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

AMPHASTAR PHARMACEUTICALS INC. *

O

Plaintiff *

vs. * EDCV-09-0023 MJG

AVENTIS PHARMA SA, et al. *

Defendants *

* * * * * * * * *

DECISION RE: JURISDICTION

Plaintiff Amphastar Pharmaceuticals Inc.("Amphastar") filed this qui tam action against a competitor,[1] Defendant Sanofi-Aventis S.A. ("Aventis")[2] pursuant to the False Claims Act ("FCA"), 31 U.S.C. § 3729 (2006 ed.[3]).

Aventis contends that the Court lacks subject matter jurisdiction. The Court, finding that the jurisdictional

---

[1] At all times relevant hereto, the parties have been competitors in the pharmaceutical industry.

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

[3] 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 Cty. Soil & Water Conservation Dist. v. United States ex rel. Wilson, 559 U.S. 280, 283 n.1 (2010). Accordingly, all references to the FCA herein refer to the 2006 edition.

question presents issues of fact, conducted an evidentiary hearing.

The Court has heard testimony, reviewed the exhibits, and had the benefit of the arguments of counsel. The Court now issues this Memorandum of Decision as its findings of fact and conclusions of law in compliance with Rule 52(a) of the Federal Rules of Civil Procedure. The Court finds the facts stated herein based upon its evaluation of the evidence, including the credibility of witnesses, and the inferences that the Court has found it reasonable to draw from the evidence.

As set forth in the instant decision, the Court has determined that Amphastar failed to prove that the Court had jurisdiction over its claims and, by virtue of that decision, Judgment shall be entered herewith dismissing the case.

There appear to be substantial questions regarding the validity of the underlying theory of Amphastar's case. As stated in a recent law review article:[4]

> Amphastar's FCA suit was based on the novel theory that Aventis defrauded the government when it fraudulently acquired its patent by engaging in inequitable conduct while prosecuting its patent application before the United States Patent and Trademark Office ("USPTO"). . . . This lawsuit is

[4] Gregory Michael, William Newsom, & Matthew Avery, The New Plague: False Claims Liability Based on Inequitable Conduct During Patent Prosecution, 25 Fordham Intell. Prop. Media & Ent. L.J. 747, 749-50 (2015)(footnotes omitted).

> currently being litigated and it is unclear whether Amphastar's theory of FCA liability based on inequitable conduct is even valid, let alone whether Amphastar will prevail.

However, because the Court finds that the instant case must be dismissed for lack of jurisdiction, there is no discussion herein of the potential validity of an FCA claim based upon Aventis' alleged inequitable conduct in the prosecution of a patent application.

Furthermore, while the discussion herein refers to certain aspects of the conduct of counsel for Aventis in regard to the evidentiary hearing, the instant decision does not resolve the issues presented by such conduct. The Court shall issue a separate decision regarding the action to be taken – including the possible imposition of sanctions – by virtue of Amphastar's counsel's conduct.

## I. PROCEDURAL BACKGROUND[5]

In 1995, Aventis obtained United States Patent No. 5,318,618 ("the '618 Patent") for an anticoagulant drug, enoxaparin. In March 2003, Amphastar filed an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration

[5] For additional background, see Memorandum and Order Re: Motion to Dismiss, ECF No. 78.

("FDA"), requesting the right to manufacture and sell a generic version of enoxaparin.

On August 4, 2003, Aventis sued Amphastar, alleging infringement of the '618 Patent by virtue of the filing of the ANDA.[6] Civil No. 03-0887 MRP ("the Patent Case"). After extensive litigation in this Court and the United States Court of Appeals for the Federal Circuit, the case concluded on September 25, 2008. On that date, the Federal Circuit affirmed this Court's (Judge Pfaelzer's) decision that the '618 Patent was unenforceable due to inequitable conduct in regard to the prosecution.[7] Aventis Pharma S.A. v. Amphastar Pharms., Inc., 525 F.3d 1334 (Fed. Cir. 2008).

On December 31, 2008, Amphastar (by its counsel) sent a letter to the United States and several states, disclosing its intention to file a qui tam action, stating:

> During Amphastar's litigation against Aventis, Amphastar discovered that Aventis has committed frauds against both the United States Patent & Trademark Office and the

[6] When an ANDA applicant files a certification of invalidity, unenforceability, or noninfringement, this action constitutes a constructive act of infringement. This provides the patent holder standing to file an infringement action within 45 days after notice. Filing suit prevents the FDA from approving the ANDA for 30 months from the notice date, thereby excluding the would-be entrant from the market. This consequence may, in some circumstances, present antitrust issues.

[7] Aventis contends that, by virtue of subsequent Federal Circuit decisions and other grounds, the inequitable conduct finding should not be considered binding in the instant case.

> United States Food & Drug Administration, which have resulted in false claims for overpayment from the government, including Medicare and Medicaid.

Ltr. 1, Dec. 31, 2008, provided to the Court and Aventis under seal, ECF No. 186-1.

On January 7, 2009, Amphastar filed the qui tam Complaint [ECF No. 1] on behalf of the United States ("the Government") and several States ("the States"). Amphastar alleges that, by virtue of fraud perpetrated vis-à-vis the USPTO and the FDA, Aventis fraudulently inflated the price of enoxaparin charged to the Government and the States.

On October 21, 2011, the United States and the States declined to intervene in the case. ECF Nos. 30, 31. The Complaint was unsealed on October 28, 2011. ECF No. 32. Amphastar elected to proceed with the case pursuant to 31 U.S.C. § 3730 (c)(3).

On January 19, 2012, Aventis filed Defendants' Motion to Dismiss False Claims Act Qui Tam Complaint [ECF No.43-1], contending (1) pursuant to Rule 12(b)(6),[8] that the Complaint did not adequately plead the submission of false claims, and (2) pursuant to Rule 12(b)(1), that the case should be dismissed on jurisdictional grounds. The Court ruled on the motion, granting

[8] All Rule references herein refer to the Federal Rules of Civil Procedure.

dismissal on Rule 12(b)(6) grounds, granting Amphastar leave to file an amended complaint to cure the pleading problem, and recognizing that that there was a potential jurisdiction question. As stated in Decision on Pending Motions:

> If Plaintiff can amend the Complaint so as to avoid dismissal pursuant to Rule 12(b)(6), the Defendant may, nevertheless, have a valid Rule 12(b)(1) defense. However, the question of subject matter jurisdiction may present issues of fact that will best be resolved on a more complete record at the dismissal stage (with further evidence) or at the summary judgment or trial stage.

