United States District Court
Northern District of California

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

ZACHARY SILBERSHER, et al.,

Plaintiffs,

v.

ALLERGAN INC., et al.,

Defendants.

Case No. 18-cv-03018 JCS

ORDER DENYING MOTIONS TO DISMISS AND SETTING CASE MANAGEMENT CONFERENCE FOR JANUARY 15, 2021 AT 2:00 PM

Dkt. Nos. 63, 68, 131

I. INTRODUCTION

This action is brought under the federal False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733, by Plaintiff-Relator Zachary Silbersher ("Relator") on behalf of the United States and numerous States (the "States")[1] against two sets of defendants: 1) the "Allergan Defendants" or "Allergan"[2]; and 2) the "Adamas Defendants" or "Adamas."[3] Each set of defendants brings a motion to dismiss (hereinafter, the "Allergan Motion" and the "Adamas Motion" and collectively, the "Motions"). For the reasons stated below, the Motions are DENIED.[4]

[1] Relator brings this action on behalf of California, Colorado, Connecticut, Delaware, the District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Virginia, and Washington.
[2] The Allergan Defendants are: Allergan, Inc., Allergan USA, Inc., Allergan Sales, LLC, and Forest Laboratories Holdings, Ltd. For purposes of this motion, the term "Allergan Defendants" does not include Defendant Allergan PLC, which has been dismissed from this action, even though references to "Allergan" in the operative complaint include Allergan PLC.
[3] The Adamas Defendants are: Adamas Pharma, LLC and Adamas Pharmaceuticals, Inc.
[4] The parties have consented to the jurisdiction of the undersigned magistrate judge pursuant to 28 U.S.C. § 636(c).

II. BACKGROUND

A. First Amended Complaint

The operative complaint in this action is the First Amended Complaint ("FAC"). In the FAC, Relator alleges that the Adamas and Allergan Defendants misled the United States Patent Office ("Patent Office") into issuing invalid patents protecting the drugs Namenda XR® and Namzaric®, thus perpetuating their monopoly power and allowing them to overcharge the federal government and the States for these drugs under various programs, including Medicare and Medicaid. FAC ¶¶ 1-8.

Relator is a citizen of the State of New York whose "profession focuses on investigating invalid pharmaceutical patents that brand manufacturers use to protect their drugs from price competition." *Id.* ¶ 9. He alleges that he has "[t]hrough his independent investigation . . . uncovered non-public information supporting the claims set forth" in the FAC. *Id.* He further alleges that his "independent research and investigation has generated information that is independent of, and materially adds to, any publicly-disclosed allegations and transactions." *Id.* According to Relator, he is an "original source" of information within the meaning of the FCA and he provided the information on which his claims are based to the States and the federal government before he initiated this action. *Id.* ¶ 10.

Relator alleges that Allergan, Inc., Allergan USA, Inc., Allergan Sales, LLC, and Forest Laboratories Holdings, Ltd. are subsidiaries or divisions of Allergan PLC, which was called Activas PLC until June 15, 2015. *Id.* ¶ 17. Activas PLC acquired Forest Laboratories, Inc. on July 1, 2014 and acquired Allergan, Inc. on March 17, 2015. *Id.* ¶¶ 17, 49. Relator alleges that "Defendant Forest Laboratories Holdings, Ltd. is an Irish corporation with its principal place of business at Cumberland House, 1 Victoria Street, Hamilton HMU, Bermuda" and that "Allergan is the successor-in-interest to Forest Laboratories, LLC (f/k/a Forest Laboratories, Inc.) and is liable for any damages to which Forest is liable." *Id.* ¶ 16.[5]

[5] As noted above, the FAC defines "Allergan" as including Allergan, Inc., Allergan USA, Inc., Allergan Sales, LLC, Forest Laboratories Holdings, Ltd, and the now-dismissed Allergan PLC. FAC at 1.

Defendant Adamas Pharma, LLC is a Delaware limited liability company with its principal place of business in Emeryville, California; Defendant Adamas Pharmaceuticals, Inc. is a Delaware corporation, also based in Emeryville, California. *Id.* ¶¶ 18-19. According to Relator, in 2012, Adamas Pharmaceuticals, Inc. entered into a commercialization and development agreement with Forest Laboratories, Inc. with respect to memantine hydrochloride ("memantine") drugs. *Id.* ¶¶ 50, 59. Relator alleges that "[a]s part of that agreement, Adamas . . . granted Forest an exclusive license to all of the Went Patents[,]" discussed below. *Id.*

Namenda XR® is a delayed-release drug whose active pharmaceutical ingredient ("API") is memantine. *Id.* ¶ 50. It is used to treat patients with dementia related to Alzheimer's disease. *Id.* According to Relator, generics of Namenda XR® first became available on February 21, 2018, after the Federal Circuit invalidated patents asserted by Defendants in connection with that drug. *Id.* Relator alleges that Allergan's United States net revenue for Namenda XR® was approximately $452.8 million in 2017, $627.6 million in 2016 and $759.3 million in 2015. *Id.* ¶ 52.

Namzaric® is also a delayed-release drug prescribed to treat patients with dementia related to Alzheimer's disease. *Id.* ¶ 53. It has two APIs: memantine hydrochloride and donepezil hydrochloride. *Id.* ¶ 54. Relator alleges that "[g]eneric manufacturers have been ready to enter the market since at least July 13, 2015, but they have been prevented from doing so by the fraudulently-obtained patents asserted by Defendants" and that "[t]o date, no generic manufacturer has entered the market for Namzaric®." According to Relator, Allergan launched Namzaric® on May 18, 2015; its net revenue for Namzaric® was approximately $130.8 million in 2017, $57.5 million in 2016 and $11.2 [million] in 2015." *Id.* ¶ 56.

Relator alleges that "Defendants listed three categories of patents for Namenda XR® and Namzaric® in the [Food and Drug Administration ("FDA")]'s database of "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book[,]" thereby preventing generic manufacturer's from entering the market. FAC ¶ 57.

The first category of patents is the Went Patents, a group of eleven patents that list Dr.

Gregory T. Went, PhD., the founder and CEO of Adamas, as the first inventor.[6] *Id.* ¶ 58. For Namenda XR®, six of the Went Patents are listed in the Orange Book (the '209, '708, '379, '752, '085, and '233 patents), while all eleven are listed for Namzaric®. *Id.* According to Relator, the Went Patents "are all generally directed to an extended release formulation for memantine." *Id.*

The parent patent for all of the Went Patents is the '291 patent, which was issued on November 15, 2011. *Id.* ¶ 61. Relator alleges that on June 21, 2010, during prosecution of the '291 patent application, the Examiner issued an Office Action that rejected the pending claims as anticipated. *Id.* ¶ 62. In response, on November 5, 2010, Dr. Went and his co-inventors amended the independent claims of the '291 patent application and submitted a declaration by Dr. Went (the "Original Went Declaration" or "2010 Went Declaration") in which he discussed the results of two clinical studies conducted by Adamas, the C106 Study and the ME110 Study. *Id.* ¶ 63. Relator alleges that Dr. Went misrepresented the results of these studies in his declaration, asserting that they showed "no incidence" of certain side effects when in fact, the opposite was true. *Id.* ¶¶ 66-69, 73. According to Relator, on September 23, 2011, the Examiner allowed the claims based upon the alleged "unexpected results" sworn to by Dr. Went in this declaration. *Id.* ¶ 73.

Relator alleges that Dr. Went and Adamas continued to resubmit the same fraudulent data and did not correct these misrepresentations when applying for nine additional patents, misleading the Patent Office into granting the applications based on them. *Id.* ¶¶ 73-90. However, Relator alleges, during prosecution of U.S. Patent Application No. 12/757,824 ("the '824 Application"), on May 7, 2012, Dr. Went submitted another declaration ("the 2012 Went Declaration") in which he again described the ME110 Study but provided a table of actual results and stated that they showed "little incidence" (rather than "no incidence") of side effects with the extended release

[6] The Went Patents are U.S. Patent Nos. 8,058,291 ("the '291 patent"); 8,168,209, as corrected ("the '209 patent"); 8,173,708 ("the '708 patent"); 8,283,379 ("the '379 patent"); 8,293,794 ("the '794 patent"); 8,329,752 ("the '752 patent"); 8,338,485 ("the '485 patent"); 8,338,486 ("the '486 patent");8,362,085 ("the '085 patent"); 8,580,858, as corrected ("the '858 patent"); and 8,598,233 ("the '233 patent").

formulation. *Id.* ¶¶ 68-69. That application was rejected by the Examiner on the basis that the extended release formulation that it claimed did "not present better results in regards to side effects." *Id.* ¶ 70. Adamas then abandoned that application. *Id.* According to Relator, Adamas continued to rely on the Original Went Declaration or slightly modified versions of that declaration that continued to misrepresent the results of the ME110 Study and the Examiner continued to allow the patents for the same reasons it allowed the '291 patent. *Id.* ¶¶ 74-84.

The second "category of patents" listed for Namenda XR® and Namzaric® upon which Relator relies is a single patent, U.S. Patent No. 8,039,009 ("the '009 patent"). *Id.* ¶ 91. Relator alleges that the '009 patent was originally assigned to Forest Laboratories, Inc., and expires September 24, 2029." *Id.* According to Relator, the '009 patent is "directed to a method of treating Alzheimer's disease with a once-daily sustained release oral dose of memantine." *Id.* ¶ 92. Relator alleges that the application was amended to add the "once-daily" requirement after it had been rejected "at least six times" by the Patent Office, and based on this amendment the Patent Office allowed the '009 patent. *Id.*

Relator alleges "[t]he once-daily limitation in the '009 [p]atent is invalid as obvious in view of U.S. Patent No. 6,479,553 ("the '553 [p]atent"), which expressly teaches treating Alzheimer's disease by administering memantine once daily." *Id.* ¶ 93. According to Relator, the '009 patent was acquired by fraud because "Defendants were aware of the teachings of the '553 patent, yet, on information and belief, Defendants intentionally failed to alert the Patent Office to the teachings of the '553 patent when they amended the application for the '009 patent to include the once-daily limitation." *Id.* ¶¶ 93-94. Relator alleges that the '553 patent had been disclosed during prosecution of the '009 patent on September 28, 2009, but the disclosure was about 18 months before the amendment that required once-daily administration, on March 15, 2011, and therefore the once-daily teaching of the '553 patent had no relevance to the '009 patent application at that time and would not have been considered by the Examiner. *Id.* ¶ 96. Relator alleges that "when Forest amended the application for the '009 patent to require once-daily administration, it intentionally declined to inform the Patent Office of the material relevance of the '553 patent, because the '553 patent expressly taught the very limitation added to the claims . . . that justified

allowance of the '009 patent." *Id.* ¶ 97.

The "third category" of patents is U.S. Patent No. 5,061,703 (the '703 patent"). *Id.* ¶ 4. Because the parties have not relied on the allegations related to that patent in their briefs the Court does not summarize them here.

Relator alleges that Defendants used the Went Patents and the '009 patent to prevent generic manufacturers from entering the market. *Id.* ¶¶ 104-109. "As a direct result of Defendants' fraudulent scheme, Defendants have unlawfully excluded generic manufacturers from introducing lower-priced generic alternatives for Namenda XR® and Namzaric®, allowing Defendants to charge monopoly prices." *Id.* ¶ 110. Relator further alleges that for Defendants to sell Namenda XR® and Namzaric® to federal agencies or otherwise qualify Namenda XR® and Namzaric® for reimbursement under Medicare and Medicaid, they were required to list the drugs on the Federal Supply Schedule ("FSS") and "supply [to the General Services Administration ('GSA')] a 'written justification for offered pricing, a mechanism for 14 future potential pricing adjustments, and proof that the price is fair and reasonable.'" *Id.* ¶¶ 112-113 (citation omitted). According to Relator, "[b]y definition, Namenda XR®'s and Namzaric®'s pricing that Defendants supplied in connection with the FSS was not fair and reasonable" because "Defendants . . . had artificially inflated Namenda XR®'s and Namzaric®'s prices through the unlawful exclusion of generic competitors" and therefore Defendants' "statements to the GSA were expressly false statements." *Id.* ¶ 113. Relator further alleges that Defendants made "express and implied misrepresentations that [their] prices were fair and reasonable – and not inflated through the unlawful exclusion of competitors." *Id.* ¶ 117.

Relator alleges that "each and every claim for payment or reimbursement for Namenda XR® and Namzaric® that would have been substituted for a less expensive generic equivalent . . . constituted a False Claim" that violated the federal FCA and the respective State false claims acts. In particular, according to the Relator, "each False Claim was for an unlawfully elevated, maintained, or stabilized price for Namenda XR® or Namzaric® contrary to express representations and implied certifications by Defendants to the federal government that the price of Namenda XR® or Namzaric® reflected in each False Claim was 'fair and reasonable,' and not

unlawfully elevated, maintained, or stabilized in violation of applicable law, including applicable antitrust laws." *Id.* ¶¶ 132-133.

B. The Motions

In the instant motions, the Allergan and Adamas Defendants ask the Court to dismiss Relator's FCA claims under the public disclosure bar that is found in 31 U.S.C. § 3730(e)(4). In particular, they argue that the FCA claims are barred because the allegations of fraud and all of the transactions on which Relator's FCA claims are based were publicly disclosed in documents that were filed on the Patent Office's Patent Application Information Retrieval ("PAIR") website. They further contend Relator does not fall under the "original source" exception to the public disclosure bar. In addition, both sets of Defendants argue that Relator has failed to allege facts sufficient to state a claim against them under the FCA. Because Relator has not stated viable claims under the FCA, Defendants argue, the Court should dismiss those claims under Rule 12(b)(6) and decline to exercise jurisdiction over the State law claims. In any event, they assert, the State law claims are insufficiently alleged and should be dismissed on the merits if the Court chooses to exercise jurisdiction over them.

Relator challenges these arguments, asserting that in light of amendments to the FCA that were made by Congress in 2010, availability of information on the Patent Office's website is not sufficient to trigger the public disclosure bar. He further contends the public disclosure bar does not apply because he is an "original source." He also argues that he has alleged sufficient facts to state an FCA claim against both the Allergan Defendants and the Adamas Defendants, and that his State law claims are adequately pled as well. He notes that the Texas Attorney General has "requested Relator to inform the Court that the Texas causes of action do not require the presentment of a false claim, and most do not require proof of materiality." Opposition to Allergan Motion at 30.

C. The *Valeant* Decision

On May 11, 2020, Judge Donato issued a decision in an FCA case brought by the same relator based on a theory similar to the one in this case. *See United States ex rel. Silbersher v. Valeant Pharm. Int'l, Inc.*, 445 F. Supp. 3d 393 (N.D. Cal. 2020) ("the *Valeant* decision"). In that

case, the defendants brought a motion to dismiss based on the public disclosure bar, pointing to disclosures in proceedings that took place before the Patent Trial and Appeal Board ("PTAB") that resulted in the patent at issue in that case being invalidated, as well as news articles about the proceeding. The Court found that the public disclosure bar applied because the PTAB proceeding was a "Federal . . . hearing" under 31 U.S.C. § 3730(e)(4)(A)(ii) and the articles about that proceeding constituted "news media" under 31 U.S.C. § 3730(e)(4)(A)(iii). It further concluded that Relator was not an "original source."

With the Court's permission, the Allergan Defendants filed a statement of recent decision in the instant action informing the undersigned of Judge Donato's decision, dkt. No. 129, and Relator filed a response, dkt. no. 128. Subsequently, the Adamas Defendants requested leave to file a supplemental statement of recent decision addressing arguments made by Relator in his response to Allergan's statement of recent decision. *See* dkt. no. 131. In their proposed supplemental statement of recent decision, the Adamas Defendants argue, for the first time, that the proceeding before the Patent Office in this case, like the PTAB Proceeding in the *Valeant* case, was a "Federal . . . hearing" for the purposes of 31 U.S.C. § 3730(e)(4)(A)(ii). Relator opposed the request of the Adamas Defendants, arguing that it was improper to make this new argument and that the remainder of the supplemental statement merely repeats arguments already made by Allergan. Dkt. No. 132. Relator argues further that if the Court considers Adamas's new argument, it fails on the merits.[7]

The State of California, through the State Insurance Commissioner, also weighed in, filing a Statement of Interest in which it informed the Court that it "has a significant interest in stopping fraudulent practices that raise the price of prescription drugs." Dkt. No. 133. According to the State of California, "Relator's suits, if successful, may set an important precedent that would discourage drug companies from taking advantage of the ex parte nature of patent proceedings by withholding or misrepresenting material information relating to patentability – and thereby significantly reduce the amount governments and insurers pay for important medicines." *Id.* With

[7] The Court GRANTS the Adamas Defendants' request and considers the new argument, even though it is untimely. As discussed below, the Court rejects this argument on the merits.

respect to the *Valeant* decision, the State of California states as follows:

> We also understand that, relying on the [*Valeant* decision], defendants in this case have sought to argue government authorities were placed "on notice" of the alleged fraud because of information pieced together from various patent filings with the [Patent Office]. We respectfully disagree with the reasoning in the [*Valeant* decision] and with the notion that government agencies are placed on notice of fraud based on patent filings.
>
> Mr. Silbersher's suits are neither "parasitic" nor "opportunistic." We are not aware of any government agency that regularly monitors patent filings to determine whether there has been a material omission or misrepresentation in applications for pharmaceutical patents, particularly given the specialized expertise and amount of resources that would be required to do so. We therefore welcome the efforts of relators like Mr. Silbersher to help identify instances where drug patents are not just invalid, but fraudulent – particularly in a case like this, where there was apparently no preexisting government investigation concerning the alleged fraud. Such efforts, if successful, may help lower the price of medicine and the cost of health insurance, which is consistent with our mission.

Id.

III. ANALYSIS

A. Legal Standards

1. The FCA

Under the FCA, any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," or who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim" is liable for a civil penalty "plus 3 times the amount of damages which the Government sustains because of the act of that person." 31 U.S.C. § 3729(a)(1)(A)-(B). The elements of an FCA claim are: "'(1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due.'" *United States Ex Rel. Rose v. Stephens Inst.*, 909 F.3d 1012, 1017 (9th Cir. 2018), cert. denied sub nom. *Stephens Inst. v. U.S. ex rel. Rose*, 139 S. Ct. 1464 (2019) (quoting *United States ex rel. Hendow v. University of Phoenix*, 461 F.3d 1166 (9th Cir. 2006)).

