UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

ZACHARY SILBERSHER, et al.,

Plaintiffs,

v.

VALEANT PHARMACEUTICALS INTERNATIONAL, INC., et al.,

Defendants.

Case No. 3:18-cv-01496-JD

ORDER RE MOTION TO DISMISS

Re: Dkt. No. 36

This is a qui tam action under the federal False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733, and the counterpart statutes of twenty-eight states, and the District of Columbia. In a "corrected first amended complaint," Dkt. No. 10 ("CFAC"), plaintiff-relator Zachary Silbersher alleges that defendants fraudulently obtained U.S. Patent No. 8,865,688 (the "'688 patent"), which allowed them to raise the price for the prescription drug Apriso by wrongfully excluding generic competitors. The false claim is said to be the inflated prices that Medicare, Medicaid and other government agencies paid for Apriso prescriptions.

Silbersher is an attorney, and the CFAC is based on a patent litigation case he handled that invalidated the '688 patent. He was never an employee or an insider at any of the defendant companies. The United States has declined to intervene, Dkt. No. 8, and no state or the District of Columbia has sought to join as a plaintiff.

The Valeant and Salix defendants move to dismiss the CFAC under Federal Rule of Civil Procedure 12(b)(6) on three grounds: (1) it does not allege an actionable false claim; (2) the claim is foreclosed by the FCA's public disclosure bar; and (3) the claim sounds in fraud and has not been alleged with the degree of particularity required by Rule 9(b). Dkt. No. 36. Valeant and Salix also moved to stay discovery pending disposition of the Rule 12(b)(6) motion. Dkt. No. 41.

Defendant Dr. Falk Pharma GmbH, a German corporation headquartered in Breisgau, Germany, joins the motions and the arguments Valeant and Salix make against the CFAC and to stay discovery. Dkt. Nos. 42, 52. Falk also filed a separate motion under Rule 12(b)(2) that challenged personal jurisdiction in this District, which the Court denied. Dkt. Nos. 43, 108.

The Court heard oral argument on the Rule 12(b)(6) motion. Dkt. No. 94. The case was stayed in all aspects pending this order. *Id.* The federal FCA claim is dismissed under the public disclosure bar, and the Court declines to exercise jurisdiction over the state law claims. The motion to stay discovery is terminated as moot.

BACKGROUND

As alleged in the CFAC, defendants make and sell Apriso, a drug used to treat inflammatory bowel conditions like ulcerative colitis. Dkt. No. 10 ¶ 2. The active ingredient in Apriso is mesalamine, which is said to have been used "for decades" for ulcerative colitis and "has long been off-patent." *Id*. To ensure that mesalamine reaches the bowel and is not metabolized in the stomach, it can be encased in a protective enteric coating that dissolves only in the colon. *Id*. ¶¶ 3-4. Apriso is a coated and extended release formulation of mesalamine that was approved for sale in the United States in 2008. *Id*. ¶¶ 2, 4.

The patent situation for mesalamine changed in October 2014, when the United States Patent and Trademark Office ("USPTO") issued the '688 patent, which has been assigned to Falk at all times relevant to this case. *Id.* ¶¶ 44, 80-82. The '688 patent relates to the remission of ulcerative colitis. Claim 1 recites a "method of maintaining the remission of ulcerative colitis in a subject comprising administering to the subject a granulated mesalamine formulation . . . once per day in the morning, without food." '688 patent, col. 34, ll. 11-15. The patent's other independent claim, claim 16, is identical to claim 1, but adds the limitation of "advising the subject that granulated mesalamine should not be taken with antacids." *Id.* at col. 35, ll. 5-6.

After the '688 patent was issued, generics manufacturers sued to invalidate it. Dkt. No. 10 ¶¶ 15-16. The key proceedings took place before the Patent Trial and Appeal Board ("PTAB"). The lead plaintiff was GeneriCo, LLC, which filed a petition in December 2015 for inter partes review ("IPR") of the '688 patent. *GeneriCo, LLC v. Dr. Falk Pharma GmbH*, Case IPR2016-

00297, 2017 WL 2211672, at *1 (P.T.A.B. May 19, 2017). IPR was instituted to determine whether claims 1 and 16 were unpatentable as obvious over prior art that was available before the '688 patent application was filed. *Id*. at *3; *see also* 35 U.S.C. § 103(a) (2006).