ECF No. 77, 2.

On December 3, 2013, Amphastar filed the Amended Complaint [ECF No. 81]. The case proceeded pursuant to the Initial Scheduling Order [ECF No. 89].

On February 28, 2014, Aventis filed Defendants' Motion for Summary Judgment for Lack of Jurisdiction Pursuant to 31 U.S.C. § 3730(e)(4)(B)'s Disclosure Requirement [ECF No. 204]. Aventis asserted that the Court had determined[9] that the case was "based upon the public disclosure of allegations or transactions in a . . . civil . . . hearing." Therefore, by virtue of 31 U.S.C. § 3730(e)(4)(A), the suit could have been brought by Amphastar only if it were an "original source."[10] Since there was no

[9] In the Memorandum and Order Re: Motion to Dismiss, ECF No. 78.

[10] The FCA defines an "original source" as one who "has direct

factual question as to the contents of Amphastar's prefiling disclosure letter, Aventis sought summary judgment dismissing the case, because, it alleged, the disclosure letter was not adequate to comply with 31 U.S.C. § 3730(e)(4)(A).

On April 4, 2014, the Court denied Aventis summary judgment, stating:

> In view of the conflicting judicial decisions in other circuits and the absence of clear guidance from the United States Court of Appeals for the Ninth Circuit, I will not dismiss the case based upon the alleged inadequacy of the December 31, 2008 letter. Aventis has, most definitely, presented a non-frivolous contention that is preserved for appellate review.
>
> The matter shall proceed through the evidentiary hearing and a decision whether Amphastar is "an individual who has direct and independent knowledge of the information on which the allegations are based." 31 U.S.C. § 3730(e)(4)(B).

Letter Order, ECF No. 232.

On June 9, 2014, the Court – at the request of Aventis - certified the issue of the adequacy of Amphastar's disclosure for interlocutory appeal pursuant to 28 U.S.C. § 1292(b). Cert. Order, ECF No. 262. The United States Court

---

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).

of Appeals for the Ninth Circuit accepted the interlocutory appeal which, at this writing, remains pending.

## II. THE JURISDICTIONAL PREREQUISITES

Amphastar, as a qui tam plaintiff (often referred to as a "relator"), 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 FCA provides, in pertinent part, that:

> No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a . . . civil . . . hearing unless the action is brought by the Attorney General or the person bringing the action is an original source of the information [on which the allegations are based].

31 U.S.C. § 3730(e)(4)(A) (emphasis added).

An "original source" for FCA purposes is defined as:

> an individual[11] 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).

[11] It appears undisputed that the term "individual" as used herein would include a corporate person such as Amphastar.

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).[12]

III. DISCUSSION

Aventis contends that Amphastar has not established that the Court has subject matter jurisdiction. In particular, Aventis contends that Amphastar has failed to prove that it:

- Voluntarily provided the information on which the case is based to the Government before filing the action.
- Had a hand in the public disclosure of allegations.
- Had direct and independent knowledge of the information on which the allegations are based.

This Court has, albeit expressing "serious doubts about the issue,"[13] declined to dismiss the case by virtue of the asserted inadequacy of Amphastar's pre-filing disclosure. As noted above,

---

[12] However, as of this writing there is a serious question regarding the continuing validity of the "had a hand in disclosure" requirement in view of the Supreme Court decision in Rockwell Int'l Corp. v. United States ex rel. Stone, 549 U.S. 457, 463 (2007). The issue is the subject of a pending en banc review in the Ninth Circuit Court of Appeals. United States ex rel. Hartpence v. Kinetic Concepts, Inc., No. 12-55396, 2014 WL 6779101 (9th Cir. 2014).

[13] See Memorandum and Order Re: Summary Judgment (Disclosure) 13, ECF No. 245.

this decision is the subject of a pending interlocutory appeal and will not be addressed herein.

The question of whether Amphastar had a hand in the public disclosure of allegations is rendered moot by the Court's decision that Amphastar did not have the jurisdictionally requisite direct and independent knowledge and shall not be addressed herein.

Therefore, the instant decision addresses the question of whether Amphastar has proven that it had direct and independent knowledge of the allegations on which the action is based.

A. Direct and Independent Knowledge

A relator must prove both direct and independent knowledge of the information on which its allegations are based. Horizon Health, 565 F.3d at 1202.

To have had direct knowledge to satisfy the FCA jurisdictional requirement, a relator must have had firsthand knowledge of the alleged fraud and have obtained this knowledge through its own labor unmediated by anything else. Id. (citing Alcan, 197 F.3d at 1020); see also United States ex rel. Devlin v. California, 84 F.3d 358, 360-61 (9th Cir. 1996)(citing cases); United States ex rel. Aflatooni v. Kitsap Physicians Servs., 163 F.3d 516, 524-25 (9th Cir. 1999)(citing cases).

The knowledge is independent if the relator had evidence on which the allegations were based before the public disclosure of any allegations. Devlin, 84 F.3d at 361 n.5; Horizon Health, 565 F.3d at 1202; Wang v. FMC Corp., 975 F.2d 1412, 1417 (9th Cir. 1992). Suspicions and speculation do not constitute independent knowledge under § 3730(e)(4)(B). Malhotra v. Steinberg, 770 F.3d 853, 860 (9th Cir. 2014).

B. The Allegations

In the Amended Complaint [ECF No. 81], Amphastar alleged that:

- Aventis fraudulently obtained the '618 Patent by misrepresenting to the USPTO the superior half-life properties of the claimed pharmaceutical. Compl. ¶¶ 11-17.

- Aventis falsely reported to the FDA that its manufacturing process had not changed since 1981, and represented that a generic drug manufacturer must show that its process was equivalent. Compl. ¶ 25.

1. The Alleged Fraud on the USPTO

In 1980, Aventis obtained a French patent, FR 8010791, relating to mixtures of low molecular weight heparin. Aventis then filed related applications in the European Patent office and the USPTO. In 1984, the application in the USPTO was abandoned after Aventis failed to oppose the USPTO's prior-art rejections.

In 1981, European Patent No. 40,144 ("the European Patent") was published. In 1985, an opposition to the European Patent was filed, resulting in the patent's revocation for insufficiency of disclosure and lack of reproducibility.