"The FCA allows private individuals, referred to as 'relators,' to bring suit on the Government's behalf against entities that have violated the Act's prohibitions." *U.S. ex rel.*

Mateski v. Raytheon Co., 816 F.3d 565, 569 (9th Cir. 2016) (citing 31 U.S.C. § 3730(b)(1)). "Such suits are commonly called *qui tam* suits." *Id.* In a *qui tam* suit, the relator asserts the FCA claim "on behalf of the government, which may choose to intervene in the action" and "[i]f the relator is successful, she is entitled to a share of the recovery, whether or not the government intervenes." *Seal 1 v. Seal A*, 255 F.3d 1154, 1158 (9th Cir. 2001) (citing 31 U.S.C. §§ 3730(d)(1), (2)). As discussed further below, Congress has amended the FCA on a number of occasions in an effort to "strike a balance between encouraging private persons to root out fraud and stifling parasitic lawsuits . . . ." *Graham County*, 559 U.S. 280, 295 (2010).

2. Rule 12(b)(6)

A complaint may be dismissed under Rule 12(b)(6) of the Federal Rules of Civil Procedure for failure to state a claim on which relief can be granted. "The purpose of a motion to dismiss under Rule 12(b)(6) is to test the legal sufficiency of the complaint." *N. Star Int'l v. Ariz. Corp. Comm'n*, 720 F.2d 578, 581 (9th Cir. 1983). Generally, a plaintiff's burden at the pleading stage is relatively light. Rule 8(a) of the Federal Rules of Civil Procedure states that a "pleading which sets forth a claim for relief . . . shall contain . . . a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a).

In ruling on a motion to dismiss under Rule 12(b)(6), the court analyzes the complaint and takes "all allegations of material fact as true and construe[s] them in the light most favorable to the non-moving party." *Parks Sch. of Bus. v. Symington*, 51 F.3d 1480, 1484 (9th Cir. 1995). Dismissal may be based on a lack of a cognizable legal theory or on the absence of facts that would support a valid theory. *Balistreri v. Pacifica Police Dep't*, 901 F.2d 696, 699 (9th Cir. 1990). A complaint must "contain either direct or inferential allegations respecting all the material elements necessary to sustain recovery under some viable legal theory." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 562 (2007) (citing *Car Carriers, Inc. v. Ford Motor Co.*, 745 F.2d 1101, 1106 (7th Cir. 1984)). "A pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 555). "[C]ourts 'are not bound to accept as true a legal conclusion couched as a factual allegation.'" *Twombly*, 550 U.S. at 555 (quoting *Papasan v. Allain*, 478 U.S.

265, 286 (1986)). "Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 557) (alteration in original). Rather, the claim must be "'plausible on its face,'" meaning that the plaintiff must plead sufficient factual allegations to "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (quoting *Twombly*, 550 U.S. at 570).

3. Rule 9(b)

Rule 9(b) establishes a heightened pleading standard for claims based on fraud. "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). "To satisfy Rule 9(b), a pleading must identify 'the who, what, when, where, and how of the misconduct charged,' as well as 'what is false or misleading about [the purportedly fraudulent] statement, and why it is false.'" *United States ex rel. Cafasso v. Gen. Dynamic Sys., Inc*., 637 F.3d 1047, 1055 (9th Cir. 2011) (alteration in original) (quoting *U.S. ex rel. Ebeid v. Lungwitz*, 616 F.3d 993, 998 (9th Cir. 2010)). The allegations "must be specific enough to give defendants notice of the particular misconduct which is alleged to constitute the fraud charged so that they can defend against the charge and not just deny that they have done anything wrong." *United States ex rel. Silingo v. WellPoint, Inc.*, 895 F.3d 619, 628 (9th Cir. 2018) (quoting *Bly-Magee v. California*, 236 F.3d 1014, 1019 (9th Cir. 2001)). Scienter, however, may be pleaded generally. *Id*. at 631.

B. Requests for Judicial Notice

Presently before the Court are three requests for judicial notice: 1) Allergan Defendants' Request for Judicial Notice in Support of Allergan Defendants' Motion to Dismiss Relator's First Amended Complaint [dkt. no. 66] ("Allergan RJN"); 2) Adamas Request for Judicial Notice in Support of Motion to Dismiss by Adamas Pharma, LLC and Adamas Pharmaceuticals, Inc. [dkt. no. 70] ("Adamas First RJN"); and 3) Adamas Request for Judicial Notice in Support of Motion to Dismiss by Adamas Pharma, LLC and Adamas Pharmaceuticals, Inc. [dkt. no. 96] ("Adamas Second RJN"). In all of the requests for judicial notice, the Allergan and Adamas Defendants ask the Court to take judicial notice under Federal Rule of Evidence 201(b)(2) of documents that they

rely upon to show that Relator's allegations of fraud and/or the transactions upon which they are based have been publicly disclosed.

"Under Federal Rule of Evidence 201, the court 'can take judicial notice of "[p]ublic records and government documents available from reliable sources on the Internet," such as websites run by governmental agencies.'" *United States ex rel. Integra Med Analytics LLC v. Providence Health & Servs.*, No. CV 17-1694 PSG (SSX), 2019 WL 3282619, at *4 (C.D. Cal. July 16, 2019) ("*Integra*") (quoting *Gerritsen v. Warner Bros. Entm't Inc*., 112 F. Supp. 3d 1011, 1033 (C.D. Cal. 2015) (quoting *Hansen Beverage Co. v. Innovation Ventures*, LLC, No. 08-CV-1166-IEG (POR), 2009 WL 6598891, at *2 (S.D. Cal. Dec. 23, 2009))). The Court has reviewed Defendants' requests and finds that all of the exhibits fall within the categories of documents of which courts may take judicial notice under Rule 201(b)(2), as Relator concedes.[8] *See* Dkt. Nos. 81, 87 & 100 (Relator's responses). Accordingly, the Court takes judicial notice of the existence of the documents attached to Defendants' requests for judicial notice, though it does not take judicial notice of the "truth of the facts recited therein." *See Lee v. City of Los Angeles*, 250 F.3d 668, 690 (9th Cir. 2001); *see also United States ex rel. Ambrosecchia v. Paddock Labs., LLC*, 855 F.3d 949, 954 (8th Cir. 2017) ("In evaluating whether the public disclosure bar applies, we may 'consider matters incorporated by reference or integral to the claim, items subject to judicial notice, [and] matters of public record.'" (citation omitted)).

C. Whether Relator's FCA Claims Fail Under the Public Disclosure Bar

1. History of the Public Disclosure Bar

"As originally enacted, the FCA did not limit the sources from which a relator could acquire the information to bring a *qui tam* action." *Graham County*, 559 U.S. at 295. Thus, in *United States ex rel. Marcus v. Hess*, 317 U.S. 537 (1943) ("*Hess*"), the Supreme Court "upheld the relator's recovery even though he had discovered the fraud by reading a federal criminal

[8] Relator argues in his responses that the Court nonetheless should decline to take judicial notice of the documents on the grounds that they are "not helpful" in deciding the instant motions. These arguments duplicate Relator's arguments on the merits and are more appropriately resolved in the context of ruling on the motions to dismiss brought by the Adamas and Allergan Defendants. Therefore, the Court does not address Relator's arguments in ruling on the requests for judicial notice.

indictment—a quintessential 'parasitic' suit." *Id*. In *Hess*, the relator brought a *qui tam* action against individuals who had engaged in collusive bidding for contracts with local government entities that were largely paid for by the federal government under the authorization of the Federal Public Works Administrator. 317 U.S. at 543. The same individuals had already been criminally indicted for defrauding the government and had paid a fine of $54,000 for doing so. *Id*. The defendants and the Government (which filed an amicus brief at the request of the Court) argued that the relator had merely obtained the information on which his claims were based from the criminal indictment and therefore should not be permitted to bring an FCA claim, but the Court rejected that argument on the basis that the relator "contributed much to accomplishing one of the purposes for which the Act was passed." *Id*. at 545. In particular, it pointed out that the relator's suit had "result[ed] in a net recovery to the government of $150,000, three times as much as the fines imposed in the criminal proceedings." *Id.*

In response to the *Hess* decision and other similar "piggy-back" lawsuits, Congress enacted what came to be known as the "government knowledge bar," which "preclude[d] *qui tam* actions 'based upon evidence or information in the possession of the United States, or any agency, officer or employee thereof, at the time such suit was brought.'" *Graham County*, 559 U.S. at 294 (citing Act of Dec. 23, 1943, 57 Stat. 609 (codified at 31 U.S.C. § 232(C) (1946 ed.))); *United States ex rel. Findley v. FPC-Boron Employees' Club*, 105 F.3d 675, 680 (D.C. Cir. 1997) ("*Findley*")("*Qui tam* litigation surged [in the 1930s and 1940s] as opportunistic private litigants chased after generous cash bounties and, unhindered by any effective restrictions under the Act, often brought parasitic lawsuits copied from preexisting indictments or based upon congressional investigations."). After this change, the number of *qui tam* actions dwindled. *Graham County*, 559 U.S. at 294. As the *Findley* court noted, "by restricting *qui tam* suits by individuals who brought fraudulent activity to the government's attention, Congress had killed the goose that laid the golden egg and eliminated the financial incentive to expose frauds against the government." 105 F.3d at 680; *see also United States ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 297–98 (3d Cir. 2016) ("*Moore*") ("[T]his 'government knowledge defense' did not just eradicate the parasitic lawsuits; it eliminated most FCA lawsuits, for courts strictly

interpreted [the government knowledge provision] as barring FCA actions even when the government knew of the fraud only because the relator had reported it.").

In 1986, Congress once again amended the FCA to make it "'a "more useful tool against fraud in modern times[.]"'" *Id*. (quoting *Cook County v. United States ex rel. Chandler*, 538 U.S. 119, 133 (2003) (quoting S.Rep. No. 99–345, p. 2 (1986) (hereinafter "S. Rep. 99-345"))). The Senate Report that accompanied the 1986 amendments stated that the purpose of the amendments was to address the "severe" problem of fraud against the federal government and pointed to the "proliferation of cases [of fraud against the government] among some of the largest Government contractors." S. Rep. 99-345 at pp. 1-2. Among the changes enacted in 1986 was replacement of the government knowledge bar with the public disclosure bar. *Graham County*, 559 U.S. at 294 ("[A]pparently conclud[ing] that a total bar on *qui tam* actions based on information already in the Government's possession thwarted a significant number of potentially valuable claims[,]" Congress replaced the government knowledge bar with the public disclosure bar in order to "strike a balance between encouraging private persons to root out fraud and stifling parasitic lawsuits such as the one in *Hess*.").

Under the 1986 amendments to the FCA, the public disclosure bar provided as follows:

> No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

31 U.S.C. § 3730(e)(4)(A). An "original source" was defined as "an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information." 31 U.S.C. § 3730(e)(4)(B).

In 2010, Congress amended the FCA once again, as part of the Patient Protection and Affordable Care Act ("ACA"). *See* Pub. L. No. 111–148, § 10104(j)(2), 124 Stat. 119, 901–02 ("2010 amendments"). Among other things, the 2010 amendments reflected an effort by Congress to "fix[ ] the False Claims Act's public disclosure provision . . . [to] fairly and appropriately

empower whistleblowers to come forward to expose fraud, which is a crucial way to save the government money and ensure the health and well-being of Americans." 155 Cong. Rec. S13661-01, 155 Cong. Rec. S13661-01 (daily ed. Dec. 21, 2009), S13693 (statement of Sen. Leahy).

A report by the House of Representatives that addressed the proposed changes to the FCA explained that the amendments were aimed at court decisions since the 1986 amendments that had "limited the reach of the False Claims Act, jeopardizing billions in Federal funds." H.R. Rep. No. 111-97 (2009) ("H.R. 111-97"), p. 5. With respect to proposed changes to the public disclosure bar, the report stated:

> When the 1986 amendments were enacted, Congress expressly stated that the public disclosure bar was intended to bar only truly parasitic *qui tam* lawsuits; the provision was not intended to bar suits solely because the Government already knew of the fraud or could have learned of the fraud from information in the public domain, such as from a media report. Congress drafted the public disclosure bar to provide a balance between "encouraging people to come forward with information and preventing parasitic lawsuits." Yet, despite this clear congressional intent and Department of Justice recommendations, courts have used the public disclosure bar to dismiss relators who provided important information in cases still being pursued by the Government.

Id. at pp. 6-7.

As amended in 2010, the public disclosure bar now provides:

> (4)(A) *The court shall dismiss an action or claim under this section, 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 subsection (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.

31 U.S.C. § 3730(e)(4) (amended language in italics).

"The italicized language has radically changed the 'hurdle' for relators." *Moore*, 812 F.3d at 298. First, the jurisdictional language in § 3730(e)(4)(A) has been removed, making the public disclosure bar an affirmative defense rather than a matter of jurisdiction. *Prather v. AT&T, Inc.*, 847 F.3d 1097, 1102 (9th Cir.), *cert. denied*, 137 S. Ct. 2309 (2017). Second, allowable disclosures under romanette (i) have been limited to disclosures in a federal hearing in which the Government was a party. Third, the second channel of disclosure, which previously included any "congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation[,]" was modified to remove the word "administrative" and add the phrase "other Federal" before report. 31 U.S.C. § 3730(e)(4)(A)(ii). This narrowed the scope of the public disclosure bar by excluding state and local reports as permissible channels for disclosure. *See, e.g.*, *Graham Cnty.*, 559 U.S. at 283 & n.1. Finally, the definition of an "original source" no longer contains a "direct" knowledge requirement, instead requiring that an original source have "knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions." 31 U.S.C. § 3730(e)(4)(B).

2. Contentions of the Parties

a. The Allergan Motion

Allergan argues that Relator's FCA claims fail under the public disclosure bar because they are based on information that is drawn from the "public patent prosecution files, which have been available for many years to anyone with an Internet connection." Allergan Motion at 10. In particular, Allergan points to the prosecution histories of the patents at issue, all of which have been published on the Patent Office's Patent Application Information Retrieval website ("PAIR"). *Id.* at 10 n. 10.[9] Allergan also points to allegations in the FAC that refer to publicly available

[9]The Patent Office's Manual of Patent Examining Procedure explains that:

> [t]here is both a public and private side to PAIR. In public PAIR, information is available relating to issued patents, published patent applications, and applications to which a patented or published application claims domestic priority. In private PAIR, an applicant (or

materials filed with or published by the U.S. Federal Trade Commission ("FTC"), the U.S. Securities and Exchange Commission ("SEC") and the U.S Food and Drug Administration ("FDA"), arguing that these also publicly disclosed the allegations and/or transactions that are the basis of Relator's claims. *Id*. at 12 (citing FAC ¶¶ 47- 48, 58 104-109, 112-116, 132-136, 155; Declaration of Emma Strong in Support of Allergan Defendants' Motion to Dismiss Relator's First Amended Complaint ("Strong Decl."), Exs. 48-55, 58-66). Allergan further asserts that Relator is not an "original source" under either of the tests set forth in 31 U.S.C. § 3730(e)(4)(B). *Id*. at 8-9.

As to the FCA claims based on Allergan's alleged fraud in connection with the Went Patents, Allergan argues that Relator essentially admits in the FAC that his claims are based on "what '[t]he prosecution histories for the Went patents . . . show.'" *Id*. at 11 (quoting FAC ¶ 90). In particular, Allergan points to Relator's allegation that "in sum" Dr. Went made a "false" statement in the application and "knew this was false because in a separate, related patent application within the same family, he disclosed the actual results of the ME110 Study." *Id*. (quoting FAC ¶ 83). Further, Allergan argues, the "embellishments" on Relator's theory alleged in the FAC are based on other publicly available materials in the Went Patent prosecution history. *Id.* (citing FAC ¶¶ 58-90; Strong Decl., Ex. 35 (Feb. 8, 2011 Non-Final Rejection); *id.*, Ex. 36 (May 11, 2011 Declaration of Sid Gilman); *id.*, Ex. 37 (June 21, 2010 Office Action); *id.*, Ex. 43, (October 24, 2012 Office Action); *id.*, Ex. 44 (May 8, 2013 Abandonment)).

Similarly, as to the FCA claims based on Allergan's alleged fraud in obtaining the '009

> his or her registered patent attorney or registered patent agent) can securely track the progress of his or her application(s) through the [Patent Office]. Private PAIR makes available information relating to unpublished patent applications, but the applicant must associate a Customer Number with the application to obtain access.

Manual of Patent Examining Procedure § 1730(II)(B)(1)(c). As Allergan correctly notes, "[patent applications are 'published . . . promptly after the expiration of a period of 18 months from the earliest filing date for which a benefit is sought.'" Allergan Motion at 10 n. 10 (quoting 35 U.S.C. § 122(b)(1)(A)). "After that point, the 'complete record of the proceedings before the [Patent Office]' *Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005), is a 'matter[ ] of public record' under 37 C.F.R. § 1.11(d) (promulgated Sept. 20, 2000) . . . ." *Id*. In this case, it is undisputed that all of the materials from the patent prosecution histories upon which Relator relies are available on public PAIR.

patent, Allergan argues that the allegations of the FAC show that both the "true" and "false" state of affairs were publicly disclosed because Relator alleges that Forest Laboratories made a particular disclosure of prior art "at an earlier phase of the prosecution" but failed to do so again later, leading to the allegedly improper issuance of the patent. *Id*. (citing FAC ¶ 96 (referring to Strong Decl., Ex. 31 (Aug. 14, 2006 Information Disclosure Statement); *id.*, Ex. 30 (Oct. 7, 2009 List of References); *id.*, Ex. 29 (June 16, 2005 Specification); and *id.*, Ex. 27 (Mar. 15, 2011 Claims))); *see also* Allergan Motion, Appendix A (Prior Public Disclosures chart) ("Allergan Appendix A"). In addition, Allergan argues that "[e]verything that follows after the Relator's allegations about the [Patent Office] proceedings is also readily available in the public record, and . . . Relator often helpfully even cites the relevant source" in the FAC. Allergan Motion at 12 (listing allegations in the FAC and public records cited); *see also* Allergan Appendix A.

