 3730(e)(4)(B) requires individuals to provide the government with "information" only, while § 3730(b) requires individuals to provide the government with much more—"[a] copy of the complaint and written disclosure of substantially all material evidence and information the person possesses." § 3730(b)(2). At the same time, the provisions vary in that § 3730(e)(4)(B) incorporates a requirement that information be provided to the government "voluntarily," a requirement wholly absent from § 3730(b).

In Johnson, the court addressed the timing of the pre-filing disclosure[8] and decided that there was no requirement to

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[7] When any private plaintiff files a qui tam complaint, there is a requirement to serve on the government a copy of the complaint and "written disclosure of substantially all the material evidence and information the person possesses." 31 U.S.C. § 3730(b)(2). "The requirements of § 3730(b)(2) are not jurisdictional. . . ." United States ex rel. Lujan v. Hughes Aircraft Co., 67 F.3d 242, 245 (9th Cir. 1995).

[8] There was, and still is at this time, a split in authority among the circuits regarding when the relator must have provided the information to the government. See, e.g., Duxbury, 579 F.3d at 22 (discussing other circuits' approaches); United States ex rel. Davis v. D.C., 679 F.3d 832, 838 (D.C. Cir. 2012)(deciding

inform the government prior to the public disclosure. Id. at 1019. The court did not address the sufficiency of the disclosure, but referred to it as "information only" as distinct from the "much more" that is required when filing the lawsuit. Id. at 1016. In Johnson, the pre-filing notification was comprised of a letter, including a draft of the qui tam complaint, indicating that the complaint would be filed two weeks later unless the state or federal officials contacted the relator in the meantime. Id. at 1011-12. The sufficiency of that notification was not disputed or discussed in Johnson.

Aventis contends that Amphastar's pre-filing notification must disclose the information of which Amphastar claims to have direct and independent knowledge, i.e., details of the scientific experiments upon which Amphastar relies for establishing direct and independent knowledge. Aventis relies in part on United States ex rel. Branch Consultants, L.L.C. v. Allstate Ins. Co., 782 F. Supp. 2d 248 (E.D. La. 2011), which states:

> "the information" that the relator must provide to the government before filing is "the information on which the allegations are based," about which the relator must have "direct and independent knowledge." This implies that the relator must disclose to the government the information it relies

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to no longer require the disclosure prior to the public disclosure).

> upon in asserting that it is an original source.

Id. at 269 (quoting 31 U.S.C. § 3730(e)(4)(B)). In Allstate, the court found that the relator's pre-filing disclosures were insufficient with regard to specific defendants based largely on the fact that the disclosures did not specifically identify the defendants. See id. at 270-72. However, where the disclosure had contained "at least some specific information" as to other defendants, the disclosure was deemed adequate. Id. at 272.

In the instant case, Aventis is the sole defendant and was identified in the pre-filing notification. Further, the text of § 3730(e)(4)(B) leads the Court to conclude that the information an original source must provide to the government is the information underlying the relator's allegations rather than the details of how the relator can satisfy the direct and independent knowledge requirement. See Rockwell Int'l Corp. v. United States, 549 U.S. 457, 470-71 (2007) ("[W]e agree that the 'information' to which subparagraph (B) speaks is the information upon which the relators' allegations are based.").[9]

[9] The Court did not elaborate further on the pre-filing disclosure requirement. Rockwell, 549 U.S. at 475 ("[W]e need not decide whether [the relator] met the second requirement of original-source status, that he have voluntarily provided the information to the Government before filing his action.")

There remains the unresolved question of how specific or comprehensive the information provided to the Government must be. It appears that the information must consist of more than allegations but can be less than the full disclosure required by § 3730(b)(2). Aventis argues that Amphastar's letter contains no more than notice and a summary of the allegations it intended to make in the complaint. The notice and summary, however include a description of the fraudulent scheme, the identity of the defendant, the pertinent patent, the drug at issue, and the prior litigation. Amphastar contends that the information provided, together with the information readily available from the prior litigation, was adequate to satisfy the intent of the pre-filing requirement,[10] especially when, as here, the relator is also a source of the public disclosures as required by the Ninth Circuit.

The Ninth Circuit, considering the legislative history of the Act, has held that "the intent of the Act was to provide standing for qui tam plaintiffs who provide some of the information related to the claim even if the essential elements were already publicly disclosed. . . ." United States ex rel.

[10] As opposed to the intent of the § 3730(b)(2) filing disclosure, which allows for the Government to make an informed decision on whether to participate. See U.S. ex rel. Milam v. Regents of Univ. of California, 912 F. Supp. 868, 890 (D. Md. 1995).

Barajas v. Northrop Corp., 897 F. Supp. 1274, 1277 (C.D. Cal. 1995). Analyzing whether the plaintiff in Barajas was an original source of a fraud contention, the court stated that he did not have to prove that he informed the government specifically about that fraud, as long as the information supplied triggered the investigation that led to the specific allegation. Id. at 1278. This appears consistent with the Ninth Circuit requirement that the relator "played some part, whether direct or indirect, in the public disclosure of the allegations." United States v. Northrop Corp., 9 F.3d 407, 411 (9th Cir. 1993).

The Barajas conclusion is also consistent with the statement that "§ 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 . . . ." United States ex rel. Springfield Terminal Ry. Co. v. Quinn, 14 F.3d 645, 656-57 (D.C. Cir. 1994). It follows that the information supplied in a pre-filing disclosure may be sufficient if it provides the Government with any essential element of the fraudulent scheme. Such an interpretation would be consistent with one of the purposes of the original source rule, which is

to limit recovery under the FCA to those who have functioned as true whistleblowers.[11]

Although the Court has serious doubts about the issue, it concludes that the Ninth Circuit would not hold the notice letter – minimal though it is – insufficient to satisfy the pre-filing disclosure requirement of the FCA.

IV. CONCLUSION

For the foregoing reasons:

1. Defendants' Motion for Summary Judgment for Lack of Jurisdiction Pursuant to 31 U.S.C. § 3730(e)(4)(B)'s Disclosure Requirement [Document 204] is DENIED.

2. The Original Source Phase shall proceed pursuant to the Second Original Source Phase Scheduling Order [Document 225] issued March 24, 2014.

SO ORDERED, on Monday, May 12, 2014.

/s/
Marvin J. Garbis
United States District Judge

[11] The intent of the FCA is to encourage private individuals who are aware of fraud against the government to bring such information forward at the earliest possible time and to discourage persons with relevant information from remaining silent. Wang v. FMC Corp., 975 F.2d 1412, 1419 (9th Cir. 1992)(citing H.R. Rep. No. 660, 99th Cong., 2d Sess. 22 (1986)).