In 1991, Aventis filed a New Drug Application ("NDA") with the FDA to obtain marketing approval for enoxaparin in the United States. Also in 1991, Aventis filed a patent application in the USPTO relating to mixtures of low molecular weight heparin. The application resulted in the 1995 issuance of the '618 Patent.

The '618 Patent prosecution history included successive rounds of rejection and appeal relating to the assertion that the claimed mixtures had a longer plasma half-life than those disclosed in the known prior art, particularly Aventis' own patent, the European Patent. In the course of the USPTO proceedings, Aventis presented what became Example 6 of the '618 Patent, purporting to show half-life improvement over enoxaparin produced pursuant to the European Patent.

In support of its arguments, Aventis submitted to the USPTO declarations of its employee, Dr. Andre Uzan ("Dr. Uzan"), comparing the half-life data between the '618 compounds and the European Patent compounds and asserting that the differences were statistically significant. The data presented in Example 6,

however, did not include complete dosage information – the unspecified dose amount for the European Patent compound was 60 mg., compared to a disclosed 40 mg. dose of the '618 product.

The USPTO ultimately accepted Aventis' responses to the office actions – claimed by Amphastar to have been fraudulent - and issued the '618 Patent in 1995. Thus, Amphastar claims, Aventis obtained the '618 Patent by virtue of a fraud on the USPTO.[14]

a. Amphastar's Product Development

Amphastar, a generic pharmaceutical firm, was founded in 1999 by its President, Yong Feng Zhang ("Zhang"), and his wife, Dr. Mary Luo, a scientist and Amphastar's Chief Operating Officer.

Zhang sought to find a branded pharmaceutical on which to base a generic product. He researched the market, patent status, and technical complexity of the various options considered. He decided that enoxaparin produced by Aventis and sold under the brand name Lovenox® was a good prospect for a generic product. Zhang found Aventis' enoxaparin listed in the FDA Orange Book and saw that the '618 Patent cited the European Patent as prior art. He believed that it might be possible to

[14] Aventis denies that there was any such fraud.

create a generic enoxaparin by utilizing the disclosure in the European Patent and obtained an English translation of it – Irish Patent 51283.

Zhang assigned an Amphastar employee, Jeff Ding ("Ding"), as project manager. The development of a generic enoxaparin began in 2000. Robert Fei ("Fei"), working under Ding, performed experiments in connection with the product development. These experiments led to the ability of Amphastar to manufacture a generic enoxaparin and submit its ANDA application to the FDA on March 4, 2003.

b. Amphastar's Alleged Knowledge

Amphastar's contention regarding its alleged direct and independent knowledge was acknowledged by its counsel during closing arguments as follows:

> THE COURT:
>
> The plaintiff's contention is that Dr. Fei conducted these experiments in order to ascertain, or in order to develop a product based upon the 144 patent. He did produce such a product. He compared that product, relevant result, particularly this half-life study, and found that it did not improve or that it was just as good as the results of what Aventis had from this 618 patent.
>
> That Dr. Zhang was informed -- and we can get into the details -- of the experiments, et cetera. And he then knew that the example 6 was a false statement.

> And that, therefore, that's original source. Is that from a 100,000 feet, Mr. Weir, that's essentially where it is?
>
> MR. WEIR: Yes.

Hr'g Tr., Closing, 64:11-23.[15]

Amphastar sought to prove its contention through testimony presented by Zhang. Zhang said that he received oral reports of the experiments. He said that, at some unspecified time from 2001 through March 2003[16] ("about 2002"[17]), he came to believe that the '618 Patent included a fraudulent misrepresentation to the USPTO as to the half-life benefit of the invention. Zhang testified that he had concluded that Example 6 in the '618 Patent was false. He testified that he made this discovery based on his belief that Amphastar had created a bioequivalent enoxaparin with the same molecular weight and half-life properties as Lovenox® by following the European Patent.

---

[15] The Court held an evidentiary hearing lasting four days from July 7, 2014 to July 10, 2014. After post-hearing briefs were submitted, the Court then heard closing arguments on October 10, 2014. For ease of reference herein, the hearing transcripts are referenced by the number of the day and AM or PM, i.e., "Day 1 AM" refers to July 7, 2014 morning session, "Day 2 PM" refers to July 8, 2014 afternoon session, etc. The hearing transcript for October 10, 2014 closing arguments is referenced as "Closing."

[16] When Amphastar filed its ANDA application.

[17] "In last deposition, I was asked many times what time. I said not exactly remember. I said about 2002." Zhang, Hr'g Tr., Day 3 AM, 81:2-3. See also Hr'g Tr., Day 3 AM, 63:17-64:7; 79:17-82:10; Hr'g Tr., Day 3 PM, 5:21-6:2.

There is no documentation of this purported discovery. Nor did Zhang testify at trial that he communicated this discovery to anyone except for a reference to his deposition testimony in which he had said that he had talked to Ding about it in 2002 and to his wife. Hr'g Tr., Day 3 AM, 64:2-5. Neither Ding nor Zhang's wife testified confirming the existence of the conversations. No witness – neither Zhang, his wife, Ding, nor anyone else - testified regarding the content of these purported conversations.

The Court does not accept as true, Zhang's testimony that he reviewed results of the experiments and comparisons of the generic enoxaparin to Aventis' Lovenox® and the claims of the '618 Patent and concluded that Example 6 of the '618 Patent presented false statements. The Court does not believe Zhang's testimony that, prior to the filing of the Patent Case, he had the knowledge of the alleged fraud that he claims.

i. Inconsistent Actions

Amphastar's contention that it, by Zhang, had discovered Aventis' fraud on the USPTO by March 2003 is refuted by inconsistent actions taken by, and on behalf of, Amphastar.

In the Patent Case, filed August 4, 2003, Aventis sued Amphastar and Teva Pharmaceuticals USA, Inc. ("Teva") for

infringement of the '618 Patent, based on the ANDA applications they had filed. Although Amphastar now contends that, prior to the commencement of the suit, Zhang (its President) had discovered that the '618 Patent included a material false statement, neither it nor its co-defendant, Teva, presented any defense based thereon. It was not until June 7, 2004, after discovery in the Patent Case was underway, that Amphastar filed a Motion for Leave (After the Fact)to File its Amended Answer and Counterclaim ("Amend Motion"). Defs.' Ex. 14.[18] In this motion, Amphastar stated:

> Pursuant to Federal Rules of Civil Procedure, Rule 15(a) and based on facts recently developed in this litigation, Amphastar has added new affirmative defenses and several antitrust claims to its answer and counterclaim against Plaintiffs.