In May 2017, the PTAB concluded that claims 1 and 16 were unpatentable as obvious.[1] The PTAB construed the '688 patent to address problems with prior mesalamine delivery systems such as "sensitivity to conditions that increase gastric pH and cause premature release of mesalamine (e.g., ingestion of a meal)." *GeneriCo*, 2017 WL 2211672, at *2 (citation omitted). It determined that the method in the '688 patent was an obvious solution over several publicly available prior art references. These included two press releases by Salix, one of which specifically announced the "successful completion" of clinical trials of a granulated mesalamine formulation with an enteric coating, *id*. at *8, and three academic papers: (1) the "Davis -- 1985" study by S. S. Davis, *The Design and Evaluation of Controlled Release Systems for the Gastrointestinal Tract*, 2 J. Controlled Release 27-38 (1985); (2) the "Marakhouski" study by Y. Marakhouski, et al., *A Double-Blind Dose-Escalating Trial Comparing Novel Mesalazine Pellets with Mesalazine Tablets in Active Ulcerative Colitis*, 21 Alimentary Pharmacology Therapeutics 133-40 (2005); and (3) the "Brunner" study by M. Brunner, et al., *Gastrointenstinal Transit and Release of 5-Aminosalicylic Acid from ^{153}Sm-Labelled Mesalazine Pellets vs. Tablets in Male Healthy Volunteers*, 17 Alimentary Pharmacology Therapeutics 1163-69 (2003), *id*. at *3, *8-*9. Davis --1985 discussed the effect of food on stomach pH and gastric emptying in connection with orally administered medications, as well as the positioned release of drugs in the colon, and used the treatment of ulcerative colitis as an example. *Id*. at *8.

The PTAB made a detailed analysis of this prior art in the course of invalidating the '688 patent. *See id.* at *8-*19. Among other findings, it noted that the Salix press releases disclosed "the elements recited in the preamble [to the '688 patent] and most of paragraph [a] of claim 1" for the administration of a granulated mesalamine formulation. *Id*. at *9. It determined that the "without food" limitation "is suggested by either Marakhouski or Brunner in view of Davis --

[1] Because the claims were identical save for the antacid advisory and an omission of the article "a" from claim 16, the PTAB confined its discussion to claim 1. *GeneriCo*, 2017 WL 2211672, at *3.

1985," and that these references would have indicated that the method described in the Salix press releases "could be advantageously and successfully practiced by administering granulated mesalamine without food." *Id.*

The PTAB also found that a person of ordinary skill in the art would have been aware of these teachings and motivated to combine them to obtain the advantages of a granulated mesalamine formulation administered independent of food. *Id*. at *14-*15. Consequently, it concluded that GeneriCo had established that claims 1 and 16 of the '688 patent were unpatentable as obvious. *Id*. at *24.

News sources immediately published reports of GeneriCo's victory and its implications for Apriso. Law360, for example, a national legal publication with wide readership, ran a story on May 19, 2017, announcing that GeneriCo "had shown the challenged patent claims would have been obvious." Matthew Bultman, *Part of Apriso Patent Nixed in IPR with Hedge Fund Ties*, Law360 (May 19, 2017, 4:58 p.m. EDT), https://www.law360.com/articles/926213/part-of-apriso-patent-nixed-in-ipr-with-hedge-fund-ties. The article expressly linked the PTAB's finding of obviousness to Apriso, reporting that the decision "invalidated part of a patent covering Apriso, an ulcerative colitis treatment." *Id.*[2]

Falk appealed the PTAB decision to the Federal Circuit. The appeal was pending when the CFAC was filed, Dkt. No. 10 ¶ 16, but in June 2019, the Federal Circuit affirmed the decision in all respects. *Dr. Falk Pharma GmbH v. GeneriCo, LLC*, 774 F. App'x 665 (Fed. Cir. 2019).

Plaintiff-relator Silbersher was deeply involved in GeneriCo's litigation against the '688 patent. He served as a lead counsel for GeneriCo in the PTAB proceedings, and again in defending the decision before the Federal Circuit on GeneriCo's behalf. *GeneriCo*, 2017 WL 2211672; *Dr. Falk Pharma GmbH*, 774 F. App'x at 666.

The '688 patent litigation is the foundation on which the CFAC is built. The FCA claim is premised on the allegation that defendants wrongfully obtained the '688 patent by advising the

[2] The Law360 article meets the standards for admissibility set forth in Federal Rule of Evidence 201(b). The Court takes judicial notice of it solely as an indication of what information was in the public realm at the time. *See Von Saher v. Norton Simon Museum of Art at Pasadena*, 592 F.3d 954, 960 (9th Cir. 2010).