According to Allergan, the transactions described in the public record with respect to the Went Patents and '009 patent are sufficient to constitute public disclosures under the Ninth Circuit's decisions in *A-1 Ambulance Serv., Inc. v. California*, 202 F.3d 1238, 1243 (9th Cir. 2000) and *Amphastar Pharm. Inc. v. Aventis Pharma SA*, 856 F.3d 696, 700 (9th Cir. 2017), which "confirm that Relator's Complaint must be dismissed." *Id*.

In addition to arguing that the "transaction" prong of the public disclosure bar is satisfied, Allergan asserts that the "allegation" prong is met because the allegation that Defendants improperly obtained various patents that allowed them to charge monopoly prices was the subject of a "widely publicized 2014 suit [in which] the State of New York alleged that certain defendants engaged in anticompetitive conduct aimed at keeping generic competitors to Namenda® from entering the market by suspending sales of an earlier version of Namenda® (Namenda® IR) upon its launch of the new Namenda® XR." *Id*. at 13-14. Allergan points to a *Law360* article that described a "follow-up class action," stating:

> Defendants' exclusionary conduct has delayed, prevented and impeded the sale of generic memantine hydrochloride [Namenda®] in the U.S., and unlawfully enabled Forest to sell significantly more branded memantine hydrochloride at artificially inflated prices," the complaint said. "As a consequence, plaintiff[s] . . . have sustained substantial losses and damage . . . in the form of overcharges.

Id. at 14 (quoting Strong Decl., Ex. 65 (June 9, 2015 *Law360* Article)). Although the investigation by the State of New York did not expressly allege fraud on the Patent Office, Allergan argues that it was sufficient to show that an in-depth review of Allergan's conduct with respect to the Namenda® line of patents was conducted and therefore, that Relator's "overlapping allegations about Defendants' alleged foreclosure of generics was not necessary to put the government 'on the trail' of any alleged fraud." *Id*. (citing *United States ex rel. Reed v. KeyPoint Gov't Sols.*, 923 F.3d 729, 744 (10th Cir. 2019)). This conclusion is further supported, Allergan argues, by the fact that in December 2014 a generic manufacturer initiated a proceeding before the Patent Office challenging the validity of one of the Went Patents, the '085 patent, based on anticipation and obviousness. *Id*. (citing Strong Decl., Ex. 47 (petition for *Inter Partes* review of the '085 patent)).

Allergan argues further that all of these public disclosures occurred in a public source recognized by the FCA. *Id*. First, it argues that the documents that are part of the prosecution histories of proceedings before the Patent Office constitute government "reports" under § 3730(e)(4)(A)(ii) because prosecution histories are, by law, published as "an official, formal statement of federal proceedings." *Id*. at 15 (citing 37 C.F.R. § 1.211). Likewise, it argues that the SEC filings and FDA materials upon which Relator relies are government "reports" under the FCA. *Id*. at 15-16. Second, Allergan contends that "[t]o the extent they did not occur in federal 'reports,' the disclosures here occurred in 'news media' as the term is used" in the FCA. *Id*. at 16. In addition, Allergan argues that the Patent Office prosecution histories, SEC filings and FDA materials discussed above also qualify as "news media" because they are all available online on websites "expressly designed for the purpose of disclosing them" and also through various commercial services. *Id*. at 16-17.

Finally, Allergan argues that Relator is not an original source. *Id*. at 17. According to Allergan, Relator has not alleged any facts establishing that before any public disclosure was made he voluntarily provided the government the "information on which allegations or transactions in [the] claim are based." *Id*. (quoting 31 U.S.C. § 3730(e)(4)(B)(ii)). Although Relator does allege he is an original source, this is not enough to defeat the public disclosure bar, Allergan asserts,

because these allegations are conclusory and are not supported by specific factual allegations. *Id.* (citing *United States v. Kimberly-Clark Corp.*, No. LA CV-14-08313 JAK (JPRx), 2017 WL 10439690, at *8 (C.D. Cal. Nov. 30, 2017)).

Further, Allergan argues that because Relator's knowledge is derived from piecing together public disclosures, he cannot qualify as an original source. *Id.* at 18. In particular, Allergan argues that Relator did not have preexisting knowledge that he provided to the government prior to public disclosure of the information; nor did he have "independent knowledge" prior to public disclosure. *Id.* (citing *Amphastar*, 856 F.3d at 705; *Malhota v. Steinberg*, 770 F.3d 853, 860 (9th Cir. 2014)). Allergan also argues that Relator cannot be an original source simply "by applying specialized knowledge of legal and patent issues to publicly disclosed 'transactions.'" *Id.* (citing *U.S.A. ex rel. Calva v. Impac Secured Assets Corp.*, No. SACV161983JVSJCGX, 2018 WL 6016152, at *8 (C.D. Cal. June 12, 2018); *Prather v. AT&T, Inc.*, 847 F.3d 1097, 1105 (9th Cir.), *cert. denied*, 137 S. Ct. 2309 (2017); *A-1 Ambulance*, 202 F.3d at 1245).

Relator argues in his Opposition that the public disclosure bar does not apply to his FCA claims against Allergan because the 2010 amendments to the FCA narrowed the public disclosure bar, limiting the types of hearings and proceedings that trigger the public disclosure bar and lowering the threshold for qualifying as an original source. Allergan Opposition at 3, 21-22. Relator argues that Allergan's reliance on the investigation and lawsuit against Allergan by New York State is misplaced because it did not involve "substantially the same allegations or transactions," as is required under § 3730(e)(4)(A); rather, it involved a different drug (Namenda® IR) and there was no allegation of fraud on the Patent Office in that lawsuit. *Id.* at 22-23 (citing *Mateski*, 816 F.3d at 577). Similarly, Relator argues, the proceeding by a generic manufacturer before the PTAB in which it challenged one of the Went Patents was not a proceeding that involved the federal government and thus does not satisfy § 3730(e)(4)(A)(i)). *Id.* at 23. Relator further asserts that Allergan does "not even suggest that the challenger alleged fraud on the Patent Office" in the PTAB proceeding, which the PTAB would not have had jurisdiction to consider in any event because it "has no jurisdiction to hear claims based on fraud." *Id.* (citing 35 U.S.C. § 311(b)).

Relator also rejects Allergan's argument that the transactions from which fraud can be inferred were publicly disclosed because they are reflected in the publicly available patent prosecution histories, countering that the publication of patent prosecution histories on PAIR does not make them federal "reports" or "news media" under the FCA. *Id*. at 23-24. According to Relator, "[l]ike the PACER system for courts, PAIR reproduces the vast majority of documents submitted in a patent prosecution [and] as with PACER, documents appear on PACER in real time as they are filed electronically." *Id.* Relator points out that while Allergan contends these documents fall under the 31 U.S.C. § 3730(e)(4)(A)(ii) as "reports," it "assiduously avoids" the argument that the patent prosecution history constitutes a "hearing in which the Government or its agent is a party" for the purposes of 31 U.S.C. § 3730(e)(4)(A)(i) because a "patent prosecution is an *ex parte* administrative proceeding in which the Government is not a party." *Id*. As such, Relator argues, patent proceedings "fall squarely within the category of hearings that Congress sought to carve out of the public disclosure bar in 2010." *Id*.

Relator argues that his interpretation of the public disclosure bar in the wake of the 2010 amendments is supported "[f]irst and foremost" by the statutory text of 31 U.S.C. § 3730(e)(4). *Id*. at 25. In particular, he argues that Allergan's reading of the statute would nullify the new limitation that Congress added to the public disclosure bar in romanette (i) when it inserted the phrase "in which the Government or its agent is a party." *Id.* According to Relator, such an interpretation of the public disclosure bar violates the rule of statutory construction that "the specific governs the general" and courts are "obliged to give effect, if possible, to every word Congress used." *Id*. (quoting *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 645 (2012) and *Nat'l Ass'n of Mfrs. v. Dep't of Def.*, 138 S. Ct. 617, 632 (2018)). Were the Court to accept Allergan's reading of the statute, Relator contends, the new limitation in romanette (i) would be nullified for "each and every proceeding with a public docket – a tremendous share of private hearings including not only patent prosecutions, but also private federal litigation (for which PACER automatically posts electronically filed documents to the web)." *Id*.

Relator argues further that there has been no case since the 2010 amendments in which a court has held that "documents available only on PAIR trigger the public disclosure bar under the

current version of the statute." *Id*. He further asserts that the Supreme Court's decision in *Schindler Elevator Corp. v. U.S. ex rel. Kirk*, 563 U.S. 401, 409 (2011) ("*Schindler*") supports his reading of the amended version of the public disclosure bar as that case emphasizes the "ordinary meaning" of the language of the public disclosure bar and the necessity of considering the provision's "entire text" as an "integrated whole." *Id*. at 25-26 (citing *Schindler*, 563 U.S. at 408). Relator also argues that the "PAIR system is nothing like" the written response that the Supreme Court found in *Schindler* was a "report" under the FCA. *Id*. In that case, Relator contends, the written response to a Freedom of Information Act ("FOIA") request was "prepared by federal employees who were required to 'notify the person making such request of [the agency's] determination and the reasons therefor,'" and thus "fell within the ordinary definition of a 'report.'" *Id*. at 26 (citing *Schindler*, 563 at 410). In contrast, Relator asserts, "nobody would say that an affidavit, prepared by a private inventor and submitted to the Patent Office in connection with a patent application, constitutes a 'Federal report' or 'news media.'" *Id*.

Relator also argues that to the extent Allergan relies on cases in which courts have found that databases available on government websites "should qualify as 'reports' when they are 'readily available' and 'easily navigable,'" those cases do not apply to PAIR because the PAIR database does not meet those requirements. *Id*. at 26-27 (citing Allergan Motion at 16 (quoting *United States ex rel. Rosner v. WB/Stellar IP Owner, L.L.C.*, 739 F. Supp. 2d 396, 405, 407 (S.D.N.Y. 2010) and citing *United States ex rel. Calilung v. Ormat Indus., Ltd*., No. 3:14-CV-00325-RCJ, 2015 WL 1321029, at *16 (D. Nev. Mar. 24, 2015) (holding under the current version of the public disclosure bar that SEC filings are "reports" because they are "required by the SEC and the information contained therein [is] made readily available to the public on easily navigable websites by the SEC"); *United States, ex rel. Liotine v. CDW Gov't, Inc.*, No. 05-33-DRH, 2009 WL 3156704, at *6 (S.D. Ill. Sept. 29, 2009) (holding under pre-2010 version of the FCA that information on a university website was not a report because "several steps had to be taken to even locate the article as it is currently archived on the University's website" and therefore it was not "readily available to the public.")). According to Relator, unlike the websites in the cases upon which Allergan relies, the PAIR database is not "easily navigable" as it contains "the entire

histories for millions of patent applications, is difficult to search (and cannot be searched using external search engines), and . . . utilizes opaque docket sheets providing almost no descriptive information about the contents of particular files." *Id*. at 27.

Similarly, Relator asserts that the policy behind the public disclosure bar would not be served by finding that documents on PAIR are "reports" as this database contains "mountains of raw information submitted by third parties" and there is "no reasons to assume that the government is likely to be aware of the information in the database." *Id*. at 27. According to Relator, because patent applicants are required to provide the Patent Office with all material related to patentability, including prior art – and those prior art citations "by their very nature are public" – Allergan's argument would, if accepted, lead to the result that "there could *never* be a *qui tam* action based on a defendant's knowing omission of prior art materials to the Patent Office . . . ." *Id*. at 27-28.

Finally, Relator argues that Allergan's "news media" argument was recently rejected in *Integra*, No. CV 17-1694 PSG (SSX), 2019 WL 3282619, at *11 (C.D. Cal. July 16, 2019), and that this Court should reject that argument for the reasons stated in *Integra*. According to Relator, in *Integra* the court found that cases that have "treat[ed] broad swaths of the Internet as 'news media' have ignored the Supreme Court's guidance in *Schindler* to construe terms in the public disclosure bar consistently with their ordinary meaning." *Id*. at 28.

As to the question of whether Relator is an "original source" and therefore falls outside the ambit of the public disclosure bar (as Relator contends), Relator argues that this is a fact question that cannot be resolved on the pleadings. *Id*. at 28-29. In addition, while he acknowledges that a relator's specialized expertise did not make a relator an "original source" prior to 2010, Relator argues that the amended definition of "original source" allows claims based on a relator's knowledge "about the intricacies of drug patents" because "[u]nder the new statute, the key question is whether the Relator's knowledge 'materially adds to' the publicly disclosed allegations or transactions." *Id*. at 29 (quoting *Moore*, 812 F.3d 294, 306 (3d Cir. 2016)).

In its Reply, Allergan asserts that Relator does not dispute that: 1) "substantially the same . . . transactions" were publicly disclosed in public Patent Office sources; and 2) he obtained the

information that is the basis for his FCA claims against Allergan from those public documents and not from his own "primary knowledge." Allergan Reply at 2. Allergan rejects Relator's argument that documents in patent prosecution histories are not "reports" under the FCA as amended in 2010, arguing that in amending subsection § 3730(e)(4)(A) Congress "reinforced the 'broad ordinary meaning of "report"' in the pre-2010 statute." *Id*. at 3 (quoting *Schindler*, 563 U.S. at 408).

Allergan also argues that the report at issue in *Schindler*, a "VETS-100" filing that the government was required to publish under FOIA, was analogous to the documents in the patent prosecution histories here, which the government is also required by law to publish. *Id*. at 4 (citing *Schindler*, 563 U.S. at 411 & n. 6). According to Allergan, "[t]he only notable difference from the facts in *Schindler* is that someone (like Relator here) can go online, find the materials connected to a certain patent application (or various other criteria), press 'search,' and see the official records right away rather than typing up the same request, mailing it off, and paying a fee for copies returned weeks or months later under FOIA." *Id*. Allergan argues that if anything, this difference lends support to the conclusion the public prosecution histories are "reports" under the reasoning of *Schindler*. *Id*.

Courts have applied similar reasoning, Allergan asserts, to a "wide variety of materials submitted to federal agencies under various regulatory schemes and subsequently released to the public[,]" including drug product utilization data submitted to the FDA and customs data provided by shippers to the Department of Homeland Security. *Id*. at 4-5 (citing Allergan Motion at 15 n. 11) (citing *United States ex rel. Colquitt v. Abbott Labs*., 864 F. Supp. 2d 499, 518 (N.D. Tex. 2012) , *aff'd*, 858 F.3d 365 (5th Cir. 2017); *United States ex rel. Doe v. Staples, Inc*., 932 F. Supp. 2d 34, 40 (D.D.C. 2013), *aff'd*, 773 F.3d 83 (D.C. Cir. 2014); *United States ex rel. Customs Fraud Investigations, LLC v. Victaulic Co.*, 2014 WL 4375638, at *10 (E.D. Pa. Sept. 4, 2014); *United States ex rel. Conrad v. Abbott Labs., Inc*., No. 02–11738, 2013 WL 682740, at *5 (D. Mass. Feb. 25, 2013)). Similarly, Allergan argues, courts have uniformly found that the FCA's definition of a federal "report" in the wake of the 2010 amendments covers "the vast trove of dense corporate filings submitted to the SEC under the securities laws and made public on the SEC's EDGAR

website." *Id*. at 5 (citing *United States ex rel. Calilung v. Ormat Indus*., Ltd., No. 3:14-CV-00325-RCJ, 2015 WL 1321029, at *16 (D. Nev. Mar. 24, 2015)). Allergan argues that Relator offers no explanation why corporate filings with the SEC that are available on EDGAR would be "reports" under the FCA while public filings with the Patent Office available on PAIR would not be "reports." *Id*.

Allergan also rejects Relator's argument that filings on PAIR should not be considered "reports" because it is unlikely the government would have reviewed patent dockets or be "likely to know" the information. *Id*. According to Allergan, the Supreme Court has "squarely rejected" this approach, holding that the question of whether the government knows the information "is 'not . . . the right question' because the 'statutory touchstone, once again, is whether the allegations of fraud have been "public[ly] disclos[ed]," § 3730(e)(4)(A), not whether they have landed on the desk of a DOJ lawyer.'" *Id.* (quoting *Graham Cty*., 559 U.S. at 300).

Allergan also challenges Relator's argument that the patent prosecution materials are not "news media," asserting that this is an "expansive category" and that by leaving this subsection unchanged when it amended the FCA in 2010, Congress implicitly approved the many pre-2010 court decisions interpreting the term broadly to include information on public websites maintained to disseminate information to the general public. *Id*. at 6 (citing *United States ex rel. Shea v. Cellco P'ship*, 863 F.3d 923, 933, 934 (D.C. Cir. 2017) (stating that "[n]either party disputes that publicly available websites can fall in that category" both before and after amendments); *United States ex rel. Harper v. Muskingum Watershed Conservancy Dist*., No. 5:13-CV-2145, 2015 WL 7575937, at *6 (N.D. Ohio Nov. 25, 2015) ("Courts have repeatedly held that information on readily accessible public websites constitutes public disclosure." (quotation omitted)), aff'd, 842 F.3d 430 (6th Cir. 2016)). Allergan argues that to the extent the court in *Integra* adopted a narrower interpretation of "news media," that case is distinguishable because the actual materials in that case were directed to an internal audience, were designated "Proprietary and Confidential," and could only be accessed by typing in a precise URL, which brought up hundreds of folders that were labeled only in "gibberish" file names; in contrast, PAIR contains materials that Congress has determined should be made available to the public and is public-facing. *Id*. at 7 (citing

Integra, 2019 WL 3282619, at *13).