Amend Motion 2 (emphasis added).

Aventis promptly filed a motion to strike the amended answer and counterclaim. Amphastar responded on June 14, 2004, stating:

> As to the unenforceability of the '618 patent based on inequitable conduct, all of the facts and evidence upon which this affirmative defense is based are in the possession and control of Aventis.

[18] Amphastar had already filed, without the required leave of the court, its Amended Answer and Counterclaim on May 21, 2004. See Civil Minutes – General 5-6, Case 5:03-cv-00887-MRP-PLA, ECF. 286, August 4, 2004.

Defendant Amphastar's Memorandum of Points and Authorities in Opposition to Aventis' Motion to Strike Amended Answer and Counterclaim 2, Defs.' Ex. 15 (emphasis added).

If Amphastar had believed that the experiments on which Zhang purportedly relied demonstrated – or were even relevant to – fraud by Aventis, this would have been a false statement.

Amphastar, moreover, listed evidence on which it based its contention, stating:

> This evidence includes the Declaration of Andre Uzan filed in 1994 in connection with the prosecution of the '618 patent. The Uzan declaration includes data purportedly regarding studies of the compound claimed in the '618 patent, but which data was included in an article published in 1988, two years before the earliest priority date of the '618 patent. The evidence of inequitable conduct also includes Aventis' recent USPTO filings in a proceeding seeking reissuance of the '618 patent, which filings admit inaccuracies in the original prosecution of the patent.

Id. (internal citations omitted). Amphastar did not mention the supposedly significant experiments.

Shortly after the patent litigation ended on September 25, 2008, Amphastar proceeded to prepare the instant qui tam lawsuit.

On December 31, 2008, Amphastar – by Jan Weir, Esquire, its counsel in the instant case – sent its disclosure letter to comply with the FCA obligation "voluntarily [to provide] 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). The letter stated, in pertinent part:

> We write to inform you that Amphastar plans on bringing an action as a qui tam relator on behalf of both the United States government and various state governments under the federal False Claims Act ("FCA") and the respective state False Claims Acts against Aventis Pharmaceuticals, Inc. ("Aventis" or "Defendant"). During Amphastar's litigation against Aventis, Amphastar discovered that Aventis has committed frauds against both the United States Patent & Trademark office and the United States Food & Drug Administration, which have resulted in false claims for overpayment from the government, including Medicare and Medicaid.

Ltr. 1, Dec. 31, 2008, ECF No. 186-1, provided to the Court and Aventis under seal (emphasis added).

At the post-hearing argument on October 10, 2014, Amphastar's counsel - author of the disclosure letter – stated that his statement in the December 31, 2008 letter that "during Amphastar's litigation against Aventis, Amphastar discovered" did not mean learned through discovery. Rather it meant only that the knowledge was obtained during the litigation.

> MR. WEIR:
>
> And, finally, with respect to the letter that I wrote, we said during litigation, I didn't say from discovery. It just was during litigation. And I don't believe I was saying something that cut it

> off and narrowed it. It was just a reference that during litigation this is what we came up with. I don't think I was limiting it to any particular time.

Hr'g Tr., Closing, 157:19-25.

However, the Patent Case was filed August 4, 2003, well after the purported discovery by Zhang. Amphastar's counsel was asked about the fact that Zhang's purported (pre-March 2003) "discovery" allegedly occurred prior to the commencement of the Patent Case. He then stated that when he said "during litigation," he was not referring to the time that the litigation was pending.

> THE COURT: You said discovered during litigation.
>
> MR. WEIR: During this litigation we discovered, I didn't say we discovered from Aventis, I didn't say -- it was just a --
>
> THE COURT: Where did you discover it from in the litigation other than from Aventis?
>
> MR. WEIR: The -- as I said --
>
> THE COURT: Was that after the litigation started is when you did the experiments? You were finished with those.
>
> MR. WEIR: I think that litigation entails a presuit investigation, it includes the ANDA letters, the ANDA filing. It included broadly, the effort to invalidate the patent or to --

Hr'g Tr., Closing, 158:1-13.

Amphastar's counsel did not address his June 7, 2004 representation to this Court on behalf of Amphastar in the Patent Case. In that statement, he said that the information on which Amphastar based its affirmative defenses, including inequitable conduct, was "based on facts recently developed in this litigation." Amend Motion 2 (emphasis added).

The Court rejects Mr. Weir's creative definitional arguments.

The Court finds that Amphastar's actions are inconsistent with, and refute, the contentions it now presents to establish its alleged direct and independent knowledge.

ii. Fei Did Not Produce Enoxaparin By Following the European Patent[19]

Amphastar's basic premise is that Fei produced enoxaparin utilizing the disclosure in the European Patent – without following the teachings of the '618 Patent – and proved that the half-life characteristics of Fei's product were not inferior to those claimed to result from the process in the '618 Patent. However, the Court finds that Fei produced enoxaparin for Amphastar by varying from the methods described in the European

[19] Accordingly, there was no meaningful comparison of product half-lives.

Patent and substantially utilizing the teachings of the '618 Patent.

Fei, at his deposition, testified that Ding gave him the '618 Patent,[20] but in the evidentiary hearing, Fei testified that he paid it little attention.[21] Nevertheless, Fei admitted that he obtained and followed specific directions from Ding. The evidence establishes that Fei utilized teachings in the '618 Patent that are not found in the European Patent. Ding, although an Amphastar employee, and not shown to be unavailable for the hearing, did not testify. The Court finds that Ding utilized the teachings of the '618 Patent to direct Fei's actions.

(a) Fei's Notebooks

During the time Fei was working to produce a generic enoxaparin for Amphastar, he maintained two sets of notebooks. There was a set of "preliminary" yellow notebooks and a set of "final" blue notebooks. Fei testified:

---

[20] Hr'g Tr., Day 2 AM, 20:16-22.

[21] Asked at the hearing whether he recalls Ding giving him the '618 Patent, Fei said: "Give me only -- Ding can give me because he's my supervisor, but I just said I'm not interested for that patent because I'm concentrate on the Irish patent, so maybe he give me, I just take a look. I didn't pay more attention on this patent. So I have many work to do on the Irish patent. There's a lot example to try. That's it." Hr'g Tr., Day 2 AM, 21:8-18.

> One is yellow book, one is blue book. Blue book is formally. One is roughly. Yellow book is roughly. I just wrote only the raw data on the yellow book. Yeah. Is very roughly. Not -- not very -- very complete or detailed. Not in detail.