USPTO during patent prosecution that "administering the claimed granulated mesalamine formulation without food was *not* obvious." Dkt. No. 10 ¶ 9 (emphasis in original). Silbersher references the patent law doctrine of inequitable conduct, which makes the claims in a patent unenforceable or invalid when the applicant violated the duty of candor during prosecution by deliberately omitting material prior art. *Id.* ¶ 72. He alleges that defendants "withheld" the Brunner and Marakhouski studies from the USPTO to falsely suggest that the advantage of administering the formulation without food was "unexpected," *id.* ¶¶ 14-15, and "because they knew these papers would render the patent invalid as obvious in light of prior art," *id.* ¶ 99. The CFAC has a number of additional allegations about other omissions and inconsistencies in defendants' statements to the USPTO, *see, e.g.*, *id.* ¶¶ 88-98, but the heart of Silbersher's case is that defendants obtained the '688 patent by "willful deceit," as "confirmed" by the PTAB decision, *id.* ¶ 15.

The CFAC further alleges that defendants obtained the patent to exclude competition from generic versions of Apriso and maintain prices at supracompetitive levels. *Id.* ¶ 5. It says that competition would have lowered the price of Apriso "by at least 80%," and defendants would have lost "at least 90% of Apriso's market share." *Id.* ¶ 24. The '688 patent allowed defendants to escape these adverse impacts by keeping generic formulations of Apriso out of the market from July 2012 through the filing of the CFAC in October 2018, and, Silbersher says, possibly beyond. *Id.* ¶¶ 118-122.

The linchpin of the FCA claim is the allegation that the artificially high prices made a false claim out of "each and every" Apriso prescription covered by Medicare, Medicaid, and other government agencies. *Id.* ¶¶ 28-30. The CFAC says that defendants falsely certified that Apriso's price was "fair and reasonable" when it was "unlawfully elevated as a result of Defendants' false, fraudulent, and misleading statements to the Patent Office." *Id.* ¶ 30. The CFAC alleges that Medicare reimbursed over 460,000 Apriso claims for approximately $183 million between 2011 and 2016. *Id.* ¶ 31. State Medicaid programs are said to have paid out approximately $65 million for over 175,000 claims during the same period. *Id.* ¶ 33.

The CFAC does not say why the government expenditures on Apriso between 2011 and 2016 are in play under the FCA. The '688 patent was not issued until October 2014, *id.* ¶ 7, and it was not invalidated by the PTAB until May 2017, *id.* ¶ 15. No generic manufacturers are alleged to have been blocked from entering the market until "possibly" July 2012. *Id.* ¶ 122. It is also unclear how or why "the number and cost of false claims Defendants submitted . . . continued to increase in 2017 and 2018," after the '688 patent was invalidated. *Id.* ¶ 33.

DISCUSSION

I. LEGAL STANDARDS

Rule 8 requires a complaint to provide "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). To meet that rule and survive a Rule 12(b)(6) motion to dismiss, a plaintiff must allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 556). The plausibility analysis is "context-specific" and not only invites, but "requires the reviewing court to draw on its judicial experience and common sense." *Id.* at 679.

"A claim under the FCA must not only be plausible, but pled with particularity under Rule 9(b)." *Godecke v. Kinetic Concepts, Inc.*, 937 F.3d 1201, 1208 (9th Cir. 2019) (citations omitted). It must "state with particularity the circumstances constituting fraud or mistake, including the who, what, when, where, and how of the misconduct charged. In addition, the plaintiff must set forth what is false or misleading about a statement, and why it is false." *Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 998 (9th Cir. 2010) (internal quotations and citations omitted).

The Court may consider judicially noticeable materials on a motion to dismiss. *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 999 (9th Cir. 2018). "Courts may take judicial notice of publications introduced to indicate what was in the public realm at the time, not whether the contents of those articles were in fact true." *Von Saher v. Norton Simon Museum of Art at Pasadena*, 592 F.3d 954, 960 (9th Cir. 2010). Similarly, "when a court takes judicial notice of

another court's opinion [on a Rule 12(b)(6) motion], 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." *Lee v. City of Los Angeles*, 250 F.3d 668, 690 (9th Cir. 2001) (internal quotation and citation omitted). Defendants filed a request for judicial notice, Dkt. No. 37, which relator did not oppose, Dkt. No. 44.

II. THE FALSE CLAIMS ACT

At heart, the motion to dismiss asks whether Silbersher may bring a qui tam action based on public litigation before the PTAB, a federal tribunal of administrative judges within the USPTO. The answer depends on the meaning and scope of the public disclosure bar and original source provisions in the FCA in light of amendments Congress made in 2010.

A. Background And Current Law

As many cases have observed, the FCA originated during the Civil War to fight corrupt suppliers who committed fraud against the United States. *See Vermont Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 781-82 (2000). The FCA imposes civil liability on one who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). It provides two mechanisms of enforcement. The government can bring suit, *id.* § 3730(a), or, as in this case, a private person may file a qui tam action as a relator "for the person and for the United States Government . . . in the name of the Government," *id.* § 3730(b)(1). The FCA incentivizes whistleblower suits by awarding the relator a bounty in the form of a substantial share of the fraudulent payments that are recovered, plus attorney's fees and costs. *Id.* § 3730(d).