Finally, Allergan argues that the 2010 amendments to the FCA did not change the definition of "original source" or the rule that reliance on specialized knowledge is not sufficient to avoid the public disclosure bar. *Id*. at 7 (citing *United States ex rel. Calva v. Impac Secured Assets Corp*., No. SACV 16-1983 JVS(JCGx), 2018 WL 6016152, at *8 (C.D. Cal. June 12, 2018); *Ormat*, 2015 WL 1321029, at *19). Allergan argues that Relator concedes he is not an "original source" under the pre-2010 version of the FCA. *Id*. It also argues that Relator's reliance on *Moore* is misplaced because in that case, the relator relied on specific details learned through discovery that were not publicly disclosed about the "crux of the alleged fraud." *Id.* at 8 (citing *Moore*, 812 F.3d 294 (3d Cir. 2016)). Moreover, Allergan argues, the Third Circuit subsequently "weighed in directly on the issue, explaining that it still 'appl[ies] the public disclosure bar to parasitic suits in which a relator uncovers a fraud based only on the application of background knowledge or experience to the publicly available facts.'" *Id*. (quoting *United States v. Omnicare, Inc*., 903 F.3d 78, 89 (3d Cir. 2018)).

b. The Adamas Motion

Adamas, like Allergan, invokes the public disclosure bar in its motion. Adamas argues that Relator's complaint "does little more than repeat 'inequitable conduct' allegations from previous patent infringement litigation" relating to Namenda XR® and Namzaric® in 2014 and 2015. Adamas Motion at 1 (citing Declaration of Anthony Portelli in Support of Motion to Dismiss Amended Complaint ("Portelli Decl."), Exs. 1-4 (Answers and Counterclaims by defendants Amneal Pharmaceuticals LLC ("Amneal") and Amerigen Pharmaceuticals, Inc.("Amerigen") in three District of Delaware lawsuits brought against them by Forest Laboratories (hereinafter, "the Delaware actions")). In particular, Adamas asserts that Amneal and Amerigen, manufacturers seeking to manufacture generics of Namenda XR® and Namzaric®, asserted in the Delaware actions that six of the Went Patents had been obtained by inequitable conduct committed during prosecution, namely, intentional misrepresentations in the Original Went Declaration and two similar Went declarations submitted to the Patent Office regarding the side effect results of the ME110 Study. *Id*. at 6-7 (citing Portelli Decl., Ex. 1 (Amneal Amended

Answer, filed July 2014 in Delaware actions)). According to Adamas, Amneal and Amerigen cited the 2012 Went Declaration (which contained the actual data from the ME110 Study, as discussed above) to show that the misrepresentations were intentional. *Id.*; *see also* Adamas Motion, Attachment A (comparing allegations in FAC with alleged public disclosures in Delaware actions).

Adamas further asserts that it disclosed the inequitable conduct allegations from the Delaware actions to the Patent Office in 2016, when it filed two Information Disclosure Statements ("IDSs") listing documents relevant to patent applications in the Went family of patents and including in the list the Amneal Amended Answer. *Id*. at 7 (citing Portelli Decl., Ex. 5 (April 4, 2016 IDS filed in connection with Patent Application 15/090,396); *id.*, Ex. 6 (April 4, 2016 IDS filed in connection with Patent Application 15/090,400)). In both IDSs, the Amneal Amended Answer is listed as document no. 540. *Id*. According to Adamas, the Amneal Amended Answer was attached to the IDSs. *Id*. Adamas further represents that the patent litigation with Amneal and Amerigen settled before the inequitable conduct allegations were adjudicated and that the Federal Circuit invalidated six of the Went Patents for other reasons in 2018. *Id*. According to Adamas, the settlement agreements were sent to the Antitrust Division of the U.S. Department of Justice and the U.S. Federal Trade Commission and neither objected to the agreements. *Id*.

Adamas argues that the allegations of fraud by Amneal and Amerigen are "substantially the same allegations" as Relator asserts in this case for the purposes of § 3730(e)(4)(A). *Id*. at 12-13. Adamas further asserts that even apart from Amneal and Amerigen's allegations, all of the transactions necessary to establish fraudulent conduct had been publicly disclosed before Relator brought this action because, as Allergan also argues, all of the material transactions necessary to show that fraud had occurred were in the patent prosecution history and had been publicly disclosed on PAIR. *Id*. at 13-15. Like Allergan, Adamas argues that these materials qualify as both federal "reports" and "news media" under §§ 3730(e)(4)(A)(ii) & (iii).

Adamas also argues that Relator is not an original source under the FCA for the same reasons offered by Allergan.

In his Opposition, Relator makes many of the same arguments he makes against Allergan

in support of his contention that the public disclosure bar does not apply. Relator also rejects the additional arguments made by Adamas that the public disclosure bar applies because the same allegations of fraud were already made in the Delaware actions by Amneal and Amerigen and disclosed in the IDSs submitted to the Patent Office. Adamas Opposition at 16-18. Relator argues that the allegations of fraud made by Amneal and Amerigen in the Delaware actions do not constitute public disclosures under the post-2010 version of the FCA because that litigation did not include the government as a party, as is now required under § 3730(e)(4)(A)(i). *Id*. at 16. Nor does the fact that these documents are available on PACER make them federal "reports" or "news media," Relator argues, as such a reading of the FCA would be inconsistent with the plain meaning of § 3730(e)(4)(A) and the reasoning of *Integra* for the same reasons materials posted on PAIR are not federal "reports" or "news media." *Id.* at 17. Relator also argues that the IDSs do not constitute public disclosures, asserting that "they do not actually disclose anything material about the fraud alleged in the Complaint [but rather], they merely list the generic ANDA filers' pleadings – without any description whatsoever – along with thousands of other references also missing any meaningful descriptions." *Id.* at 18.

In its Reply, Adamas argues that the IDSs contain "substantially the same allegations" as Relator advances in this case and that Relator mischaracterizes the IDSs when he says they are merely a list of patent infringement litigation documents; in fact, Adamas argues, an IDS must include legible copies of the documents listed in it as attachments and thus the Amneal counterclaims were included with the IDSs that were submitted to the Patent Office.[10] Adamas Reply at 5. Adamas further contends that Relator is wrong in asserting that the IDSs could not have alerted the government to the fraud alleged by Amneal and Allergan given that the Patent Office is required, under federal regulations, to review the documents attached to IDSs. *Id*. (citing 37 C.F.R. §§ 1.97 & 1.98(a)). Further, Adamas asserts, the Patent Examiner certified that she did, in fact, consider the documents disclosed in the IDSs. *Id*. (citing Second Declaration of Anthony Portelli in Support of Motion to Dismiss Amended Complaint by Adamas Pharma, LLC ("Second

[10] At oral argument, Adamas conceded, however, that while the IDSs are available on PAIR, the documents listed in them (including Amneal's Amended Answer in the Delaware actions) are not.

Portelli Decl."), Exs. 1 & 2 (copies of IDSs that were marked up and signed by the Patent Examiner)). Adamas argues that Relator's reliance on the fact that the government was not a party to the patent litigation in which Amneal and Amerigen made their fraud allegations is misplaced because the materials filed in these cases are both federal "reports" and "news media" even if they do not qualify as a public disclosure under § 3730(e)(4)(A)(i). *Id*. at 5-7.

3. Discussion

"The public disclosure bar is triggered if three conditions are met: '(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 "based upon" the allegations or transactions publicly disclosed.'" *United States ex rel. Solis v. Millennium Pharm., Inc*., 885 F.3d 623, 626 (9th Cir. 2018) (quoting *Mateski*, 816 F.3d at 570) (citation omitted). Here, the parties' disputes turn on the first and third elements of this test as it is undisputed that the disclosures cited in Defendants' motions were "public." For the reasons stated below, the Court finds that the "based upon" requirement is satisfied but that the disclosures did not occur through one of the channels specified in the statute.

a. Are Relator's Claims Based Upon Substantially Similar Allegations or Transactions?

"[F]or a relator's allegations to be 'based upon' a prior public disclosure, 'the publicly disclosed facts need not be identical with, but only substantially similar to, the relator's allegations.'" *Mateski*, 816 F.3d at 573 (citation omitted). Facts showing fraud may be publicly disclosed either in the form of direct allegations of fraud or through disclosure of transactions that give rise to an inference of fraud. *Id.* at 571 (holding that although the terms "allegation" and "transaction" as used in § 3730(e)(4)(A) are not defined in the FCA, courts have held that "allegation" refers to a direct claim of fraud and "transaction" refers to facts from which fraud can be inferred.). In the latter scenario, fraud is publicly disclosed where the "material elements of the allegedly fraudulent 'transaction' are disclosed in the public domain.'" *Id*. (quoting *United States ex rel. Found. Aiding the Elderly v. Horizon W*., 265 F.3d 1011, 1014 (9th Cir.), opinion amended on denial of reh'g sub nom. *United States ex rel. Found. Aiding the Elderly v. Horizon W., Inc*., 275 F.3d 1189 (9th Cir. 2001) and citing *A-1 Ambulance Serv., Inc. v. California*, 202

F.3d 1238, 1243 (9th Cir. 2000)).

i. Allegations of Fraud

Allergan and Adamas assert that the same allegations of fraud that are the basis for Relator's claims in this action were disclosed in: 1) a lawsuit brought by the State of New York ("the New York action") in which it was alleged that Allergan engaged in anticompetitive conduct aimed at keeping generic competitors to Namenda® XR from entering the market; 2) a challenge to the '085 patent brought before the Patent Office based on obviousness and anticipation; and 3) the assertions of fraud by Amneal and Amerigen in the Delaware actions. Only the last of these involved allegations of fraud that are substantially similar to the allegations in this case.

In the New York action, the misconduct alleged by the State of New York was *not* inequitable conduct before the Patent Office, which is the crux of Relator's fraud claim here. Instead, in the New York lawsuit it was alleged that Allergan engaged in anticompetitive conduct aimed at keeping generic competitors to Namenda® XR from entering the market by suspending sales of an earlier version of Namenda®. Nor does Allergan's citation to *United States ex rel. Reed v. KeyPoint Gov't Sols*., 923 F.3d 729 (10th Cir. 2019) support its position. In that case, the court states that in determining whether allegations are "substantially similar[,]" "the operative question is whether the public disclosures were sufficient to set the government 'on the trail of the alleged fraud without [the relator's] assistance.'" 923 F.3d at 744 (citation omitted). But that case simply held that there need not be "complete identity of allegations" so long as the "essence" of the fraud was publicly disclosed. *Id*. at 745. The misconduct alleged in the New York lawsuit does not satisfy that requirement.

Likewise, the challenge to the '085 patent brought before the Patent Office was based on anticipation and obviousness. Allergan identifies no specific allegations of fraud in that proceeding. Further, the Court has reviewed the Petition for Inter Partes Review supplied by Allergan, *see* Strong Decl., Ex. 47, and finds no allegations of fraud, much less any that are substantially similar to the fraud alleged by Relator in this case.

On the other hand, the allegations of fraud by Amneal and Amerigen in the Delaware

actions *do* mirror Relator's fraud allegations with respect to the Went Patents. *See* Portelli Decl., Exs. 1-4.[11] In particular, Amneal and Amerigen – like Relator – alleged that the Went Patents were obtained on the basis of declarations by Dr. Went that were knowingly false and misleading with respect to their characterization of the results of the ME110 Study and that were submitted in order to overcome the Examiner's objections. Therefore, the Court concludes that to the extent Relator relies on alleged fraud in connection with the issuance of the Went Patents, substantially similar allegations were disclosed in the Delaware actions.

ii. Transactions Disclosing Fraud

As stated above, the public disclosure bar is triggered not only when direct claims of fraud have been publicly disclosed but also where the material elements of the allegedly fraudulent transaction are disclosed. *See Mateski*, 816 F.3d at 571. The Ninth Circuit has adopted the analysis of the D.C. Circuit in *United States ex rel. Springfield Terminal Ry. v. Quinn*, 14 F.3d 645, 654 (D.C.Cir.1994) ("*Springfield*") with respect to the determination of whether a fraudulent transaction has been publicly disclosed under the FCA. *U.S. ex rel. Found. Aiding The Elderly v. Horizon W.*, 265 F.3d at 1014. In *Springfield*, the court stated:

> On the basis of plain meaning . . . , if X + Y = Z, Z represents the allegation of fraud and X and Y represent its essential elements. In order to disclose the fraudulent transaction publicly, the combination of X and Y must be revealed, from which readers or listeners may infer Z, i.e., the conclusion that fraud has been committed.

14 F.3d at 654. "That the disclosed transactions themselves may not have pointed directly to any wrongdoing is . . . of no moment." *A-1 Ambulance Serv., Inc.*, 202 F.3d at 1245. Likewise, the fact that a relator recognized the fraud because of the relator's unique knowledge or experience does not save the claim from the public disclosure bar if the underlying transactions have been

[11] The Court notes that one of these documents, namely, Amneal's July 21, 2014 Amended Answer, Affirmative Defenses and Counterclaims, was listed in IDSs that were submitted to the Patent Office and are publicly available on PAIR. *See* Second Portelli Decl.,¶ 5 and Exs. 1 & 2, item 540. Defendants conceded at oral argument, however, that while the documents listed in the IDSs were attached to the IDSs that were submitted to the Patent Office, these attached documents are not on PAIR and can be obtained only by requesting them from the Patent Office. Thus, the IDSs do not publicly disclose any of the allegations of fraud contained in Amneal's Amended Answer, Affirmative Defenses and Counterclaims. Rather, the relevant public disclosure for the purposes of the Court's analysis is the disclosure that occurred when Amneal filed this document in the Delaware actions.

publicly disclosed and the relator does not fall under the "original source" exception. *Id*.

The Court finds that the prosecution histories of the patents at issue in this case disclose the material elements of the fraud that is the basis for Relator's claim, both with respect to the Went Patents and the '009 patent, as they reveal both the true and false state of affairs with respect to the alleged fraud. In particular, with respect to the Went Patents, the publicly available prosecution history contains the Original Went Declaration and other similar declarations submitted to overcome the patent examiners' objections and also the 2012 Went Declaration that Relator contends shows that these earlier declarations were fraudulent. Likewise, the publicly available prosecution history for the '009 patent reveals that although Forest Laboratories initially disclosed the prior art that is the basis of Relator's fraud allegation, it did not alert the Patent Office 18 months later, when it amended the application to add a "once-daily" limitation, that this prior art taught the same once-daily administration. Therefore, the Court concludes that substantially the same transactions were publicly disclosed on PAIR before Relator initiated this action.[12]

b. Did the Disclosures Occur Under One of the Channels Specified in the FCA?

The most difficult question the Court must answer is whether the disclosures discussed above were made through one of the channels that triggers the public disclosure bar under the FCA. The disclosures cited by Allergan and Adamas do not fall under romanette (i) of § 3730(e)(4)(A) because that section applies only to "Federal criminal, civil, or administrative hearing[s]" in which the federal government was a party and it is undisputed that the Government was not a party to the patent prosecutions here. Defendants contend, however, that the publicly available patent prosecution histories on PAIR make the disclosures discussed above "reports" under subsection (ii) or "news media" under romanette (iii) (or both). Adamas also asserts that the disclosures were made through one of the channels allowed under the FCA because the patent prosecutions are "Federal . . . hearing[s]" under romanette (ii). To decide whether Defendants are

[12] Although Allergan points to certain SEC filings that disclose facts similar to ones alleged in Relator's complaint, *see* Allergan Motion, Appendix A at 2, 4-6, these filings do not disclose the material elements of the allegedly fraudulent transaction.

correct, the Court must grapple with the significance of the 2010 amendments to the FCA. For the reasons set forth below, the Court concludes that in the wake of the 2010 amendments to the public disclosure bar, the disclosures on PAIR are neither "reports" nor "news media." The Court further concludes that the patent prosecutions are not "Federal . . . hearing[s]" for the purposes of the public disclosure bar.[13]

i. Federal Report

To determine whether the patent prosecution documents discussed above constitute "Federal report[s]" under the current version of the public disclosure bar, the Court considers "the provision's 'entire text,' read as an 'integrated whole.'" *Schindler*, 563 U.S. at 408 (quoting *Graham County*, 559 U.S. at 290 n. 12). Taking this approach, the interaction between §§ 3730(e)(4)(A)(i) and (ii) is of particular significance in construing the phrase "Federal report" in the public disclosure bar. When Congress amended the FCA in 2010, it limited the scope of § 3730(e)(4)(A)(i) by adding the words "in which the Government or its agent is a party," reflecting "Congress's intent to exclude from the public disclosure bar information disclosed at hearings in cases in which the Government is *not* a party, conceivably in part based on a presumption that the Government is less likely to learn about events that transpire in cases it is not involved with." *Integra*, 2019 WL 3282619, at *11.

Here, it is undisputed that patent prosecution is an *ex parte* administrative proceeding in which the Government is not a party. Consequently, the limitation Congress added to romanette (i) of the public disclosure bar in 2010 would be all but eviscerated as to any federal administrative matter if the Court were to adopt the broad reading of "Federal report" urged by Defendants, as doing so would result in an interpretation under which *any* federal proceeding with a public docket – regardless of whether or not the Government was a party – would become a

[13]It is clear to the Court that the pleadings filed by Amneal and Amerigen in the Delaware actions do not qualify under any of the three categories because the federal government was not a party to the Delaware actions for the purposes of subsection (i) of § 3730(e)(4)(A) and Defendants have repeatedly stated that they are *not* arguing that availability of these pleadings on PACER makes them "reports" under subsection (ii). Even if Defendants had made this argument, the Court would reject it for the same reasons it concludes availability of a document on PAIR does not make it a "report" under the public disclosure bar, as discussed below.

permissible channel that could trigger the public disclosure bar. The amendment to the language of romanette (i) was clearly intended to carve out from that portion of the public disclosure bar, *inter alia*, federal proceedings to which the government was not a party. Defendants' construction would add those proceedings back into romanette (ii). Such a result would be inconsistent with the rule that courts are "'obliged to give effect, if possible, to every word Congress used.'" *Nat'l Ass'n of Mfrs. v. Dep't of Def.*, 138 S. Ct. 617, 632 (2018) (quoting *Reiter v. Sonotone Corp.*, 442 U.S. 330, 339 (1979)).

Such a result also flies in the face of the well-accepted rule of statutory construction that "'the specific governs the general.'" *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 645 (2012) (quoting *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 384 (1992)). As the Court in *RadLAX* explained, while this canon of construction is "perhaps most frequently applied to statutes in which a general permission or prohibition is contradicted by a specific prohibition or permission[,]" it also applies to situations such as the one here, "in which a general authorization and a more limited, specific authorization exist side-by-side." *Id.* In that scenario, the canon requires that the "terms of the specific authorization must be complied with," which "avoids . . . the superfluity of a specific provision that is swallowed by the general one, 'violat[ing] the cardinal rule that, if possible, effect shall be given to every clause and part of a statute.'" *Id.* (*quoting D. Ginsberg & Sons, Inc. v. Popkin*, 285 U.S. 204, 208 (1932)); *see also HCSC-Laundry v. United States*, 450 U.S. 1, 6 (1981) ("[I]t is a basic principle of statutory construction that a specific statute, . . . controls over a general provision . . . particularly when the two are interrelated and closely positioned").