Hr'g Tr., Day 2 AM, 40:11-15.

The contents of these notebooks were critical evidence in the evidentiary hearing. There were proceedings relating to the notebooks prior to the evidentiary hearing. On February 12, 2014, Amphastar stated:

> Amphastar did conduct experiments that exposed Aventis's fraud and that qualify Amphastar as an original source, but Amphastar has already produced those documents.

Joint Stipulation Regarding Defendants' Motion to Compel Responses to Defendants' Second Set of Requests for Production 32, ECF No. 200 (sealed).

However, the purported copies of Fei's notebooks that Amphastar produced, and stipulated as exhibits that were used in the evidentiary hearing, were not complete copies of the original documents in Amphastar's possession. Unknown to Aventis, Amphastar had, in its possession, original notebooks that included contents relevant to the evidentiary hearing that were omitted from the copies stipulated in evidence.

(b) Amphastar's Counsel's Conduct

Serious issues are presented by the conduct of Amphastar's counsel in regard to Fei's notebooks.[22]

The copies of the notebooks stipulated in evidence did not contain certain pages. Of course, this much was known to Aventis' counsel who believed – as did the Court – that the exhibits were the same as the original documents. I.e., the Court and Aventis believed that the originals in Amphastar's possession had the same pages missing as the copies in evidence and that every page in the stipulated exhibits was a true and complete copy of the corresponding page in the original notebook in Amphastar's possession. Hence, Aventis' counsel were contending that because exhibits were missing pages that might contain relevant information, the Court should infer that the missing contents would include evidence adverse to Amphastar.[23]

---

[22] These issues shall be addressed in a separate decision regarding the action to take in light of Amphastar's counsel's conduct.

[23] In addition, certain of Fei's notebooks for the relevant period were somehow "lost." Presumably, the Court could draw an inference that the contents of the lost notebooks not produced would be adverse to Amphastar's position. However, the evidence that was produced present ample indicia that Fei did not produce the enoxaparin sold by Amphastar by merely following the method of the European Patent and that the disclosure of '618 Patent was a substantial source of guidance for his experimental actions. Hence, the Court need not rely upon any inferences based on "lost" notebooks.

Neither the Court nor Aventis' counsel were aware (1) that the originals from which the exhibits had been copied contained some of the pages missing from the exhibits, and (2) that one notebook copy stipulated in evidence included what appeared to be a copy of a blank page and/or a page with a blank space that was not blank in the original – but contained relevant contents.

In argument, Amphastar's counsel admitted that, prior to the evidentiary hearing, he knew that among the exhibits stipulated to be copies of Fei's notebooks were incomplete copies.

> THE COURT: . . . Are you saying you were not aware that there was anything in evidence, where you had an original that was not perfectly consistent with what was in evidence? You're saying you were totally unaware of it or you were aware of it. Now we can talk about –
>
> MR. WEIR: I was aware.

Hr'g Tr., Closing, 19:23-20:3.

> THE COURT: [Y]ou knew you had an original [of Exhibit 39, Fei's yellow notebook from 2001] with page 92.
>
> MR. WEIR: I -- I knew I had the original. Page 92 was in it, in the original, and it was not in the copy. I knew about that before the hearing.

Hr'g Tr., Closing, 43:19-22.

Even if, as Amphastar's counsel contends,[24] he knew of only one stipulated exhibit that lacked content that was in the original in his possession, his conduct was inexcusable. He claims that, despite having this knowledge prior to the hearing, he did not check the other stipulated notebook exhibits[25] to ascertain – as was the case – that there was more than one incomplete copy. Nor did he notify the Court or opposing counsel that at least one of the stipulated exhibits lacked contents that were in an original document in his possession.

Rather, Amphastar's counsel misled the Court (and Aventis) into proceeding with the evidentiary hearing on the false premise that the copies of Fei's notebooks stipulated as evidence were not different from the original notebooks. He said, in his opening statement:

> MR. WEIR
>
> We are going to show you contemporaneously -- sorry for the mispronunciation of that -- notebooks that were done by Mr. Robert Fei. He was the scientist at enoxaparin who did the synthesis work. I have the originals of the notebooks with us. We have produced in the case copies and the copies are all marked. I've provided the originals to counsel for inspection, and they'll be here

[24] The Court will consider Amphastar's counsel's veracity on this, and other matters, in a separate decision regarding his conduct to be issued hereafter.

[25] The Court, while stating what Amphastar's counsel has said in this regard, is not addressing herein the veracity of his statement.

> throughout the case for inspection, but the original notebook – they're all bound notebooks. The original notebook is old, more than 10 years old, and it's falling apart, but they're all here in their original form.

Hr'g Tr., Day 1 AM, 11:25-12:9 (emphasis added).

Amphastar's counsel's statement that "I have the originals of the notebooks with us. We have produced in the case copies and the copies are all marked. . . ." gave the false impression that the copies Amphastar had produced and stipulated in evidence were true and complete copies of the original documents.

By the time of argument – when the fact that the notebook copies in evidence lacked relevant contents that were in the original notebooks in Amphastar's possession was known – Amphastar's counsel sought to disavow his statement that, at the beginning of the evidentiary hearing, "they're all here in their original form."

> THE COURT:
>
> Mr. Weir states in his opening statement, "I have the originals of the notebooks with us." I assume, Mr. Weir, you had the originals.
>
> MR. WEIR: At that moment I did not have all the originals. I had the originals that I believe that I was going to present to the Court and -- during the direct examination of our witnesses.

> . . . .
>
> THE COURT: Okay. All right. So you said, "I have the originals," but you meant "I had some originals"?
>
> MR. WEIR: Yes.

Hr'g Tr., Closing, 10:24-11:6, 12:22-24.

In the course of the hearing, it became perfectly clear that the Court and Aventis' counsel had been and were proceeding on the false premise – known to be false by Amphastar's counsel - that the stipulated exhibits were true and complete copies of the originals.

For example, on the fourth and final day of the evidentiary hearing:

> THE COURT: On this original notebook business, I don't know the fuss we're making about it. Unless there is some question of legibility -- and I haven't heard any question that the copies that are in evidence are inaccurate copies of what's in the original.
>
> . . . .
>
> They're [Aventis' counsel are] not making a contention that, if I understand it, the copies of these -- of all notebooks that are in evidence are in any way inaccurate copies of original notebooks that are in the possession of Amphastar. They are making an issue, as I understand it, that the absence of certain things means they couldn't look at it and they want to make arguments based on the absence of those things.
>
> MR. DAWSON [AVENTIS' COUNSEL]:

Thank you. Correct.