The public disclosure bar restricts the information that can be used in a qui tam case to pursue these generous incentives. *Graham Cty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 293-94 (2010). The basic idea is that if the government already had notice to investigate the potential fraud, a private action would be "parasitic," and should not be rewarded. *Id.* at 294.

Congress has modified the disclosure bar on several occasions to find "the golden mean between adequate incentives for whistle-blowing insiders with genuinely valuable information and

discouragement of opportunistic plaintiffs who have no significant information to contribute of their own." *Id.* (citation omitted). From the enactment of the FCA to World War II, there were no constraints on the sources of information that could be used as the basis of a qui tam action. This period of openness culminated in 1943, when the Supreme Court permitted a relator to recover for a false claim he "discovered" simply by reading a federal criminal indictment. *Id.* (citing *United States ex rel. Marcus v. Hess*, 317 U.S. 537 (1943)). Congress promptly reacted by amending the FCA to prohibit actions "based upon evidence or information in the possession of the United States . . . at the time such suit was brought." *Id.* (citation omitted).

The 1943 disclosure bar proved to be an over-correction that sharply reduced "the volume and efficacy of qui tam litigation." *Id*. Congress responded with amendments in 1986 aimed at striking a better "balance between encouraging private persons to root out fraud and stifling parasitic lawsuits" based on public sources. *Id.* at 294-95. There is no dispute the 1986 amendments were intended to encourage more private enforcement lawsuits. *Id*. at 298 (citing S. Rep. No. 99-345, at 23-24 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 5266, 5288-89). At the same time, Congress sought to "*bar* a subset of those suits that it deemed unmeritorious or downright harmful." *Id*. (emphasis in original).

Congress amended the disclosure bar again in 2010 in the Patient Protection and Affordable Care Act, the well-known healthcare reform bill. These amendments are the current law, and they govern this case. Silbersher does not allege that defendants made any false claims for payment until July 2012 at the earliest, so the 2010 amendments apply here. *See Hughes Aircraft Co. v. United States ex rel. Schumer*, 520 U.S. 939, 946 n.5 (1997).

As the public disclosure bar states (31 U.S.C. § 3730(e)(4)):

> (A) The court shall dismiss an action or claim under this section [FCA], unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed --
>
> (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;
>
> (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or

> (iii) 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.
>
> (B) For purposes of this paragraph, "original source" means an individual who either (i) prior to a public disclosure under (e)(4)(a), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.

With the 2010 amendments, Congress changed public disclosure from a jurisdictional issue to a defense. Prior to 2010, the FCA stated that "[n]o court shall have jurisdiction" over a qui tam claim where the public disclosure bar applied. 31 U.S.C. § 3730(e)(4)(A) (2006). "After the 2010 Amendments, a court could assert jurisdiction over the relator's complaint and entertain public disclosure as a defense." *Prather v. AT&T, Inc.*, 847 F.3d 1097, 1103 (9th Cir. 2017). Consequently, the public disclosure bar is properly considered in a motion to dismiss when the material facts are not in dispute, which is true here. *See id.* at 1102 (citing *United States ex rel. Osheroff v. Humana, Inc.*, 776 F.3d 805, 810 (11th Cir. 2015)).

B. The CFAC Would Have Been Barred Before 2010

The 2010 amendments are critical to the CFAC. Silbersher acknowledges that, without the amendments, the 1986 disclosure bar would be fatal to his claims. As his attorney said at oral argument, "[b]efore 2010, there would be no case." Dkt. No. 102 at 12:24.

This forthright concession is well taken. In a strikingly similar case, the Ninth Circuit affirmed the dismissal of virtually identical FCA claims under the 1986 disclosure bar. *Amphastar Pharmaceuticals Inc. v. Aventis Pharma SA*, 856 F.3d 696, 701 (9th Cir. 2017). A generic drug manufacturer had established in another action that a drug patent was unenforceable because the patentee had engaged in inequitable conduct by withholding material disclosures from the USPTO. *Id.* at 701-02. The generic company subsequently filed a qui tam complaint alleging that the patentee had "obtained an illegal monopoly" over the drug "and then knowingly overcharged the United States." *Id.* at 702. The circuit court affirmed dismissal on the grounds that the material allegations of fraud had been publicly disclosed in the litigation, and so were barred under

the 1986 disclosure rules, which applied there. *Id.* at 702 n.7, 711. Silbersher is quite right to recognize that he wouldn't have a leg to stand on before the 2010 amendments.