In order to give effect to Congress's 2010 amendments of the FCA to specifically exclude from the public disclosure bar disclosures made in federal hearings where the Government was not a party, the Court rejects Defendants' broad interpretation of the term "Federal report[s]" in the post-2010 version of the FCA as encompassing any disclosures made during patent prosecution that are publicly available on PAIR.

Nor does the Court's instruction in *Schindler* that courts must consider the "ordinary meaning" of the word "report" point to a contrary conclusion. *See* 563 U.S. at 510. In *Schindler*,

the relator based his FCA claims on information his wife obtained in response to Freedom of Information Act ("FOIA") requests made to the Department of Labor and the question before the Court was whether these responses were "reports" within the meaning of the public disclosure bar (as it existed prior to the 2010 amendments). *See* 563 U.S. at 406. The responses consisted of letters and emails describing "the records found for each year, including years for which no responsive records were located," and providing copies of the 99 reports that had been found for those years. *Id.* Noting that the FCA does not define the word "report," the Court began its analysis by addressing the "ordinary meaning" of the word, looking to dictionary definitions. *Id.* at 407. According to the Court, "[a] 'report' is 'something that gives information' or a 'notification,' Webster's Third New International Dictionary 1925 1986), or '[a]n official or formal statement of facts or proceedings,' Black's Law Dictionary 1300 (6th ed.1990)." *Id.* at 407-408. The Court concluded that the FOIA responses in that case fell within this "broad" meaning of "report," which was consistent with the "broad scope of the FCA's public disclosure bar." *Id.* at 408.

The facts of *Schindler* fit comfortably within the ordinary meaning of the word "report" because a government employee prepared the FOIA responses that were sent to the relator in that case and selected the documents attached to the response. The disclosures here, on the other hand, are made available to the public by virtue of the fact that the Patent Office maintains a public website where it publishes patent prosecutions, as is required by law. *See* 35 U.S.C.A. § 122 (providing that with certain exceptions, "each application for a patent shall be published, in accordance with procedures determined by the Director, promptly after the expiration of a period of 18 months from the earliest filing date for which a benefit is sought under this title."). The only arguable preparation that might make these documents governmental "reports" is the promulgation of regulations implementing the requirements of §122. *See* 37 C.F.R. § 1.11 (entitled "Files Open to the Public"). Yet these regulations merely set forth the rules and procedures for making patent prosecutions public; the Court concludes that they do not turn the documents that are publicly available on PAIR into governmental "reports" under the ordinary meaning of that word.

This conclusion finds further support when the Court considers the use of the word

"report" in the context of the "'entire text'" of the public disclosure bar read as an "'integrated whole.'" *Schindler*, 563 U.S. at 408 (quoting *Graham County*, 559 U.S. at 290, 293). In *Schindler*, the Court based its interpretation of the word "report" on the "generally broad scope of the FCA's public disclosure bar" in the pre-2010 version of § 3730(e)(4)(A). However, when Congress amended the FCA in 2010, it narrowed the scope of the public disclosure bar by, among other things, excluding information disclosed at hearings in cases in which the Government was not a party. *See* 31 U.S.C. § 3730(e)(4)(A)(i). As discussed above, this exclusion would be significantly undermined if the Court were to adopt the broad interpretation of the term "report" advanced by Defendants, as any information disclosed on a federal public docket (whether it is PACER, PAIR or some other federal docket) would be considered a public disclosure merely because it has been filed there, regardless of whether or not the Government is a party in the relevant proceeding. Thus, considering as a whole the three subsections of the current version of the public disclosure bar, the Court concludes the term "Federal report" should not be construed so broadly as to encompass documents that are publicly available on PAIR.

Nor does the Court find persuasive Defendants' reliance on a handful of cases in which courts purportedly found that comparable materials were "reports" for the purposes of the FCA. *See* Allergan Motion at 15 n. 11 (citing *United States ex rel. Colquitt v. Abbott Labs.*, 864 F. Supp. 2d 499, 518 (N.D. Tex. 2012) ("*Colquitt*"); *United States ex rel. Doe v. Staples, Inc.*, 932 F. Supp. 2d 34, 40 (D.D.C. 2013) ("*Doe*"); *United States ex rel. Customs Fraud Investigations, LLC v. Victaulic Co.*, 2014 WL 4375638, at *10 (E.D. Pa. Sept. 4, 2014)("*Victaulic*"); *United States ex rel. Conrad v. Abbott Labs., Inc.*, No. 02–11738, 2013 WL 682740, at *5 (D. Mass. Feb. 25, 2013) ("*Conrad*"); Adamas Motion at 15 (citing *United States ex rel. Rosner v. W.B./Stellar I.P. Owner, LLP*, 739 F. Supp. 2d 396, 405-07 S.D.N.Y. 2010); Allergan Reply at 5 (citing *United States ex rel. Calilung v. Ormat Indus., Ltd.*, No. 3:14-CV-00325-RCJ, 2015 WL 1321029, at *16 (D. Nev. Mar. 24, 2015) ("*Calilung*")).

First, one of the cases cited by Defendants, *Victaulic*, did not address the "report" channel of disclosure at all. In *Victaulic*, the court found that reports published by trade organizations that collected and compiled certain data submitted to the United States Bureau of Customs and Border

Protection qualified as "news media" under the FCA's public disclosure bar (pre-2010 version). 2014 WL 4375638, at *10 (reasoning that "at minimum, a publicly available website may qualify as 'news media' where the information provided is to some extent curated – that is, where the authors or editors of the website actively gather and disseminate information, provide search tools for the public to analyze data, provide some editorial content, or exercise some control over the information provided – and where the information bears at least some of the 'indicia of reliability or substantiation' common to more traditional news media sources."). The case did not address whether the trade publication was a "report" or suggest that that requirement might apply (under either the pre-2010 version of the FCA or the post-2010 version). Therefore, the case sheds no light on the question before the Court here.

The remaining cases cited by Defendants, most of which apply the pre-2010 version of the public disclosure bar, also do not persuade the Court that the disclosures on PAIR were "reports" under the current version of the public disclosure bar. In *Doe,* the FCA claims were based on shipping data contained in reports published by PIERS Global Intelligence Solutions ("PIERS"), a company which "compiles manifest information submitted to Customs by all shippers." 932 F. Supp. 2d at 40. The court concluded that "while not a traditional news source, this site qualifie[d] as 'news media' in light of the ample precedent in favor of broad construction of the channels of public disclosure listed in § 3730(e)(4)(A)." *Id.* It pointed to the Court's observation in *Schindler* that the "sources of public disclosure in § 3730(e)(4)(A), especially 'news media,' suggest that the public disclosure bar provides 'a broa[d] sweep.'" *Id.* (quoting 563 U.S. at 408). It also noted that "other courts have found similar trade publications to be 'news media.'" *Id.* (citing *United States ex rel. Alcohol Found. v. Kalmanovitz Charitable Found.*, 186 F.Supp.2d 458, 463 (S.D.N.Y. 2002)).

The court went on to find that the same information had been disclosed in "administrative reports" within the meaning of the pre-2010 version of § 3730(e)(4)(A) because "[t]he shipping information underlying the PIERS trade reports is also available to public subscribers through the U.S. Customs and Border Protection Automated Manifest System." *Id.* (citing 19 CFR §§ 4.7, 103.31(a) (requiring Customs to provide vessel manifest information to the press)). The court

provided no reasoning in support of its conclusion, however, and did not conduct any analysis of *Schindler* or its implications for whether the information available through the Government's automated system in that case was a "report" for the purposes of the FCA. Even assuming the court in *Doe* was correct, however, there is nothing to suggest that the automated system in that case was a docket sheet intended to disclose the history of any federal proceedings (much less proceedings in which the Government is not a party). Consequently, while the holding in that case may be consistent with the current version of the FCA under the facts of that case (a question the Court need not decide), it does not point to the same conclusion here; in contrast to the website in *Doe*, PAIR implicates subsection (i) of the public disclosure bar because it is a docket of federal proceedings in which the Government is not a party. As discussed above, construing the term "report" as encompassing such a website appears to be inconsistent with Congress's 2010 amendment of the public disclosure bar to exclude disclosures made in such proceedings. Therefore, the Court concludes that *Doe* does not support Defendants' position.

Similarly, in *Conrad*, the court found that drug product data files published quarterly by the Centers for Medicare and Medicaid Services ("CMS") were "reports" under the pre-2010 version of the public disclosure bar, but the publication at issue in that case also was not a public docket. Rather, it was a "consolidated list of all the covered outpatient drugs and any associated DESI codes that drug manufacturers ha[d] identified in their CMS filing[.]" 2013 WL 682740, at *5. Comparing the publication to the FOIA responses in *Schindler*, the court found that it "summarize[d] information in the agency's possession in exactly the same way that a FOIA response [did]." *Id.* The court observed that "[l]ike a FOIA response, the CMS data files represent at least some minimal preparation and synthesis by the agency, since the listings from each manufacturer and each state are sorted and compiled into a usable format." *Id.* It went on to find the data files published by CMS fit within the ordinary meaning of a "report" because they "constitute[d] official public statements by CMS" that notified recipients of "the covered outpatient drugs and DESI codes that each drug manufacturer ha[d] reported" and "how much the federal government ha[d] reimbursed the states for each covered outpatient drug." *Id.* Again, the website in *Conrad* was not a docket that reflected the history of any Federal proceedings and

therefore, the 2010 amendments to the public disclosure bar do not cast doubt on the conclusions of the court in that case but do suggest that the same result is not appropriate here. The Court also notes that documents found on PAIR are less like FOIA responses than the publication in *Conrad* because they are not summaries or compilations of the information in the Patent Office's possession. Therefore, this case also does not support Defendants' position.

Similarly, in *U.S. ex rel. Rosner v. WB/Stellar IP Owner, L.L.C.*, the court found that a database available on a state agency website was a "report" under the pre-2010 version of the public disclosure bar because it was "readily available to the public[,]" "easily navigable[,]" and did not "present raw, unanalyzed data" but instead "present[ed] synthesized tax benefit histories for many different properties over many years, organized by block and lot number." 739 F. Supp. 2d at 407.[14] Again, the information disclosed on the website at issue in that case was not a public docket like PAIR but instead, closer to the FOIA responses in *Schindler*.

The Court further concludes that in *Colquitt*, the court's reading of *Schindler* was excessively broad. In that case, the court found that summaries that were prepared by medical device manufacturers and submitted to the Food and Drug Administration ("FDA") to obtain clearance to sell the devices in interstate commerce ("510k summaries") were "administrative reports" under the pre-2010 version of the public disclosure bar. 864 F. Supp. 2d at 518. The court in that case relied on *Schindler* and a Fifth Circuit case that similarly found that a FOIA response was an "administrative report" under the FCA, *see U.S. ex rel. Reagan v. E. Texas Med. Ctr. Reg'l Healthcare Sys.*, 384 F.3d 168, 176 (5th Cir. 2004), to conclude that in order "to be an administrative report within the meaning of the FCA, a document must (1) constitute official government action and (2) provide information." *Id.* The court went on to find that both requirements were met because the 510k summaries provided information and they had been collected by the FDA as part of its administrative process. In other words, whereas in *Schindler*, the Court found that the FOIA responses fell within the ordinary meaning of the word "report"

[14] The court in *Rosner* relied on reasoning in *U.S. ex rel. Kirk v. Schindler Elevator Corp.*, 601 F.3d 94, 111 (2d Cir. 2010), some of which the Supreme Court rejected in *Schindler*, 563 U.S. 401 (2011). As the Court concludes that *Rosner* is not on point, it need not address whether it remains good law.

where an employee of the agency compiled the data that was sent to the FOIA requester, in *Colquitt*, the court found that it was sufficient that the government agency had collected and published the reports, even without any organizing, compiling or processing of the data that had been submitted to it. The undersigned concludes that this expansion of the holding of *Schindler* does not comport with the ordinary meaning of the word "report." In any event, *Colquitt* does not address the implications of the 2010 amendments to the FCA or the specific scenario here, where a treating disclosures on PAIR as "reports" under romanette (ii) appears to directly contradict Congress's intent in excluding from romanette (i) disclosures made in federal proceedings in which the Government was not a party.

Finally, *Calilung* does not change the Court's conclusion. In that case, the court found that certain SEC filings qualified as "reports" under the current version of the statute based on a Fourth Circuit case that reached a similar conclusion under the pre-2010 version of the statute. 2015 WL 1321029, at *16 (citing *United States ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694, 700 (4th Cir. 2014)). The court reasoned that the Form–10Ks, Form–10Qs, and Form–8Ks at issue in that case "were required by the SEC and the information contained therein was made readily available to the public on easily navigable websites by the SEC." *Id.* It did not address *Schindler* or the implications of the 2010 amendments, however. Nor is there any suggestion that the website at issue was comparable to a public docket for federal proceedings. Therefore, that case also does not support the conclusion that the information disclosed on PAIR in this case was a "report" under the current version of the public disclosure bar.[15]

Therefore, the Court concludes that the patent prosecution documents in which the disclosures discussed above were made do not constitute "reports" under the current version of the FCA's public disclosure bar.

[15] The Court need not reach the question of whether PAIR is "readily available" to the public or "easily navigable." In any event, that question is a fact question that is not suitable for determination on the pleadings.

ii. News Media

Defendants rely on numerous cases interpreting the term "news media" broadly to argue that documents reflecting patent prosecution histories published on PAIR are not only "reports" under the FCA but also "news media." *See, e.g.,, Bridgeport Educ.*, 2015 WL 4892259, at *6 n.4 ("[T]he Court finds that the online comment . . . qualifies as a public disclosure as news media" because it occurred on a "a well-established website designed to convey the news to the public"); *United States ex rel. Green v. Serv. Contract Educ. & Training Tr. Fund*, 843 F. Supp. 2d 20, 32 (D.D.C. 2012) ("[C]ourts that have considered the issue have construed the term to include readily accessible websites."); *United States ex rel. Unite Here v. Cintas Corp.*, No. C 06-2413, 2007 WL 4557788, at *14 (N.D. Cal. Dec. 21, 2007) ("The 'fact' of the contracts . . . was publicly disclosed in the news media, as that information was available on the Internet."); *United States ex rel. Hong v. Newport Sensors, Inc. ("Hong I")*, No. SACV131164JLSJPRX, 2016 WL 8929246, at *5 (C.D. Cal. May 19, 2016), aff'd sub nom. *United States ex rel. Juan Hong v. Newport Sensors, Inc*, 713 F. App'x 724 (9th Cir. 2018), and aff'd sub nom. *United States ex rel. Hong v. Newport Sensors, Inc*, 728 F. App'x 660 (9th Cir. 2018) ("Information publicly available on the Internet generally qualifies as 'news media.').

The Court notes, however, that although the Ninth Circuit affirmed the district court's decision in *United States ex rel. Juan Hong v. Newport Sensors, Inc*, it expressly declined to decide whether the broad definition of "news media" adopted by the trial court – *any* information that is publicly available on the Internet – was correct. *See United States ex rel. Hong v. Newport Sensors, Inc.* ("*Hong II*"), 728 F. App'x 660, 662–63 (9th Cir. 2018) ("Relator does not independently challenge the district court's broad holding that most public webpages, including the UC Irvine faculty profile, generally fall within the category of 'news media.' Accordingly, we do not address that argument here.").

Moreover, in *Integra*, Judge Gutierrez, in a thoughtful analysis of the meaning of "news media" under the current version of the public disclosure bar, concluded that this definition did not comport with the "ordinary meaning" of the term and was overly broad. No. CV 17-1694 PSG (SSX), 2019 WL 3282619 (C.D. Cal. July 16, 2019). The court in that case observed that the

defendant's "unbounded reading of the news media provision . . . seem[ed] likely to swallow limitations that Congress specifically placed on the scope of the public disclosure bar" when it amended it in 2010, and pointed to PACER to illustrate this point:

> Under Defendants' view, the mere posting of the transcript on PACER or a tweet sent to a small handful of followers could render the information from the hearing publicly disclosed under the FCA, even though it otherwise would not be. This would run contrary to the purposes underlying the public disclosure bar, and indeed the FCA itself. *See Schindler Elevator*, 563 U.S. at 412 (describing the public disclosure bar as "narrower" than its predecessor, the Government knowledge bar, which was intended to preclude "parasitic qui tam actions based on evidence or information in the possession of the United States at the time such suit was brought") (cleaned up); *United States ex rel. Fine v. Chevron, U.S.A., Inc.*, 72 F.3d 740, 742 (9th Cir. 1995) ("[T]he purpose of the qui tam provisions of the False Claims Act is to encourage private individuals who are aware of fraud being perpetrated against the Government to bring such information forward.") (cleaned up).

Id. at *12.

The court in *Integra* went on to set forth five "guideposts" for "determining whether information from an online source has been disclosed 'from the news media' within the meaning of the FCA's public disclosure bar." *Id.* at *14. First, the court found based on dictionary definitions of "news" and "media" that "the compound term 'news media' describes methods of communication that are used to convey information about recent events or other information that would commonly be found in newspapers, news broadcast, or other news sources." *Id.* "Accordingly, the extent to which the information typically conveyed by a source would be considered newsworthy is relevant to whether it is a news media source." *Id.*

Second, the court found that the term "generally carries with it a connotation of editorial independence, or at least, some separation, between the original source of information and the medium that conveys it." *Id.*

Third, the court found that "a source's intent to disseminate information widely . . . is relevant to whether it is acting as a news media entity." *Id.*

Fourth, the court found that "the more that an online source functions like [traditional news outlets like newspapers and radios and television stations], the more likely it is to be news media

under the FCA." *Id*. at *15. The court explained that "relevant to this consideration is the extent to which the conveyance of newsworthy information is the primary purpose of [the] entity publishing the online source or whether the dissemination of information is merely ancillary to some other purpose." *Id*.