Hr'g Tr., Day 4 AM, 103:9-18, 108:2-11.

It was only after the completion of all of the testimony from Amphastar's fact witnesses (including all of the testimony of Fei and Zhang), at the very end of Aventis' presentation of evidence, that the Court ascertained that the stipulated notebook exhibits were not complete copies and that relevant information absent from the exhibits was contained in original documents that Amphastar's counsel had in his possession.

In Amphastar's counsel's re-cross-examination of Aventis' last witness, Amphastar's counsel asked a question indicating that he had an original notebook that contained a page missing from one of the stipulated exhibits. He did this to show that the content of one of the missing pages that Aventis had been speaking about was, in fact, irrelevant. He did not, however, indicate that – as was the situation - he had in his possession other originals that contained relevant evidence missing from the stipulated exhibits.

Immediately upon ascertaining that at least one of the stipulated exhibits was not a true and complete copy of the original, the Court took action. The Court directed Amphastar's counsel forthwith to provide Aventis' counsel with all of the original notebooks for a rapid comparison with stipulated

exhibits during the lunch break. In that brief review, Aventis' counsel was able to determine, and report to the Court, that several of the stipulated exhibits omitted contents that were present in the original notebooks just obtained from Amphastar. One of these, Exhibit 22[26] discussed below, included purported blank pages and/or spaces that were not blank in the original notebook that Amphastar's counsel had just produced. Rather, where the stipulated exhibit had blank spaces, blank pages, or missing pages, the original had pages with relevant test results data taped thereon.

(c) Use of the '618 Patent

The Court's finding that Fei's actions in the course of producing Amphastar's enoxaparin product were guided by the teachings of the '618 Patent is supported by indicia in Fei's notebooks. A few illustrative examples suffice.

(i) Esterification Testing

The '618 Patent teaches that controlling for a degree of esterification in a range of 9.5% and 14% ensures that the depolymerization step can be consistently reproduced for

[26] Amphastar's counsel, in closing argument, stated that the first time he knew of the omission of the testing data from Exhibit 22 was when Aventis counsel told it to the Court on the last day of the hearing. Hr'g Tr., Closing, 15:12-25.

achieving the desired low molecular weight targets. The European Patent did not disclose controlling for the degree of esterification.

Fei tested for the degree of esterification and could not state the source for his doing such testing. In the evidentiary hearing, Aventis sought to establish that Fei did this testing because it was presented in the '618 Patent:

> CROSS EXAMINATION OF FEI
>
> Q. . . . And the Irish patent [the European Patent]does not teach testing for the degree of esterification, does it?
>
> A. It is very simple to testing because it's hydrolysis and test it. It's very easy to test.
>
> Q. Mr. Fei, my question was does the Irish patent, Defense Exhibit 46, teach --
>
> A. It doesn't say that.
>
> Q. It doesn't say that. Okay.
>
> But the '618 patent from Aventis does say that, doesn't it?
>
> A. I don't know the '618 say that or not, but I -- we just test it.

Hr'g Tr., Day 2 AM, 49:24-50:10.

Aventis sought to establish that the esterification testing results had been reported to Ding, supporting the contention that Ding directed the testing. As Fei testified, if the test

results had been recorded in the blue (final) notebook, the results would be communicated to Ding.

> Q. Important things you will not copy?
>
> A. Yeah. Not important and something is not necessary so I'm not copy everything.
>
> Q. Okay.
>
> A. Most of them, the important thing I would copy and write on blue book.
>
> Q. Okay. And are the blue notebooks supposed to be reviewed by your supervisor?
>
> A. I give to Jeff Ding my supervisor.

Hr'g Tr., Day 1 PM, 79:3-11.

Aventis' counsel found a reference to testing for esterification in Fei's yellow (preliminary) notebook but did not find the test results in the stipulated marked exhibit, Exhibit 22, the blue (final) notebook.

Aventis' counsel, at the time unaware that the original notebook contained test results absent from Exhibit 22, cross-examined Fei.

> Q. Okay. And if you could look back at Exhibit 22, the second [the blue final] set of notebooks for this period of time at the beginning, does it reflect that you conducted degree of esterification experiments?
>
> A. I just sent this sample to testing. Someone test it. I not testing. I just make some sample.

> Q. And you didn't record the results in the second [blue final] set of books, did you, Mr. Fei?
>
> A. No. I didn't see -- where is it? On the blue book, where is it? Which page?
>
> Q. It's Defense Exhibit 22, and I guess my question is the same as your question: Where is it? I don't see it in this exhibit.
>
> A. Your question is where this esterification testing data -- where is it on the blue book, right?
>
> Q. Yes, sir.
>
> A. I have to check all the page. I cannot find it right now. Maybe somewhere. I think -- if they have the result, they will tell me or give me a copy or give me some result. I will write down. But I -- I don't think it's very important. Just for reference.
>
> Q. I see.
>
> A. Not very important. This -- we do the esterification to test how much ester is -- is on the heparin after esterification, but it's not important.

Hr'g Tr., Day 2 AM, 50:14-51:13.

As discussed above, on the last day of the evidentiary hearing, Aventis and the Court discovered that the original blue notebook, from which Exhibit 22 had been copied, actually had the test results. Thus – contrary to Fei's testimony – the test results were considered important enough to present in the blue (final) notebook for Ding's review.

The Court finds that – as to the degree of esterification

testing, Fei did the testing at the direction of Ding pursuant to the teaching of the '618 Patent.

(ii) The Temperature and Ratio

The European Patent provides several examples of esterification reactions with differing reagent ratios and reaction temperatures. However, there is no example in the European Patent that uses the reagent ratios of 1 to 5 to 1. Nor is there an example that describes carrying out an esterification reaction at 35 degrees Celsius (95 degrees Fahrenheit). See, e.g., Hr'g Tr., Day 1 PM, 112:22-113:16.

Fei utilized the precise temperature that is taught in the '618 Patent, the temperature of 35 degrees Celsius. Hr'g Tr., Day 1 PM, 121:24-122:18. Amphastar's counsel, during closing argument, – without any testimony to that effect from Fei – misstated the evidence and argued that the temperature of 35 degrees Celsius used by Fei had come from the European Patent. Counsel stated:

> MR. WEIR:
>
> Now, as far as 35 degrees is concerned, the EP [European Patent], again, 144 provides that the esterification reaction can take place between 20 degrees C to 60 degrees C. And 35 degrees falls right in the middle of it.