Silbersher is also a far cry from the quintessential whistleblower plaintiff contemplated by the FCA. The "paradigm qui tam case is one in which an insider at a private company brings an action against his own employer. . . . Qui tam suits are meant to encourage insiders privy to a fraud on the government to blow the whistle on the crime." *United States ex rel. Fine v. Chevron, U.S.A., Inc.*, 72 F.3d 740, 742 (9th Cir. 1995) (en banc) (citation omitted); *see also Prather*, 847 F.3d at 1105 (FCA designed "to encourage insiders to come forward with [information about possible fraud] where they would otherwise have little incentive to do so." (brackets in original and internal quotation omitted)). Because Congress envisioned the paradigmatic qui tam plaintiff to be an inside employee with access to non-public evidence of fraud, the FCA contains an anti-retaliation provision that protects relators from discrimination "in the terms and conditions of employment." 31 U.S.C. § 3730(h)(1).

None of this fits Silbersher. He is, or was, a lawyer at a law firm, and does not allege that he was ever an employee or other insider of Valeant, Salix, or Falk. The CFAC indicates that his knowledge of defendants' conduct is based entirely on publicly available prior art references and other public documents, and the decision by the PTAB in favor of his client. Nothing in the CFAC reflects any non-public or insider evidence. Silbersher says that his information had not been publicly disclosed and that he is an original source, Dkt. No. 10 ¶¶ 37-38, 47, but these are wholly conclusory allegations unsupported by any facts. They are also inconsistent with the panoply of public materials that are discussed in the CFAC.

At best, Silbersher and the CFAC simply infer FCA violations from publicly available evidence. But a "relator's ability to recognize the legal consequences of a publicly disclosed fraudulent transaction does not alter the fact that the material elements of the violation already have been publicly disclosed." *Prather*, 847 F.3d at 1105 (citations omitted).

C. The CFAC Is Barred Under Current Law

To be sure, Silbersher would protest that these observations are irrelevant because they are associated with the 1986 disclosure bar, and Congress opened the door to his case in 2010. It is

true that precedents construing the pre-2010 FCA are not dispositive, but it also true that the changes in 2010 cannot be construed in a vacuum, as if the long history of the public disclosure bar did not exist. The question is whether the 2010 amendments were an incremental adjustment of the bar, or, as Silbersher argues, a major sea change such that a qui tam action that would have been an opportunistic lawsuit under prior law is now a good case.

As in all statutory interpretation cases, analysis begins with the plain words of the text. *Universal Health Servs., Inc. v. United States ex rel. Escobar*, ___ U.S. ___, 136 S. Ct. 1989, 1999 (2016). The "inquiry must cease if the statutory language is unambiguous" and "the statutory scheme is coherent and consistent." *Schindler Elevator Corp. v. United States ex rel. Kirk*, 563 U.S. 401, 412 (2011) (citations omitted).

This fundamental rule is supplemented by two other principles of interpretation. The first is that claims of a sea change in the law should be treated with caution. Congress "does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions -- it does not, one might say, hide elephants in mouseholes." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001). Silbersher's case assumes just that. It hinges on the proposition that Congress made a major change to the public disclosure bar in a short section inserted in a historic and massive healthcare reform law.

The second guiding principle is that the 2010 amendments must be construed in light of the statute as a whole and the purpose of the disclosure bar. *See Schindler*, 563 U.S. at 409-10. To "determine the meaning of one word in the public disclosure bar, we must consider the provision's 'entire text,' read as an 'integrated whole.'" *Id.* at 408 (quoting *Graham Cty.*, 559 U.S. at 290, 293 n.12). The Court bears "the conventional judicial duty to give faithful meaning to the language Congress adopted in the light of the evident legislative purpose in enacting the law in question." *Graham Cty.*, 559 U.S. at 298 (citation omitted). This is all the more true here because there is no legislative history that might shed some light on the 2010 amendments, even subject to the usual caveats about relying on such history. *See United States ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 299 (3d Cir. 2016).

While the historical path of the public disclosure bar sometimes "raises more questions than it answers," there is no doubt that Congress has always acted "to strike a balance between encouraging private persons to root out fraud and stifling parasitic lawsuits." *Schindler*, 563 U.S. at 412-13 (quoting *Graham Cty.*, 559 U.S. at 294-96). The 2010 amendments were not a flat-out rejection of the principle that qui tam suits should be barred where "the Government was on notice to investigate the fraud before the relator filed his complaint." *United States ex rel. Mateski v. Raytheon Co.*, 816 F.3d 565, 574 (9th Cir. 2016); *see also Schindler*, 563 U.S. at 410. It is still the case that the "public disclosure bar is intended to encourage suits by whistle-blowers with genuinely valuable information, while discouraging litigation by plaintiffs who have no significant information of their own to contribute." *Mateski*, 816 F.3d at 570 (citing *Graham Cty.*, 559 U.S. at 294-95).