Finally, the court concluded that "consistent with . . . *Schindler* . . . the most important consideration is whether the source in question falls within the 'broad ordinary meaning' of the term 'news media' – in other words, whether it could reasonably be described as 'news media' as at least some people would [use] that term in ordinary speech." *Id*. Applying this framework the court in *Integra* found that the question could not be decided on the pleadings under the facts of that case because "it appear[ed] that at least some of the information [that was disclosed] [came] from online sources that were not easily accessible," such as information that was marked "proprietary and confidential" and was only available on internal staff home pages. 2019 WL 3282619, at *16.

The undersigned agrees with the approach set forth in *Integra* and therefore rejects Defendants' suggestion that the information disclosed on PAIR falls under the "news media" channel simply because it can be found on the Internet. Moreover, many of the factors set forth in *Integra* for determining whether a source constitutes "news media" appear to point to the opposite conclusion. Certainly, docket sheets such as PACER and PAIR do not fall within the meaning of the term "news media" as it is ordinarily used. Most importantly, though, as Judge Gutierrez recognized in his discussion of PACER, interpreting "news media" to include a public docket such as PAIR would be contrary to Congress's intent when it amended the FCA's public disclosure bar in 2010, as it would nullify the limitation Congress added to romanette (i) for the same reasons set forth above with respect to the term "Federal report." Accordingly, the Court rejects Defendants' argument that the fraud alleged by Relator was publicly disclosed under the "news media" channel of disclosure.

iii. Federal Hearing

Although neither set of Defendants argued in the original motion papers that the alleged fraud was disclosed in a "Federal . . . hearing" within the meaning of 31 U.S.C. §

3730(e)(4)(A)(ii), Adamas argued in a supplemental brief filed after *Valeant* was decided that it was. *See* Dkt. No. 131. The Court rejects that argument and respectfully disagrees with the court's reasoning in *Valeant*.

In *Valeant*, the court held that information disclosed in a PTAB proceeding triggered the public disclosure bar because the proceeding was a "Federal . . . hearing" under 31 U.S.C. § 3730(e)(4)(A)(ii), even though the Government was not a party to it. The court reasoned that "hearing" meant "proceeding" and that the PTAB was a federal proceeding. For the reasons discussed above with respect to "Federal report" under the same subsection, that reading of the term "Federal . . . hearing" appears to be in direct conflict with what Congress intended when it amended the public disclosure bar in 2010 to limit it to disclosures that occurred in a "Federal criminal, civil, or administrative hearing *in which the Government or its agent is a party*." 31 U.S.C. § 3730(e)(4)(A)(i) (emphasis added).

Nor is the Court persuaded that the Ninth Circuit's decision in *United States ex rel. Bennett v. Biotronik, Inc.*, 876 F.3d 1011 (9th Cir. 2017), on which the *Valeant* court relied, *see* 445 F. Supp. 3d at 406, supports a contrary conclusion. In that case, the Ninth Circuit held that the government-action bar of § 3730(e)(3)[16] applies even when the Government is no longer an active participant in an ongoing qui tam lawsuit. 876 F.3d at 1016. In reaching that conclusion, the court rejected the relator's argument that its interpretation of § 3730(e)(3) would make that provision "a mere subset" of the public disclosure bar because of the overlap with § 3730(e)(4)(A)(i). *Id.* at 1018. The court found that the relator overstated the degree of overlap, noting that under the court's reading of the government action bar, that section "describe[d] numerous possible situations which would not be covered under" the public disclosure bar. *Id*. at 1019. In contrast, the *Valeant* court's interpretation of the term "Federal . . . hearing" in § 3730(e)(4)(A)(ii) results

[16] This section provides as follows:

> In no event may a person bring an action under subsection (b) which is 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.

31 U.S.C. § 3730(e)(3).

not just in a partial overlap but in virtually total nullification of the language that Congress added to romanette (i) of the public disclosure bar in 2010 as applied to any federal proceeding. As discussed above, in interpreting statutory language, courts avoid constructions that render language in the statute meaningless or superfluous. That rule supports the Court's conclusion that neither the PTAB proceedings in *Valeant* nor the prosecution history published on PAIR in this case are "Federal . . . hearing[s]" within the meaning of the current version of the public disclosure bar.

The Court also reject Adamas's argument that "[b]ecause patent prosecution is a non-adversarial 'examination' conducted by the PTO, these proceedings are a 'hearing, audit, or investigation' within the meaning of Section 3730(e)(4)(A)(ii), but not an 'administrative hearing' as that term is used in Section 3730(e)(4)(A)(i)." Dkt. No. 131 at 5. This assertion is based on the use of the word "party" in Section 3730(e)(4)(a)(i), which Adamas contends connotes adversaries and indicates that the "hearings" in this section must be adversarial. On the other hand, Adamas asserts, non-adversarial hearings are governed by Section 3730(e)(4)(a)(ii). *Id.* This argument is not supported by any authority and is unpersuasive in light of the fact that the word "party" is often used to refer to a patent applicant. *See, e.g.*, 35 U.S.C. § 133 ("Upon failure of the applicant to prosecute the application within six months after any action therein . . . the application shall be regarded as abandoned by the *parties* thereto."); 35 U.S.C. § 2(b)(2)(D) (the Patent Office "may govern the recognition and conduct of agents, attorneys, or other persons representing applicants or other *parties* before the Office"); 35 U.S.C.A. § 256 ("Whenever through error a person is named in an issued patent as the inventor, or through error an inventor is not named in an issued patent, the Director may, on application of all the *parties* and assignees, with proof of the facts and such other requirements as may be imposed, issue a certificate correcting such error."); Manual of Patent Examining Procedure, § 605.01 (stating the "applicant" is "the party making the application for patent"). The Court also notes that when Congress amended § 3730(e)(4)(A)(i), it did not include the word "adversarial" to modify "hearing," even though it referred to discovery "in any judicial or administrative proceeding of an adversarial nature" elsewhere in the FCA, *see* 31 U.S.C. § 3733(l)(7), showing that Congress knew how to

limit proceedings to those that are adversarial when it wanted to do so.

Nor does the Court find persuasive Adamas's argument that its interpretation of the public disclosure bar must be adopted so as not to read the phrase "other Federal . . . hearing" out of Section 3730(e)(4)(A)(ii). As Relator points out in his responsive brief, "like all the other 'hearings' in romanette (i), patent examination is an adjudication focused on the merits of a party's (i.e., the applicant's) legal claim. The hearings enumerated in romanette (ii), by contrast, are not typically adjudications of particular legal claims, but are instead inquiries undertaken (typically on the government's own initiative) for the purpose of obtaining information for the public's benefit." Dkt. No. 132 at ECF pp. 3-4. Because patent prosecution proceedings fall squarely within the scope of the specific provision in romanette (i), which excludes from the public disclosure bar administrative proceedings in which the Government is not a party, the Court concludes that under the canon of construction that the specific governs the general, discussed above, that provision governs over the more general phrase "other Federal . . . hearing" found in romanette (ii).

Therefore, the Court concludes that the patent prosecution history published on PAIR that disclosed the fraud alleged in this case does not constitute a "Federal . . . hearing" under romanette (ii) of the public disclosure bar. More broadly, the Court finds that the disclosures in the patent prosecution history discussed above were not made through one of the channels specified in the current version of the public disclosure bar, which therefore does not bar Relator's claims.[17]

D. Whether Relator States a Claim Under the FCA Against Allergan and Adamas

1. Background

a. The Allergan Motion

Allergan argues in its Motion that even apart from the public disclosure bar, Relator's FCA claims are insufficiently alleged and must be dismissed. First, with respect to the '009 patent, Allergan argues that Relator does not – and cannot – plausibly allege a fraud on the Patent Office because the prior art that was allegedly concealed from the Patent Office was, in fact, disclosed to

[17] Because the Court finds that no disclosures were made through a channel specified in the public disclosure bar, it need not reach the question of whether Silbersher is an "original source" under 31 U.S.C. § 3730(e)(4)(B).

it by Forest Laboratories during the prosecution of the '009 patent. Allergan Motion at 19 (citing FAC ¶¶ 94, 96). According to Allergan, "[i]t is blackletter law that there can be no inequitable conduct (*i.e.*, fraud on the U.S. Patent Office) by withholding a reference to prior art where the reference was disclosed elsewhere to the U.S. Patent Office." *Id*. (citing 37 C.F.R. § 1.56(a) (providing that "[t]he duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office . . . ."); *Fiskars, Inc. v. Hunt Mfg. Co*., 221 F.3d 1318, 1327 (Fed. Cir. 2000) ("An applicant cannot be guilty of inequitable conduct if the reference was cited to the examiner, whether or not it was a ground of rejection by the examiner.")).

Allergan further asserts that Relator has not plausibly alleged that the failure to *resubmit* the relevant prior art (the '553 patent) when the '009 patent application was amended constituted a knowing concealment, and that he simply speculates that Forest Laboratories deliberately decided not to disclose this prior art. *Id*. at 20. According to Allergan, these allegations are not sufficient to meet the pleading requirements of either Rule 9(b) or Rule 12(b)(6) of the Federal Rules of Civil Procedure. *Id*. Further, Allergan asserts, to the extent patent applicants have no duty to disclose material information that is "cumulative of information already of record[,]" Relator cannot plausibly allege scienter as to the fraud claim based on the '009 patent. *Id*. (citing 37 C.F.R. § 1.56(a)). Finally, Allergan argues that Relator has not plausibly alleged that any defendant other than Forest Laboratories was involved in the alleged fraud on the Patent Office in connection with the issuance of the '009 patent and therefore, no other defendant can be liable for any knowing misconduct under this theory. *Id*. at 21.

Similarly, Allergan argues that the allegations of fraud based on the Went Patents fail to state a claim as to the Allergan Defendants because Relator has not alleged any conduct by Allergan in connection with this claim and cannot do so. *Id*. at 21-22. According to Allergan, "Relator never articulates his theory of who, how, or when any of the Allergan Defendants – let alone any specific Allergan entity – participated in any alleged inequitable conduct" before the Patent Office, instead "resort[ing] to the artifice of group pleading, in an apparent effort to avoid

the fact that the Allergan Defendants had nothing to do with the alleged conduct relating to the Went [P]atent prosecutions." *Id*. at 22. Allergan points to the allegations in the FAC in support of its position, arguing that it sets forth a sequence of events that involved only Dr. Went's submission of false declarations to the Patent Office, all of which occurred before Adamas entered into a licensing agreement with Forest Laboratories, and that there is no relevant conduct alleged as to the Allergan Defendants. *Id*. at 22-23 (citing FAC ¶¶ 58, 61, 63, 69, 71, 74-77, 80). According to Allergan, these allegations are insufficient to satisfy Rule 9(b), which applies to fraud claims, and therefore Relator's FCA claims against Allergan based on inequitable conduct in connection with the Went Patents must be dismissed. *Id*. at 22.

Allergan further asserts that the allegations against it with respect to the Went Patents are insufficient to allege the intent required to state a claim under the FCA, namely, that the Allergan Defendants acted "with actual knowledge," "in deliberate ignorance of the truth," or "in reckless disregard of the truth." *Id*. at 23 (citing 31 U.S.C. § 3729(b)(1)). Rather, Allergan contends, "Relator never alleges that any Allergan Defendant even knew about the supposed fraud or learned about it after the fact." *Id*. Allergan concedes that the FAC alleges, in a conclusory manner, that "Defendants were aware of a study" and "misrepresented the findings of the study to the Patent Office." *Id*. (citing FAC ¶ 2). But according to Allergan, "this conclusory group allegation cannot be squared" with the more specific allegations in the Complaint that follow. *Id*. at 24.

Allergan also challenges Relator's FCA claims against it on the basis that Relator has not alleged Allergan made any "false or misleading" claims for payment to the government, which is required to state a claim under the FCA. *Id*. at 25 (citing *United States ex rel. Campie v. Gilead Scis., Inc*., 862 F.3d 890, 899 (9th Cir. 2017); 31 U.S.C. § 3729(a)(1)(A)). As a preliminary matter, Allergan contends "at least one court has expressly held that because 'misrepresentations to the [Patent Office]' years prior are 'disconnect[ed]' from 'invoices submitted to the government' they cannot constitute an FCA violation as a matter of law." *Id*. at 26 (citing *United States ex rel. Promega Corp. v. Hoffman-LaRoche Inc*. ("*Promega*"), No. 03-1447-A (E.D. Va.

Sept, 29, 2004), attached as Ex. 67 to Strong Decl.).[18] In any event, Allergan asserts, Relator has not demonstrated falsity – either by alleging facts showing factual falsity or legal falsity. *Id*. at 25.

Allergan argues that Relator fails to allege factual falsity because he does not allege facts showing that "the goods or services paid for or reimbursed by the government – *i.e.*, the Alzheimer's drugs – were defective or nonconforming in any way, or that they were otherwise misrepresented." *Id.* To establish legal falsity, Allergan argues, Relator must allege facts showing that Allergan "misrepresent[ed] compliance with a law, regulation, or contractual requirement," either by an "express false certification" that it has complied with the law or an "implied false certification," "which occurs when the defendant submits a claim for payment that makes specific representations about the goods or services provided, but knowingly fails to disclose the defendant's noncompliance with a statutory, regulatory, or contractual requirement." *Id*. (citing *United States ex rel. Rose v. Stephens Inst*., 909 F.3d 1012, 1017 (9th Cir. 2018) ("*Rose*") and quoting *Universal Health Servs., Inc. v. United States* ("*Escobar*"), 136 S. Ct. 1989, 1995 (2016)). Allergan argues that Relator has not alleged facts showing that it made either an express or an implied false certification to the government. *Id*.

To the extent Relator relies on the allegation in the FAC that Allergan was required to supply proof that the price of its drug was "fair and reasonable," *see* FAC ¶ 113, Allergan argues that this is not a certification of compliance with the law; rather, it is a certification that the prices charged are commensurate with the prices the drug manufacturer offers to its commercial customers. *Id*. at 26. Therefore, any certification that the prices Allergan charged the government were "fair and reasonable" would not have been an "express certification" of compliance with the law. *Id*. Allergan further asserts that the FAC does not actually allege that it made any such certification, much less the "who, what, when, where and how" of any such submissions. *Id*. at 25-26.

Allergan also argues that Relator does not adequately allege any implied certification, even

[18] Elsewhere in the motion, Allergan also asserts that the only other FCA case where a relator has relied on a similar theory (that a drug manufacturer "violated the FCA by foreclosing generic drugs") is *Amphastar* and in that case, as in *Promega*, the case was dismissed at the pleading stage. Motion at 4.

though it alleges that Allergan submitted "product and pricing data" under various federal programs. *Id*. at 27 (citing FAC ¶¶ 112-116). According to Allergan, this is because Relator does not allege that the product and pricing data it submitted inaccurately reflected the commercial prices charged for the drug and also does not allege that a failure to disclose noncompliance with the law made any specific statements about the drug into "misleading half-truths." *Id*. at 27 (citing *Escobar*, 136 S. Ct. at 2001).

Finally, Allergan argues that Relator has not alleged any conduct that is material. *Id.* at 28. According to Allergan, the FCA's materiality standard turns on whether "the alleged conduct had a 'likely or actual effect' on the government's payment decision and 'whether the defendant knowingly violated a requirement that the defendant knows is material to the government's payment decision.'" *Id*. at 28 (quoting *Escobar*, 136 S. Ct. at 1996). Although Relator alleges that the government "would not have paid" if it knew about the alleged fraud on the Patent Office, *see* FAC ¶¶ 155-156, Allergan argues that these allegations are entirely conclusory and are not sufficient to establish materiality. *Id*. Moreover, according to Allergan, the fact that the government continued to pay for Namenda XR® even after the relevant patents were invalidated "negates any suggestion that patent disputes would affect the government's decision to pay." *Id.* at 28-29 (citing *Escobar*, 136 S. Ct. at 2003).

In his response, Relator argues he has adequately pled his FCA claims against Allergan based on both the '009 patent and the Went Patents. As to the '009 patent, Relator argues that "even if Forest did not initially obtain the '009 [p]atent by fraud, the patent nevertheless is plainly invalid as obvious over the '553 [p]atent" and thus, Allergan engaged in conduct that is "independently culpable" under the FCA because it "knowingly or recklessly asserted the invalid patent to block generic competitors from the market so that it could charge the government monopoly prices and remove the government's ability to purchase less expensive generics." Allergan Opposition at 9.

Relator further asserts that Allergan applies the wrong standards for intent and materiality, arguing that the more stringent pleading standards that apply to an inequitable conduct defense to patent infringement do *not* apply to FCA claims, which require only that a relator plead the

common law elements of fraud. *Id*. at 9-10 (citing *Escobar*, 136 S. Ct. at 1999). Under this less stringent standard, Relator contends, he is not required to prove specific intent to defraud and materiality means only "'having a natural tendency to influence, or be capable of influencing, the receipt of money or property.'" *Id* at 10 (citing 31 U.S.C. §§ 3729(b)(1) & (4)). Because of this lower standard, even though the prior disclosure of the '553 patent to the Examiner during prosecution of the '009 patent might defeat an inequitable conduct defense, the failure of the applicants to alert the Examiner of this prior art is nonetheless sufficient to establish fraudulent conduct for the purposes of the FCA, Relator asserts. *Id*. Moreover, even if the more stringent standard were to be applied to Relator's FCA claims, Relator contends he has adequately alleged intent by alleging that Forest Laboratories "*intentionally* omitted the disclosure of the '553 [p]atent after amending the application because it knew that the disclosure would scuttle its application." *Id*. (citing FAC ¶¶ 94, 97). These allegations are sufficient to establish scienter at the pleading stage of the case, Relator contends. *Id.* at 10-11 (citing *Bristol-Myers Squibb Co. v. Ben Venue Laboratories*, 90 F.Supp.2d 522, 528 (D.N.J. 2000); *Skedco, Inc. v. Strategic Operations, Inc.*, 287 F.Supp.3d 1100, 1149–1150 (D. Or. 2018)). In addition, Relator contends, Allergan is wrong to argue that he fails to adequately plead intent under Rule 9(b) because that rule specifically provides that knowledge may be pleaded "generally." *Id*. at 11.