Hr'g Tr., Closing, 111:6-9.

However, the European Patent defines the range as minus 20 degrees Celsius to plus 60 degrees Celsius. European Patent, Pl.'s Ex. 6, 15:10-11; Hr'g Tr. Day 1 AM, 64:17-65:12. The middle of the range is not 35 degrees Celsius (95 degrees Fahrenheit) but 20 degrees Celsius (68 degrees Fahrenheit).[27]

The Court finds that Fei did not use the European Patent temperature range, but the precise teaching of the '618 Patent.

In the esterification reaction conducted by Fei, he used a ratio of reagents of 1 to 5 to 1, the same ratio taught in the '618 Patent. Fei did not identify any possible source for the ratio other than the teaching of the '618 Patent, directly or through Ding.[28] The Court finds that Fei obtained the ratio directly from the '618 Patent or indirectly by virtue of direction from Ding.

(iii) Purification of Heparin

Prior to October 2001, Fei had not been purifying the heparin used. Then, Fei began to purify the heparin, a process

[27] Even if the European Patent range had been plus 20 degrees Celsius to 60 degrees Celsius as counsel stated, the middle of range would have been 40 degrees, not 35.

[28] Amphastar has found the ratio of 1 to 5 to 1 in an example contained in U.S. Patent No. 4,440,926, a patent that was related to the European Patent. There is no evidence, however, that Fei looked at any such patent or that he got his 1 to 5 to 1 ratio from any source other than from the '618 Patent directly or from Ding.

not described in the European Patent but disclosed in the '618 Patent. Fei testified on cross examination that this was directed by Ding:

> CROSS EXAMINATION
>
> Q. But my question for you right now is the Irish patent does not teach purifying the heparin starting material, does it?
>
> A. It doesn't say that.
>
> Q. Okay. And this procedure that you used is the same procedure that's taught in Aventis's '618 patent except you doubled the amount of the reagents; is that correct?
>
> A. I don't know because my supervisor let me do that. Just according -- he let me do something, I just do it.
>
> Q. Your supervisor asked to you [sic] conduct this experiment?
>
> A. He let me do something. I just according to his advice I do something and report to him. Just that's it.

Hr'g Tr., Day 1 PM, 105:9-20.

2. Alleged Fraud on the FDA

In the Citizen Petition filed with the FDA on February 19, 2003, Aventis requested that the FDA refrain from approving any generic enoxaparin unless the manufacturing process was determined to be equivalent to Aventis' process. Pl.'s Ex. 8, 1.

In support of its position, Aventis stated:

> Aventis utilizes a process of β-elimination of uronic benzylic esters to manufacture enoxaparin. This process creates a distinct drug product with a unique chemical structure that is sensitive to specified temperature, base concentration, and duration factors in the reaction. . . .
>
> Since the initial development of enoxaparin in 1981, the steps of the manufacturing process have remained unchanged. Clinical supplies used in a few of the initial clinical studies, however, were made from batches where some of the conditions (e.g., time and temperature) were modified. Aventis conducted pivotal clinical trials on batches with and without those modifications. All of those pivotal trials were included in enoxaparin's NDA and formed the basis for enoxaparin's approval by FDA.

Id. at 10-11 (emphasis added).

In the Complaint, Amphastar alleged that Aventis falsely reported to the FDA that its manufacturing process had not changed since 1981, and falsely represented the importance of the process, requiring that any generic drug manufacturer must show that its process was equivalent. Amphastar thereafter contended that it was false for Aventis to state that the process was sensitive to certain reaction conditions such as time, temperature, and concentration. See Opp'n to Defs.' Mot. to Dismiss, ECF. No. 54, 3.

While the Court is not herein addressing the substantive merits of Amphastar's claims, it must note that the evidence now

of record does not indicate that Aventis made any such false statements to the FDA. Indeed, the testimony of the Amphastar witnesses in the evidentiary hearing indicates that pertinent reactions are, as stated by Aventis to the FDA, sensitive to time, temperature, and concentration.[29]

Even assuming that Aventis had made false statements to the FDA as alleged, Amphastar did not prove that it had direct and independent knowledge of that supposed falsity. Indeed, in argument, Amphastar acknowledged that its only witness regarding its supposed "direct and independent knowledge," Zhang, did not offer such evidence.

> MR. WEIR: . . . So regardless of how you vary the reaction conditions, they fell within the scope of the 618 claims. So the representations to the FDA, Your Honor, was that enoxaparin is sensitive to quote, specified time and temperature reactions. So they -- in the presentations they provide the Court they always omit the word "specified."
>
> THE COURT: [Ha]s Zhang testified in this case, that he became aware of, using your concept, that that was a false statement?
>
> MR. WEIR: No.
>
> THE COURT: I don't think he did.
>
> MR. WEIR: He has not.

[29] See, e.g., Defs.' Ex. 137 at 77:1-4; Hr'g Tr., Day 1 AM, 78:23-82:1; Hr'g Tr., Day 1 PM, 128:13-15; Hr'g Tr., Day 3 PM, 105:20-106:23.

THE COURT: That's fine. That's that.

Hr'g Tr., Closing, 161:2-14.

Accordingly, the Court finds that Amphastar did not have direct and independent knowledge of the information upon which it based its claims regarding alleged false statements to the FDA.

## IV. JUDICIAL ESTOPPEL

Aventis contends that Amphastar should be estopped from denying that it obtained the information on which the instant case is based through proceedings in the Patent Case.

"[W]here a party assumes a certain position in a legal proceeding, and succeeds in maintaining that position, he may not thereafter, simply because his interests have changed, assume a contrary position . . . ." New Hampshire v. Maine, 532 U.S. 742, 749 (2001) (internal quotation marks omitted). "Judicial estoppel applies to a party's stated position whether it is an expression of intention, a statement of fact, or a legal assertion." Wagner v. Prof'l Engineers in Cal. Gov't, 354 F.3d 1036, 1044 (9th Cir. 2004)(citing Helfand v. Gerson, 105 F.3d 530, 535 (9th Cir. 1997)). Judicial estoppel is a discretionary equitable doctrine, applied on a case-by-case

basis. Ah Quin v. Cnty. of Kauai Dep't of Transp., 733 F.3d 267, 270 (9th Cir. 2013)(citing New Hampshire, 532 U.S. at 750).