The factors for determining when the bar applies also have not materially changed. The bar applies when: (1) the disclosure at issue occurred through one of the channels specified in the statute; (2) the disclosure was "public"; and (3) the relator's action is substantially similar to the allegations or transactions publicly disclosed. *Id.* at 570, 573. "Courts have interpreted 'allegation' to refer to a direct claim of fraud, and 'transaction' to refer to facts from which fraud can be inferred." *Id.* at 571.

These factors warrant dismissal here, just as they did in *Amphastar Pharmaceuticals*. The prior proceeding there for inequitable conduct was held to constitute a disqualifying public disclosure even though the allegations "never mentioned any false claims submitted to or paid by the federal government and state governments." 856 F.3d at 704. The only new allegation Amphastar made in the FCA case was "that the government also bought the drug while Aventis held its illegal monopoly, but this is an obvious inference based on the publicly disclosed allegations." *Id.* As a result, the "allegations in this case are so 'substantially similar' to the prior allegations that we are satisfied the public disclosure bar applies." *Id.* (citing *Mateski*, 816 F.3d at 573-74).

So too, here. The allegations in the CFAC about the obviousness of the '688 patent, and defendants' allegedly nefarious conduct in obtaining it, were all disclosed in the PTAB

proceedings. If anything, the substantial similarity between the prior litigation and the CFAC is even more evident than in *Amphastar* because the CFAC takes its key allegations directly out of the PTAB's findings. The CFAC expressly depends on the PTAB's finding of obviousness, alleging that "Defendants' willful deceit was confirmed on May 19, 2017, when the Patent Office's Patent Trial and Appeal Board ('PTAB') invalidated the '688 Patent on the grounds it was obvious in light of the Brunner and Marakhouski articles." Dkt. No. 10 ¶ 15.

A good argument can be made that the PTAB decision also foreshadowed the CFAC's inequitable conduct theory, even though inequitable conduct is outside the scope of IPR proceedings. *See* 35 U.S.C. § 311(b). The PTAB highlighted that "Dr. Roland Greinwald is the head of research and development at Falk, with responsibility for pharmaceutical development and clinical development" and "is a co-author of Marakhouski and Brunner." *GeneriCo*, 2017 WL 2211672, at *6 (citations omitted). The point of this observation is that the failure to disclose those studies is even more suspect given that a co-author worked at Falk during the patent prosecution stage. Similarly, in concluding that it would have been obvious to a person of ordinary skill in the art to combine the two Salix press releases with the Marakhouski and Brunner studies, the PTAB found that the "evidence further establishes that all four references pertain to a granulated mesalamine formulation that was provided by or licensed from the same company -- Falk (Patent Owner)." *Id.* at *14. The PTAB raised several flags about the possibility of impropriety before the USPTO.

As in *Amphastar*, the CFAC adds nothing to the PTAB's findings except the bare assertion that defendants "intentionally withheld [prior art] from the Patent Office," Dkt. No. 10 ¶ 15, and the inference of an FCA violation. In effect, Silbersher simply seized upon a favorable patent decision in a case he litigated and added the new punchline of a false claim. That is the quintessence of the opportunistic and "parasitic" lawsuit Congress has always intended to bar. *See Prather*, 847 F.3d at 1105. The possibility that Silbersher's status as a lawyer "may have enabled [him] to formulate [his] novel legal theory of fraud is irrelevant to the question of whether the material transactions giving rise to the alleged fraud were already disclosed in the public domain in the first place." *A-1 Ambulance Serv., Inc. v. California*, 202 F.3d 1238, 1245 (9th Cir. 2000).

Silbersher does not seriously dispute the overall purpose of the public disclosure bar or the precedents as discussed so far. His main argument is that "[u]nder the plain words of the statute as it exists today, the PTAB is not an enumerated fora" that might trigger the disclosure bar. Dkt. No. 102 at 14:18-19. In his view, the PTAB litigation and decision do not amount to a disclosure under a disqualifying public channel in the current FCA, and so this lawsuit is not barred.