According to Relator, the cases Allergan cites in support of its argument that cumulative prior art need not be disclosed are distinguishable because none involved prior art that was disclosed before it became relevant to the application, as was the case with the '009 patent. *Id*. (distinguishing *Fiskars, Inc. v. Hunt Mfg. Co*., 221 F.3d 1318, 1327 (Fed. Cir. 2000); *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1185 (Fed. Cir. 1995); and *Pixion, Inc. v. Citrix Sys., Inc.*,2012 WL 1309170 (N.D. Cal. Apr. 16, 2012)). Relator argues that "context matters in determining whether an applicant satisfied its duty of candor and good faith" and therefore, that the Court should not decide *as a matter of law* that a disclosure of prior art 18 months before it became relevant to the patent application satisfied that duty. *Id*. at 11.

Relator rejects Allergan's argument that scienter is not adequately pled because Forest Laboratories relied on an "objectively reasonable" interpretation of 37 C.F.R. § 1.56 as to what

was required to be disclosed in prosecuting the '009 patent. *Id*. at 12. Relator contends this argument amounts to an "attempt to dispute Relator's well-pleaded facts," which is improper at the pleading stage of the case. *Id*. He argues that "[w]hether Forest [Laboratories'] failure to disclose was strategic, reckless, or based on good-faith misapprehension of what 37 C.F.R. § 156 requires cannot be resolved on the pleadings." *Id*.

Relator rejects Allergan's assertion that his FCA claims based on the Went Patents fail because he has alleged no relevant conduct by the Allergan Defendants, arguing that the fraud occurred not only during prosecution of the patents but also when Allergan later asserted these patents against generic competitors to take away the government's ability to choose less expensive generics that would have been sold by Defendants' competitors. *Id*. at 13. Because the Allergan Defendants were involved in this subsequent conduct, Relator argues, they are jointly and severally liable for the fraud even if they "were not present when the Patent Office was first defrauded." *Id*. (citing *Mortgs., Inc. v. United States Dist. Court*, 934 F.2d 209, 212 (9th Cir. 1991); *United States v. Bourseau*, No. 03-CV-907-BEN(WMC), 2006 WL 2961105, at *13 (S.D. Cal. Sept. 29, 2006)). Relator further argues that "Allergan would be liable even if Forest had no role in the fraud because, in cases involving allegations of inequitable conduct, the consequences of patent fraud do not disappear when a patent is transferred to an innocent third-party." *Id.* at 13-14 (citing *In re Rembrandt Techs. LP Patent Litig.*, 899 F.3d 1254, 1272 (Fed. Cir. 2018)).

Relator also argues that Allergan misrepresents the chronology of the events alleged in the FAC, ignoring allegations showing that two of the Went Patent applications were filed *after* Forest Laboratories entered into an exclusive licensing agreement with Adamas for the Went Patents, in November 2012. *Id*. at 14. In particular, according to Relator "[a]pplications for two of the Went Patents – U.S. Patent Nos. 8,580,858 and 8,598,233 – were filed after that date, on December 21, 2012 and January 28, 2013, respectively" and "[i]n connection with those applications, the same misleading statements about the ME110 Study were submitted to the Patent Office." *Id*. Therefore, Relator asserts, "[a]t a minimum, Forest was complicit in that fraud because, as the exclusive licensee, it was a real-party-in-interest for the patents at that time, and it had a duty of candor and good faith to the Patent Office that it did not honor." *Id*. (citing 37 C.F.R. § 1.56(c)(3)

(pre-America Invents Act) (duty of candor applies to "[e]very other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application")).

Relator rejects Allergan's argument that his FCA claims based on the Went Patents fail because the FAC does not allege that either Forest or the other Allergan Defendants knew of the fraud on the Patent Office with respect to the Went Patents. *Id*. According to Relator, "Forest was already the exclusive licensee when two fraudulent patent applications were submitted, and it was at least reckless with respect to the information submitted in those applications." *Id*. Relator argues further that "Dr. Went's fraud, which Allergan does not dispute, is chargeable to all those who acquire or enforce the patents." *Id*. (citing *Rembrandt*, 899 F.3d at 1272; *Avid Identification Sys., Inc. v. Crystal Import Corp.*, 603 F.3d 967, 973 (Fed. Cir. 2010) ("If an individual who is substantively involved in the preparation or prosecution of an application fails to comply with his duty of candor, then that individual's misconduct is chargeable to the applicant for the patent, and the applicant's patent is held unenforceable.")). Moreover, it argues, "[a]s the successor in interest to Forest, which was the exclusive licensee of the Went Patents, Allergan is liable for how these patents were obtained, and then used to exploit the government." *Id.*

In response to Allergan's argument that Relator has not alleged any false statements in support of his FCA claims, Relator argues that he has satisfied this requirement because the FCA covers both "misleading omissions" under *Escobar* and "situations in which an upstream fraud is used to facilitate downstream claims." *Id*. at 15 (citing *United States ex rel. Campie v. Gilead Scis., Inc.* ("*Campie*"), 862 F.3d 890, 903 (9th Cir. 2017), cert. denied sub nom. *Gilead Scis., Inc. v. U.S. ex rel. Campie,* 139 S. Ct. 783 (2019); *United States ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1174 (9th Cir. 2006) ("*Hendow*")). According to Relator, the FCA claims alleged against Allergan here are analogous to the FCA claims in *Campie*, where the court found that allegations that a drug manufacturer's claims for reimbursement for its drugs from the government were sufficient to allege falsity because the manufacturer allegedly gained approval of the drugs through false statements to the FDA. *Id*. Here, Relator contends, the facts are even stronger than

in *Campie* because the "claims for payment specifically included prices that had been unlawfully manipulated" and because Defendants knowingly listed invalid patents in the Orange Book, which "constituted additional statements that were material to false claims." *Id*.

Relator also rejects Allergan's contention that in requiring proof that prices are "fair and reasonable" the government is only concerned about commercial prices; according to Relator, the government "base[s] government prices on commercial ones, but that does not mean the government is indifferent about whether the commercial price is itself the product of a massive fraud. Rather, the government assumes that the commercial price reflects fair market conditions, and it relies on the commercial price for that reason." *Id*. at 16. To the extent the alleged fraud "taints the government's pricing," Relator alleges, it also renders the resulting claim for payment from the government fraudulent. *Id*. Relator argues that *Escobar* also supports this conclusion. *Id*. In that case, according to Relator, the FCA claims were based on use of billing codes submitted in claims for reimbursement corresponding to services such as "family therapy" and job titles such as "Social Worker, Clinical." *Id*. (citing 136 S. Ct. at 1997). Even though there was no express representation that the social workers were licensed under state law, the court concluded that use of these billing codes implied as much and therefore that they were sufficient to support the relator's FCA claims. *Id*.

Relator also rejects Allergan's assertion that the FCA claims fail because there is no allegation that it actually *did* present its pricing information to the government. *Id*. at 17-18. According to Relator, he is only required to "plead 'particular details of a scheme' with 'reliable indicia that lead to a strong inference' that claims have been submitted." *Id*. (quoting *United States ex rel. Ebeid v. Lungwitz*, 616 F.3d 993, 999 (9th Cir. 2010)). As it is undisputed that Allergan's prices for the drugs in this case are listed on the FSS, as is required to receive Medicaid reimbursement (which Allergan has allegedly received), Relator argues that it is "implausible that these representations were not made" in light of the allegations in the complaint. *Id.* at 17. Further, to the extent Allergan argues that the pricing information is not alleged to have included specific representations about compliance with the law, Relator responds that these arguments have no bearing on his theories of implied certification under *Escobar* or "upstream fraud" under

Campie. *Id.* at 18.

Relator rejects Allergan's reliance on *Promega* to argue that an FCA claim based on the theory that a drug manufacturer improperly charged monopoly prices because of fraud before the Patent Office can never state a claim because the false statements to the Patent Office are too "disconnected" from the invoices submitted to the government. *Id*. at 18-19. According to Relator, in *Campie* the Ninth Circuit explicitly rejected this "disconnect" reasoning. *Id.* at 19 (citing *Campie*, 862 F.3d at 903). Furthermore, Relator contends, *Promega* was decided before the FCA was amended and its dismissal based on the public disclosure bar is no longer good law. *Id*. Relator also rejects Allergan's suggestion that his theory fails under *Amphastar*, noting that the district court found that the relator in that case stated a valid FCA claim under a similar theory, and that the Ninth Circuit did not reach that issue on appeal because it vacated the earlier decision on jurisdictional grounds under the public disclosure bar. *Id.* at 19.

Finally, Relator contends Allergan's argument that he has not alleged facts demonstrating materiality because the government continues to pay for its drugs is incorrect. *Id*. at 20. According to Relator, price is material because a reasonable person would find it relevant to a payment decision, and in fact, the government is required to purchase generics when they are available. *Id.* Moreover, Relator contends, courts have found price goes to the "essence of the bargain" between the government and drug manufacturers and that misrepresentations that affect the size of government payments are material under the FCA. *Id*. (citing *United States ex rel. Prather v. Brookdale Senior Living Communities, Inc*., 892 F.3d 822, 834 (6th Cir. 2018), *cert. denied* 139 S. Ct. 1323 (2019); *Unihan Corp. v. Max Group Corp*., No. CV 09-07921 MMM PLAX, 2011 WL 6814044, at *7 (C.D. Cal. Dec. 28, 2011); *Grubea v. Rosicki, Rosicki & Assocs., P.C.*, 318 F. Supp. 3d 680, 701 (S.D.N.Y. 2018); *United States v. DynCorp Int'l, LLC*, 253 F. Supp. 3d 89, 102 (D.D.C. 2017)). The fact that the government has continued to pay for Allergan's drugs does not demonstrate a lack of materiality, Relator argues, as there is no allegation that the government was aware of the alleged fraud on the Patent Office when it paid for the drugs. *Id*. at 21.

In any event, Relator argues, "even though the government pays for Namenda XR, it also

pays for the generic alternatives to Namenda XR" with the result that prices have gone down. *Id.* Relator also argues that the fact that the government continued to pay for the drugs does not demonstrate a lack of materiality because "ceasing payments for Namenda XR altogether would serve little purpose, and might complicate care for patients who have been using the drug for long periods of time." *Id*. (citing *Campie*, 862 F.3d at 906). According to Relator, "[b]ecause it is at least plausible that Defendants' fraud – which the Complaint alleges had a massive effect on the price the government paid for these drugs – was material to the government's payment decisions, Allergan's materiality arguments should be rejected." *Id*.

In its Reply, Allergan reiterates its position that Relator has failed to state any viable FCA claim against it. With respect to the Went Patents, Allergan points out that Relator argued in his opposition that Forest Laboratories had already entered into an exclusive licensing agreement with Adamas when two of the Went Patent applications were filed but that Relator does not cite to any corresponding allegations in the complaint. Allergan Reply at 9. According to Allergan, this is because these facts were not pled in the complaint. *Id*. More importantly, Allergan contends, it is not sufficient to show that "Allergan was a contractual counter-party to Adamas when Adamas and Dr. Went purportedly engaged in fraud"; rather, Relator must "plead that the Allergan Defendants knowingly committed some fraud related to the Went Patents," which Relator has not done according to Allergan. *Id*.

Allergan also rejects Relator's argument that Forest Laboratories was "at least reckless" with respect to the misrepresentations that he asserts were repeated in the two Went Patent applications that were filed after Forest Laboratories entered into the exclusive licensing agreement with Adamas. *Id.* at 10. According to Allergan, this argument fails because "Relator offers no explanation (let alone well-pleaded allegations) as to why or how the Allergan Defendants should have known about any allegedly fraudulent conduct by Dr. Went, much less how they might have acted 'reckless[ly].'" *Id*. Given that a patent is presumed valid, Allergan argues, "if the Allergan Defendants had no involvement in or reason to learn of Dr. Went's alleged misconduct – and Relator has not pleaded that they did – they could not have been 'at least reckless' with respect to the Went Patents simply by licensing the patents and enforcing them."

Id.

Allergan also rejects Relator's argument that the Allergan Defendants are "'jointly and severally liable even if they were not present when the Patent Office was first defrauded' because Dr. Went's alleged fraud is 'chargeable to all those who acquire or enforce the patents.'" *Id*. First, Allergan argues, joint and several liability only applies where both of the parties are "actually liable in the first place," which is not the case here. *Id*. (citing Rest. (Third) of Torts: Apportionment Liab. § 12 (2000) ("Each person who commits a tort that requires intent is jointly and severally liable for any indivisible injury legally caused by the tortious conduct.")). Allergan further accuses Relator of "mixing and matching" theories of liability "by targeting Adamas for the alleged fraud on the Patent Office, and the Allergan Defendants for later enforcing those patents and securing government reimbursement." *Id*. Allergan argues that because the FAC includes no allegations that it was responsible for the "upstream fraud" on the Patent Office, it cannot be held liable for the "downstream" actions it took "to enforce presumptively valid patents." *Id*. at 11.

Allergan also asserts that it is irrelevant that a patent that is invalidated due to inequitable conduct remains invalid even where it has been transferred to an innocent third party. *Id*. According to Allergan, that rule is very different from transferring liability for fraud to an innocent third party, for which there is no authority. *Id*. Nor do *Rembrandt* and *Avid* support Relator's position, Allergan asserts, as neither of these cases holds that an innocent third party can be held vicariously liable for fraud. *Id*.

With respect to the FCA claims against Allergan based on alleged fraud in connection with the '009 patent, Allergan rejects Relator's argument that he can state a claim under the FCA based on failure to disclose the '553 patent in the '009 patent prosecution even if an affirmative defense of inequitable conduct would fail under *Fiskars* because of the prior disclosure of the '553 patent to the Examiner. *Id.* at 12. Allergan argues that the legal standard for inequitable conduct is "highly relevant" and that the Court should not "drive a wedge between the legal principles defining inequitable conduct and fraud on the U.S. Patent Office in the FCA context." *Id*. Allergan further asserts that Relator's attempt to distinguish the facts of *Fiskars* on the basis that

the examiner actually considered the prior art reference in that case fails because the same is true here. *Id*. In particular, Allergan points to a document in the '009 patent prosecution history – the List of References Cited by Applicant and Considered by Examiner, dated October 7, 2009, *see* Strong Decl., Ex. 30 – which reflects that all references except those that were lined through had been considered and that the '553 patent was not lined through. *Id*. at 12-13.

Allergan also contends Relator is incorrect in asserting that the '553 patent was not relevant to the '009 patent at the time it was submitted to the Examiner and therefore its submission at that point was "likely to mislead" because since 2005 the '009 patent application had always focused on a single-dose product. *Id*. at 13 (citing Strong Decl., Ex. 29 (original 2005 application) (stating that the "formulation of the present invention includes memantine . . . to be administered in a once-a-day oral dosage form"); Ex. 12 (publicly available claims as of June 16, 2005, reciting in Claim 31 a "modified release solid oral dosage form" that is "administered once a day")).

To the extent Relator argues that his FCA claims based on the '009 patent would not fail even if there was no inequitable conduct – because the patent is nonetheless invalid as obvious over the '553 patent and Allergan subsequently asserted that invalid patent – Allergan argues that Relator is incorrect. *Id*. at 13-14. First, Allergan notes that the '009 patent has never been held invalid. *Id.* at 13. Moreover, Allergan argues, a patent is presumed valid and asserting a patent that is subsequently found to be invalid is not "independently culpable conduct" under the FCA. *Id*. at 14. Allergan also argues that Relator is incorrect in asserting the Court cannot decide at the pleading stage if Forest Laboratories acted in an "objectively reasonable manner" (and therefore, that scienter has not been adequately pled) with respect to its understanding of what was required under 37 C.F.R. § 1.56. *Id*. According to Allergan, "[o]bjective reasonableness is a legal, not factual argument appropriate for determination at the motion to dismiss stage." *Id*. (citing *United States v. Allergan*, 746 Fed. App'x 101, 110 (3d Cir. 2018)).

Finally, Allergan reiterates its position that Relator has failed to allege both falsity and materiality adequately. *Id.* at 14-15. As to falsity, Allergan argues that Relator has alleged only false statements by other parties to the Patent Office but has not alleged any facts showing that the

Allergan Defendants made false claims under the FCA. *Id*. at 14. Allergan further argues that Relator has alleged no facts showing that the Allergan Defendants made any express or implied certifications that were rendered misleading and that Relator has failed to allege specific facts that "match" the allegations in *Escobar* and *Campie*. *Id*. Allergan also rejects Relator's assertion that he has provided "reliable indicia" that claims about its prices were actually made to the government, arguing that "more is required" to satisfy that standard than "mere suspicions and attenuated assumptions." *Id*. at 15. With respect to materiality, Allergan repeats its argument that Relator has alleged no specific facts showing the prices it charged the government were material, pointing out again that the government still pays claims for Namenda XR® and Namzaric®. *Id*.

b. The Adamas Motion

In its Motion, Adamas argues that Relator fails to sufficiently allege any false claim, materiality or scienter. Adamas Motion at 16-23. Like Allergan, Adamas argues with respect to the falsity requirement that Relator has not alleged any express or implied misrepresentation to the Government, even though the FAC includes conclusory allegations about "express and implied assurances" (FAC ¶ 6), "express and implied misrepresentations" (FAC ¶ 117) and "express and implied certifications" (FAC ¶ 120). *Id*. at 17. With respect to factually false claims, Adamas argues that it *cannot* be shown to have made any express representations that were factually false because Adamas was not involved in pricing or reimbursement for these products and played no role in submitting information to GSA in connection with FSS listings. *Id*. at 17-18. To the extent Relator relies on representations about the Went Patents that Adamas made to the Patent Office (which Adamas asserts are the only misrepresentations alleged with respect to Adamas) to show falsity, Adamas argues that these were not claims for payment under the FCA and therefore cannot be "false claims." *Id*. at 17-18 (citing 31 U.S.C. § 3729(b)(2)).

Further, Adamas asserts, Relator has alleged no legally false claims, either on the basis of an express certification of compliance with legal requirements or implied certification. *Id*. at 18-19. Like Allergan, Adamas contends that the GSA's "fair and reasonable" requirement is intended to ensure only that the prices charged to the government are commensurate with a drug company's commercial prices and that it is not a "catch-all regulatory obligation." *Id*. at 18. Adamas further

asserts that to the extent Relator relies on an implied certification theory, he fails to allege specific facts that satisfy the standard in *Escobar*, which requires that a relator show that the defendant failed to disclose noncompliance with material legal requirements and that this failure turned specific representations about the product into misleading half-truths. *Id*. at 19 (citing *Escobar*, 136 S. Ct. at 2001).