The fact that Amphastar took positions in the Patent Case inconsistent with its contentions in the instant case may warrant consideration of the doctrine of judicial estoppel. However, in the instant case, the Court has conducted an evidentiary hearing and decided – on the merits - that Amphastar has failed to prove that it had the jurisdictionally requisite direct and independent knowledge.

This decision renders moot the question of whether Amphastar should be estopped from presenting its contentions.

## V. LEGAL FEES AND COSTS

### A. Legal Fees Under the FCA

The FCA provides, in regard to a qui tam action:

> If the Government does not proceed with the action and the person bringing the action conducts the action, the court may award to the defendant its reasonable attorneys' fees and expenses if the defendant prevails in the action and the court finds that the claim of the person bringing the action was clearly frivolous, clearly vexatious, or brought primarily for purposes of harassment.

31 U.S.C. § 3730(d)(4).

The Ninth Circuit has stated, in the context of reversing an award of attorney's fees against an attorney under the FCA:

> In qui tam cases, a court may award attorneys' fees against the plaintiff if the "action was clearly frivolous, clearly vexatious, or brought primarily for purposes of harassment." This standard tracks our formulation as to when fees are appropriate under 42 U.S.C. § 1988 to a prevailing defendant. "A court may grant attorney's fees to a defendant under § 1988 only under the limited circumstances where the action is frivolous, unreasonable, or without foundation." As such, § 1988 cases are instructive in deciding whether fees are appropriate under the False Claims Act.[30]

Pfingston v. Ronan Eng'g Co., 284 F.3d 999, 1005-06 (9th Cir. 2002) (first quoting 31 U.S.C. § 3730(d)(4); then quoting Maag v. Wessler, 993 F.2d 718, 719 (9th Cir. 1993))(footnote in original).

In Branson v. Nott, 62 F.3d 287, 293 (9th Cir. 1995), a case filed pursuant to 42 U.S.C. § 1983, the Ninth Circuit quoted a Second Circuit decision[31] stating "[w]here there is no subject matter jurisdiction to proceed with the substantive claim, as a matter of law '[t]hat lack of jurisdiction bar[s] an award of attorneys fees under section 1988.'" The Branson court further stated:

> [A]ttorney's fees are only available under that provision [28 U.S.C. § 1988] to a party

---

[30] The False Claims Act's legislative history also indicates that Congress viewed the § 1988 standard as analogous. See S.Rep. No. 99-345, at 29 ("[The False Claims Act] standard reflects that which is found in § 1988 ..."), reprinted in 1986 U.S.C.C.A.N. 5266, 5294.

[31] W.G. ex rel. D.G. v. Senatore, 18 F.3d 60, 64 (2d Cir. 1994)(quoting Keene Corp. v. Cass, 908 F.2d 293, 298 (8th Cir. 1990)).

> who has "prevailed" on the merits. Where, as here, dismissal is mandated by a lack of subject matter jurisdiction, a defendant is not a "prevailing" party within the meaning of § 1988. "Where a complaint has been dismissed for lack of subject matter jurisdiction, the defendant has not "prevailed" over the plaintiff on any issue central to the merits of the litigation."

Id. (quoting Keene Corp. v. Cass, 908 F.2d 293, 298 (8th Cir. 1990)).

The Court concludes, therefore, that it is unable to award Aventis its attorneys' fees and expenses pursuant to 31 U.S.C. § 3730(d)(4).

B. Costs – Rule 54(d) and 28 U.S.C. § 1919

1. Rule 54(d)

"[C]osts under Rule 54(d) may not be awarded where an underlying claim is dismissed for lack of subject matter jurisdiction, for in that case the dismissed party is not a 'prevailing party' within the meaning of Rule 54(d)." Miles v. State of California, 320 F.3d 986, 988 (9th Cir. 2003).

Therefore, the Court shall not award Aventis costs pursuant to Rule 54(d).

2. 28 U.S.C. § 1919

Pursuant to 28 U.S.C. § 1919, "[w]henever any action or suit is dismissed in any district court . . . for want of jurisdiction, such court may order the payment of just costs."

"In determining 'just costs' under 28 U.S.C. § 1919, a district court should consider what is most fair and equitable under the totality of the circumstances." Otay Land Co. v. United Enters. Ltd., 672 F.3d 1152, 1157 (9th Cir. 2012). A "just costs" award is within the trial court's discretion and must be decided depending on the circumstances and equities of each case. Id.

The Ninth Circuit has articulated four factors for district courts to consider, none of which are definitive:

(1) The role played by exigent circumstances, such as hardship or culpable behavior by the parties;

(2) The strength of the plaintiff's jurisdictional claim;

(3) The significance of pending parallel litigation in state court;

(4) Other equitable considerations.

Id. at 1157-59. There is no presumption of the award of just costs, and the district court has broad discretion. Id. at 1158-59.

Upon consideration of the Otay factors in the instant case, the Court finds that an award of just costs is warranted.

Plaintiff's jurisdictional claim lacked any strength in regard to the "direct and independent knowledge" jurisdiction requisite. There was no role played by exigent circumstances, i.e., no undue hardship would result from requiring Amphastar to pay Aventis' just costs.[32] There are no relevant parallel proceedings and no other equitable considerations that would tend to favor a denial of just costs to Aventis.

Finding that an award of just costs is warranted, the Court shall exercise its discretion to award such just costs to Defendants.

Defendants may submit a bill of costs, using 28 U.S.C. § 1920 as guidance for the types of costs that may be awarded. See id. at 1160.

[32] The Court is not considering the conduct of Amphastar's counsel in regard to its 28 U.S.C. § 1919 decision.

## VI. CONCLUSION

For the reasons stated herein:

1. The Court decides that Plaintiff Relator, Amphastar Pharmaceuticals Inc., has failed to prove that it was an "original source of the information" on which the suit is based pursuant to 31 U.S.C. § 3730(e)(4)(A).

2. The Court shall dismiss this case for lack of jurisdiction by separate Order.

3. The Court shall award Defendants their "just costs" pursuant to 28 U.S.C. § 1919.

4. The Court shall retain jurisdiction to issue a decision and Order with respect to the conduct of Amphastar's counsel in regard to the evidentiary hearing.

SO ORDERED, on Monday, July 13, 2015.

/s/
Marvin J. Garbis
United States District Judge