The point is not well taken. Defendants do not dispute that the first channel in Section 3730(e)(4)(A)(i) is not applicable because the PTAB proceedings were not "a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party." But the second channel in Section 3730(e)(4)(A)(ii) is not subject to the same government-party limitation. This subsection bars the use of substantially similar allegations or transactions disclosed "in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation." This plain text shows that the government need not be a party for the bar to arise in a federal forum. And under the prior version of the FCA, a "'[h]earing' in this context is synonymous with 'proceeding.'" *A-1 Ambulance Serv.*, 202 F.3d at 1244. This construction was not changed by Congress in 2010 and carries over to the amended statute. *See Lamar, Archer & Cofrin, LLP v. Appling*, ___ U.S. ___, 138 S. Ct. 1752, 1762 (2018) (Congress is presumptively aware of a "longstanding judicial interpretation" and retains that meaning if language is not changed in amendments.).

Section 3730(e)(4)(A)(ii) encompasses the PTAB proceedings that are the foundation of the CFAC. The PTAB is an adjudicative body within the USPTO that conducts IPR trials and other proceedings before administrative patent judges. 35 U.S.C. § 6. This functionality falls squarely within the plain meaning of a federal hearing as used in Section 3730(e)(4)(A)(ii), and Silbersher offers no good reason to conclude otherwise. The possibility of some overlap in the definition of a "hearing" between Section 3730(e)(4)(A)(ii) and Section 3730(e)(4)(A)(i) is not problematic. As the Supreme Court determined in *Schindler*, the FCA "mentions 'administrative hearings' twice, reflecting intent to avoid underinclusiveness even at the risk of redundancy." 563 U.S. at 408. Those are the same "hearings" at issue here.

Nor does a potential overlap threaten to make a part of the FCA entirely redundant. Our circuit held as much when it affirmed the dismissal of a whistleblower action under Section 3730(e)(3), which prohibits qui tam suits "based upon allegations or transactions which are the subject of a civil suit or an administrative civil money penalty proceeding in which the Government is already a party." *See United States ex rel. Bennett v. Biotronik, Inc.*, 876 F.3d 1011 (9th Cir. 2017). Recognizing "there will be numerous relators who are barred both by the government action bar, § 3730(e)(3), and the public disclosure bar, § 3730(e)(4)(A)(i)" under its interpretation, the circuit nevertheless concluded, "[t]he statutes do not entirely overlap, and their redundancy does not persuade this court to read the statutory language in an overly narrow manner." *Id*. at 1019.

This is enough to dismiss the CFAC. For the sake of completeness, the Court finds that the news media bar in Section 3730(e)(4)(A)(iii) also requires dismissal. As noted, the online news service Law360 published an article on May 19, 2017, entitled *Part of Apriso Patent Nixed in IPR with Hedge Fund Ties*. *See supra* note 2 and accompanying text. The webpage (https://www.law360.com/articles/926213/part-of-apriso-patent-nixed-in-ipr-with-hedge-fund-ties) reported on the substance of the PTAB's obviousness determinations and the link to Apriso, and included all of the case name and number information needed to find the decision. The article summarized the prior art references, mentioning the Salix press releases and academic papers. The article may also have included a link directly to the PTAB's decision, which relator has conceded would bar his suit, Dkt. No. 102 at 12:23-13:2, although that is not entirely clear from the record.

These are "facts from which fraud can be inferred" in a public disclosure by the news media. *Mateski*, 816 F.3d at 571. Contrary to Silbersher's suggestion, Dkt. No. 45 at 11, the public disclosure need not contain "an explicit allegation of fraud" or "an explicit accusation of wrongdoing," *id.* at 571 (citations omitted); *see also Amphastar*, 856 F.3d at 704 (same). The government would have been "on notice to investigate the fraud before the relator filed his complaint" from the Law360 article as-is. *Mateski*, 816 F.3d at 574.

D. Silbersher Is Not An Original Source

Silbersher might have been able to move forward with the CFAC despite the disclosure bars if he had plausibly alleged that he was an original source of the disclosed information. 31 U.S.C. § 3730(e)(4)(B). He did not. He makes only a cursory and wholly conclusory allegation that he is an original source. Dkt. No. 10 ¶¶ 38, 47. No facts of any sort are offered that might show why this assertion is plausible. That will not do for Rule 8 purposes. *See Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 555).

This effectively closes the door to Silbersher as an original source, but since leave to amend will be granted, a few additional points of guidance are warranted. Silbersher says for the first time in his opposition brief that he is an original source because he disclosed the Marakhouski and Brunner studies to the PTAB while representing GeneriCo in the IPR proceedings. In addition to the fact that an argument in a brief is no substitute for an allegation in the CFAC, *see Rothschild Digital Confirmation, LLC v. Skedulo Holdings Inc.*, Case No. 19-cv-2659-JD, 2020 WL 1307016, at *5 (N.D. Cal. Mar. 19, 2020), the point is not of substantive help to him.

Pre-filing information disclosed in the course of a relator's job does not qualify as a "voluntary disclosure" under Section 3730(e)(4)(B)(i). *See Fine*, 72 F.3d at 741; *Prather*, 847 F.3d at 1107-08. To be sure, *Fine* and *Prather* involved government lawyers who were tasked with fraud investigation duties. But Silbersher was engaged in an equivalent undertaking as the lead counsel for the generic drug manufacturer in the IPR. Silbersher's job was to find and use the Marakhouski and Brunner studies, and the Salix press releases, to attack the '688 patent. He "was no volunteer. He was . . . compelled to disclose the fraud by the very terms of his employment. He no more voluntarily provided information to the government than we, as federal judges voluntarily hear arguments and draft dispositions." *Fine*, 72 F.3d at 743-44. Silbersher did not require the incentive of a qui tam recovery to risk his job or reputation to provide the invalidating prior art to the PTAB. *Id.* at 743 n.3, 745. That's what he was paid to do, and he did it successfully.

Allowing a lawyer to qualify as an original source based on information a client paid him to obtain raises a possible ethical problem as well. It could incentivize lawyers to keep an eye out

for the possibility of a personal bounty under the FCA when the attorney's attention should be focused solely on the client under the duties of loyalty and candor. *See id.* at 745 (discussing "perverse incentives" of rewarding government auditors for disclosing fraud under FCA). There is also the issue of why the lawyer should be allowed to appropriate an FCA claim from an underlying case, in lieu of the client who paid for the work. Both would be similarly situated as plaintiffs, and it is hard to see how the lawyer would necessarily have a better claim to the relator role.

Silbersher also might have qualified as an original source under the FCA if he had alleged "knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and [he] has voluntarily provided the information to the Government before filing an action." 31 U.S.C. § 3730(e)(4)(B)(2). Congress included the "materially adds" language for the first time in the 2010 amendments, and it has not yet been precisely construed. But on any reasonable understanding, Silbersher has not alleged that he materially added to the publicly disclosed information. He mentions "inconsistencies" in defendants' statements in prosecuting the '688 patent and another patent that "were not raised in the underlying IPR, or anywhere." Dkt. No. 45 at 14. How that might be relevant here is not clear, and in any event, adding a few details is hardly the stuff of an original source. *See United States ex rel. Solis v. Millennium Pharm., Inc.*, 885 F.3d 623, 627 (9th Cir. 2018).

The Court notes that the CFAC goes on at great length about a set of patents denominated as the "Otterbeck Patents." Dkt. No. 10 ¶¶ 17-18, 100-116. But it is again unclear how these patents are relevant to the false claims, since Silbersher attributes Apriso's inflated price only to the '688 patent, not the Otterbeck patents. *Id.* ¶¶ 20-25; Dkt. No. 45 at 3 n.2. They do not materially add to previously disclosed information.

As a final observation, Silbersher does not qualify as an original source under Section 3730(e)(4)(B)(2) because he did not plausibly allege that he "provided the information [about the other patents] to the Government before filing" this action. There is no allegation in the CFAC or elsewhere that Silbersher communicated with any pertinent agency before filing this lawsuit.

E. No Government Opposition To Dismissal

An FCA claim cannot be dismissed under the public disclosure bar if the federal government objects. 31 U.S.C. § 3730(e)(4)(A). The government declined to intervene in this case. Dkt. No. 8. It did not file an opposition to defendants' motion to dismiss, nor did it appear at the August 2019 hearing on the motion. Dkt. No. 94. Accordingly, dismissal on the basis of the FCA's public disclosure bar is appropriate.

III. STATE LAW CLAIMS

The Court declines to retain jurisdiction over Silbersher's remaining state law claims. *See* 28 U.S.C. § 1367(c)(3) (district court may "decline to exercise supplemental jurisdiction over a claim . . . if the district court has dismissed all claims over which it has original jurisdiction.").

CONCLUSION

The CFAC is dismissed under the public disclosure bar. The Court declines to take up defendants' other arguments for dismissal at this time. Although the efficacy of amendment is not readily apparent, the Court cannot say it would be futile. Silbersher may file an amended complaint consistent with this order by June 15, 2020. No new claims or parties may be added without the Court's prior approval. If this deadline is not feasible in light of the public health situation, the parties may agree on a new date by stipulation. If the parties cannot agree, a party may ask the Court to extend the deadline. Failure to respond to this order by June 15, 2020, will result in dismissal with prejudice under Rule 41(b). The motion to stay discovery is terminated as moot.

IT IS SO ORDERED.

Dated: May 11, 2020

JAMES DONATO
United States District Judge