Adamas argues that Relator also fails to allege any misrepresentations that would be material to the government's payment decision. *Id*. at 19-22. Adamas argues that Relator relies on the theory that compliance with the Patent Office's duty of candor and the GSA's "fair and reasonable" pricing requirement are *per se* material but that *Escobar* and its progeny reject such a *per se* approach to pleading. *Id*. at 20 (citing FAC ¶ 117; *Knudsen v. Sprint Commc'ns Co*., No. C13-04476 CRB, 2016 WL 4548924, at *13 (N.D. Cal. Sept. 1, 2016)). According to Adamas, Relator's allegations are conclusory and they are undercut by the fact that since some of the Went Patents were invalidated in 2018, there has been no change to the FDA approval status of Namenda XR® or Namzaric®, which continue to be eligible for government reimbursement (as the FAC ¶ 165 concedes). *Id*. Adamas further contends the fact that the federal government declined to intervene in this action also provides "very strong evidence" that the alleged misrepresentations are not material. *Id*. at 21 (quoting *Escobar*, 136 S. Ct. at 2003-2004 and listing the following cases in which courts have, according to Adamas, rejected FCA claims in part because the government investigated the relator's allegations and nonetheless continued to pay: *D'Agostino v. ev3, Inc*., 845 F.3d 1, 7 (1st Cir. 2016); *Coyne v. Amgen, Inc*., No 17-1522, 2017 WL 6459267, at *3 (2d Cir. Dec. 18, 2017); *United States. ex rel. Petratos v. Genentech Inc*., 855 F.3d 481, 490 (3rd Cir. 2017); *United States ex rel. McBride v. Halliburton Co*., 848 F.3d 1027, 1034 (D.C. Cir. 2017); *United States ex rel. Berg v. Honeywell Int'l, Inc*., 740 F. App'x 535, 538 (9th Cir.2018), *cert. denied sub nom. United States ex rel. Berg v. Honeywell Int'l, Inc*., 139 S. Ct. 1456 (2019)). Adamas (like Allergan) also points to *Promega*, noting that in that case, the court did not allow an FCA case against a drug manufacturer based on alleged inequitable conduct before the Patent Office to go forward. *Id*. at 21.

Adamas also argues that Relator has not adequately alleged scienter. *Id*. at 22. In order to

meet this requirement where an FCA claim is based on a theory of implied certification, Adamas contends, "'[w]hat matters is . . . whether the defendant *knowingly* violated a requirement that the defendant knows is material to the Government's payment decision.'" *Id*. (quoting *Escobar*, 136 S. Ct. at 1996 (emphasis added by Adamas)). According to Adamas, Relator does not include such allegations in the FAC. *Id*. In particular, Adamas asserts, although Relator included "barebones, conclusory" allegations that Adamas and Dr. Went "knowingly" made misrepresentations to the Patent Office, *see* FAC ¶¶ 2, 3, 5, the FAC also shows that "Dr. Went actively corrected past statements to the Patent Office on multiple occasions." *Id*. Adamas also argues that the FAC "lacks any allegation that Adamas or Dr. Went knowingly violated their regulatory obligations, or that Adamas or Dr. Went knew those regulations were material to government payment decisions." *Id*. (citing *Escobar*, 136 S. Ct. at 1996).

In his opposition brief, Relator argues that he has adequately alleged that the Adamas Defendants made false claims, asserting for the same reasons set forth in the Allergan Opposition that he has alleged facts showing falsity under both the implied certification theory of *Escobar* and the promissory estoppel theory of *Campie*. Adamas Opposition at 8-11. In addition, Relator argues, for the first time, that the patent applications themselves are false claims because they are a request for "property" under the FCA and therefore constitute an "independent violation of the FCA" by Adamas. *Id*. at 11-12.[19]

Relator rejects Adamas's argument that he has not alleged materiality, citing the arguments he made in response to Allergan's motion. *Id*. at 13. He rejects Adamas's reliance on the fact that the government continues to pay for Namenda XR® and Namzaric®, arguing that the "government does not yet know there was fraud" and that he will prove this at trial. *Id*. He argues further that the government's decision not to intervene in this action is not a reflection on the merits of his claims as there are many reasons unrelated to the merits of a *qui tam* case that may play into the government's decision and dismissal on this ground would be inconsistent with the purposes of the *qui tam* provision. *Id*. (citing *United States ex rel. Chandler v. Cook Cty., Ill*.,

[19] Because the FAC does not allege any violation of the FCA on the basis of this theory, the Court declines to reach this argument

277 F.3d 969, 974 (7th Cir. 2002), aff'd, 538 U.S. 119 (2003); *United States ex rel. El-Amin v. George Washington Univ.*, 533 F. Supp. 2d 12, 21 (D.D.C. 2008); *United States ex rel. Feldman v. van Gorp*, No. 03 CIV. 8135 (WHP), 2010 WL 2911606, at *2 (S.D.N.Y. July 8, 2010)).

Relator argues that the FAC adequately pleads scienter as to the Adamas Defendants. *Id.* at 14. In particular, he argues that under Rule 9(b) he is only required to plead scienter "generally." *Id.* (citing *Integra*, 2019 WL 3282619, at *22). To the extent Adamas argues that Dr. Went's subsequent corrections of his prior incorrect declarations show that the claims against the Adamas Defendants fail for lack of scienter, Relator contends these are fact questions that cannot be decided at the pleading stage. *Id.* According to Relator, for the purposes of a motion to dismiss, he has adequately alleged scienter based on the allegations that "Adamas's founder and CEO knew that he was intentionally misrepresenting the critical results of the ME110 Study, because he demonstrated knowledge of the actual results he failed to disclose" (FAC ¶ 83) and that "the CEO revised his original false declaration, but not with respect to the critical misrepresentation concerning the actual results of the ME110 Study, which he personally knew about" (FAC ¶¶ 80-83). *Id.*

Finally, Relator argues that he has satisfied the requirements of Rule 9(b) with respect to his claims because "[u]nder Rule 9(b), 'it is sufficient to allege particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.'" *Id.* (quoting *Ebeid ex rel. U.S. v. Lungwitz*, 616 F.3d 993, 998–99 (9th Cir. 2010)). According to Relator, he has adequately alleged the "who, what, when, where and why" of the fraud under this standard. *Id.* at 15-17.

In its Reply, Adamas rejects Relator's arguments that he has stated false claims under all of the theories advanced in his Opposition. As to the arguments addressing implied certification and promissory estoppel, Adamas makes arguments similar to Allergan's that Relator's claims fail under both theories. Adamas also challenges Relator's assertion that the patent applications are themselves false claims under the FCA. As the Court does not consider that argument, it also does not summarize here Adamas's response.

2. Discussion

a. Whether Relator Adequately Alleges False Claims or Statements

Courts construe the FCA "broadly, as it is 'intended to reach all types of fraud, without qualification, that might result in financial loss to the Government.'" *Campie*, 862 F.3d at 899 (quoting *Hendow*, 461 F.3d at 1170 (internal quotations and citations omitted)). "Such broad construction has thus given rise to a number of doctrines 'that attach potential False Claims Act liability to claims for payment that are not explicitly and/or independently false.'" *Id*. (quoting *Hendow*, 461 F.3d at 1171). In particular, in addition to recognizing claims for payment that are factually false because they misrepresent the good or service that was provided (in other words, claims for nonconforming goods), *see Campie*, 862 F.3d at 900, courts have recognized that FCA claims may be viable under a theory of implied certification, *id*. (citing *Escobar*, 136 S. Ct. at 1999), or promissory fraud. *Id*. at 902 (citing *Hendow*, 461 F. 3d. at 1173). Relator contends he has alleged false claims under both theories. For the reasons set forth below, the Court agrees.

i. Implied Certification

The "validity and scope" of the implied certification doctrine was recently addressed by the Supreme Court in *Escobar*. 136 S. Ct. at 1998. In that case, the relators were parents of Yarushka Rivera, a teenage beneficiary of Medicaid, which is "a joint state-federal program in which healthcare providers serve poor or disabled patients and submit claims for government reimbursement." 136 S. Ct. at 1996-1997. Rivera died after receiving treatment from a mental health clinic under the Medicaid program, including therapy and prescriptions for a medication that caused an adverse reaction and may have resulted in her death. *Id*. at 1997. As it turned out, many of the staff at the clinic – including the individual who prescribed the medication – were unlicensed and were not authorized to prescribe medications without supervision. *Id*. Nonetheless, the clinic received reimbursement from the government for its services, submitting invoices that used payment codes for services such as "individual Therapy" and "Family Therapy." Some of the clinic staff also "registered for a number associated with 'Social Worker, Clinical,' despite lacking the credentials and licensing required for social workers engaged in mental health counseling." *Id.* (internal quotation and citation omitted). The relators asserted

FCA claims against the clinic based on an implied false certification theory, namely, that the reimbursement claims "made representations about the specific services provided by specific types of professionals, but that failed to disclose serious violations of regulations pertaining to staff qualifications and licensing requirements for those services." *Id*. at 1997-1998.

The Supreme Court in *Escobar* held that the allegations in that case were sufficient to allege falsity under the FCA based on an implied certification theory. *Id.* at 2000. It began its analysis by recognizing that "[w]hen . . . a defendant makes representations in submitting a claim but omits its violations of statutory, regulatory, or contractual requirements, those omissions can be a basis for liability if they render the defendant's representations misleading with respect to the goods or services provided." *Id.* at 1999. In reaching this conclusion, the Supreme Court looked to the common law of fraud because the FCA does not define that term. *Id*. at 1999-2000. It declined to decide whether "*all* claims for payment implicitly represent that the billing party is legally entitled to payment" – the position taken by the government and the relators in that case. *Id*. at 2000 (emphasis). It found, however, that the facts of the case fell "squarely within the rule that half-truths – representations that state the truth only so far as it goes, while omitting critical qualifying information – can be actionable misrepresentations." *Id*. at 2000. The Court explained:

> [B]y submitting claims for payment using payment codes that corresponded to specific counseling services, Universal Health represented that it had provided individual therapy, family therapy, preventive medication counseling, and other types of treatment. Moreover, Arbour staff members allegedly made further representations in submitting Medicaid reimbursement claims by using National Provider Identification numbers corresponding to specific job titles. And these representations were clearly misleading in context. Anyone informed that a social worker at a Massachusetts mental health clinic provided a teenage patient with individual counseling services would probably—but wrongly—conclude that the clinic had complied with core Massachusetts Medicaid requirements (1) that a counselor "treating children [is] required to have specialized training and experience in children's services," 130 Code Mass. Regs. § 429.422, and also (2) that, at a minimum, the social worker possesses the prescribed qualifications for the job, § 429.424(C). By using payment and other codes that conveyed this information without disclosing Arbour's many violations of basic staff and licensing requirements for mental health facilities, Universal Health's claims constituted misrepresentations.

Id. at 2000-2001. The Court concluded that the implied certification theory can be the basis for a

claim "at least where two conditions are satisfied: first, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory or contractual requirements makes those representations misleading half-truths." *Id*. at 2001.[20]

The Court in *Escobar* went on to address the defendant's argument that there should be liability under the FCA "only if [the claimant] fails to disclose the violation of a contractual, statutory, or regulatory provision that the Government expressly designated a condition of payment." *Id*. at 2001. The Court rejected this argument, finding that this approach would be inconsistent with the text of the FCA and would also "risk undercutting" the policy goals of the FCA. *Id*. at 2002. The Court noted that "'[i]nstead of adopting a circumscribed view of what it means for a claim to be false or fraudulent,' concerns about fair notice and open-ended liability 'can be effectively addressed through strict enforcement of the Act's materiality and scienter requirements[,]'" which are "rigorous." *Id*. at 2002 (quoting *United States v. Science Applications Int'l Corp*., 626 F.3d 1257, 1270 (D.C. Cir. 2010)).

Here, Relator alleges particular facts that support an inference that Defendants submitted pricing information to the government in connection with the listing of Namenda XR® and Namzaric® on the FSS, including written justification of the prices and proof that the prices were

[20] In *United States Ex Rel. Rose v. Stephens Inst*. 909 F.3d 1012, 1017 (9th Cir. 2018), *cert. denied sub nom. Stephens Inst. v. U.S. ex rel. Rose*, 139 S. Ct. 1464 (2019) ("*Rose*"), the court acknowledged that the test that was previously applied in the Ninth Circuit to claims based on implied certification, articulated in *Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 998 (9th Cir. 2010) ("*Ebeid*"), was broader because it did not require a specific representation. In particular, the test that was used in the Ninth Circuit under *Ebeid* provided, "a relator must show that '(1) the defendant explicitly undertook to comply with a law, rule or regulation that is implicated in submitting a claim for payment and that (2) claims were submitted (3) even though the defendant was not in compliance with that law, rule or regulation.'" *Id*. (quoting *Ebeid*, 616 F.3d at 998). The court in *Rose* addressed whether this broader test was still good law in the wake of *Escobar*. *Id*. at 1018. It noted the use of the words "at least" in *Escobar*, opining that that decision did not purport to describe the *only* circumstances under which a relator could prove false certification. Nonetheless, because two previous Ninth Circuit panel had already held (albeit without discussion) that the test in *Escobar had* to be met in order to allege implied certification, the panel in *Rose* concluded that those cases were binding and therefore, that "unless and until our court, en banc, interprets *Escobar* differently," relators must satisfy the two-part test in that case in order to proceed on an implied certification theory. *Id*. (citing *United States ex rel. Kelly v. Serco, Inc.*, 846 F.3d 325, 332 (9th Cir. 2017); *Campie*, 862 F.3d at 901). Because this Court is bound by that Ninth Circuit precedent, Relator here must satisfy the two-part test set forth in *Escobar* to assert claims under a theory of implied certification.

fair and reasonable. *See* FAC ¶¶ 111-118. Although Relator does not directly allege in the FAC that Allergan submitted pricing information to the government in connection with the listing of Namenda XR® and Namzaric® on the FSS, he *does* allege that these drugs cannot be sold under Medicare or Medicaid unless they are listed on the FSS. *See* FAC ¶ 112. Further, the FAC alleges that both drugs were covered by Medicaid in all Plaintiff States and lists the specific reimbursement amounts paid for them under that program between 2013 and 2017. FAC ¶ 136. Therefore, the Court concludes that Relator has adequately alleged that Defendants certified to the government that the prices for Namenda XR® and Namzaric® were fair and reasonable. *See Ebeid*, 616 F.3d at 998–99 (holding that to meet Rule 9(b)'s pleading requirements in the context of an FCA case it is not necessary to "identify representative examples of false claims to support every allegation"; rather, it is "sufficient to allege 'particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.'") (quoting *United States ex rel. Grubbs v. Ravikumar Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009)).

The Court further finds that Relator has alleged sufficient facts to plead falsity as to these certifications. As in *Escobar*, where the use of certain billing codes misleadingly suggested that the providers were licensed to provide the services to which those codes corresponded, Defendants' certification that the prices of the drugs they were listing were "fair and reasonable" misleadingly suggested that they held valid patents on those drugs that allowed them to charge the government higher prices as a result of the monopolies they held on them. Yet Relator alleges that Defendants did not hold valid patents and that in fact, the patents were obtained on the basis of false statements made to the Patent office – both in connection with the Went Patents and the '009 patent. *See* FAC ¶¶ 57-102.

The Court rejects Defendants' argument that these certifications were not misleading, as a matter of law, because the requirement that drug manufacturers provide proof that their prices are "fair and reasonable" merely relates to whether their prices are commensurate with commercial prices charged for the same drugs and does not involve an "unbounded inquiry into whether the seller is in compliance with every conceivable law that could affect price." *See* Allergan Motion

at 26. While the government looks to commercial prices to determine whether the prices offered the government are "fair and reasonable" and may rely on those prices when there is "adequate price competition," *see* 48 C.F.R. § 15.402(a)(2)(i), Defendants have pointed to no authority suggesting that prices that are inflated as a result of a fraudulent scheme to manipulate the market as a whole would be in compliance with the "fair and reasonable" certification simply because drug companies charge their commercial customers the same inflated prices. The Court declines to take such a "circumscribed view of what it means for a claim to be false or fraudulent." *Escobar*, 136 S. Ct. at 2002. At a minimum, Defendants have not established that rejecting Relator's theory of falsity on this basis at the pleading stage of the case is appropriate.

The Court also concludes that with respect to both grounds on which Relator alleges fraud on the Patent Office, namely, the alleged fraud in connection with the issuance of the '009 patent and the Went Patents, the Relator alleges the who, what, when, where and how of the alleged fraud and therefore meets the requirements of Rule 9(b) of the Federal Rules of Civil Procedure. *See Campie*, 862 F.3d at 898 ("A claim under the False Claims Act must not only be plausible, but pled with particularity under Rule 9(b).").

The Court is not persuaded by Allergan's argument that to the extent Relator's claims are based on the '009 patent, they fail as a matter of law because the '553 patent was disclosed to the patent office during the prosecution of the '009 patent. Although Allergan has cited cases that hold in the context of determining patent validity that "when a reference was cited to the patent examiner it cannot be deemed to have been withheld," *Fiskars, Inc. v. Hunt Mfg. Co.*, 221 F.3d 1318, 1327 (Fed. Cir. 2000), the Court declines to borrow this rule to conclude that in light of the submission of the '553 patent to the Patent Office there can be no fraud under the FCA *as a matter of law* where no cases that have addressed this issue in the FCA context have been cited.

The Court also rejects Allergan's argument that as to the Went Patents it cannot be held liable under the FCA because it was not involved in prosecuting those patents. Relator's theory of the FCA claim is that the claims for payment of monopoly prices by the government for Namenda XR® and Namzaric® were fraudulent not only because of the way the patents were obtained but also because Defendants (including Allergan) knowingly asserted invalid patents against other

pharmaceutical companies to maintain their inflated prices. *See* FAC ¶¶ 104-109. Defendants have not cited any authority that persuades the Court that as a matter of law Relator cannot state a claim under the FCA on that theory.

Therefore, the Court finds that Relator has sufficiently alleged that Defendants made false claims or statements to the government under the theory of implied certification.

ii. Promissory Fraud

In *Campie*, the Ninth Circuit recognized that a viable claim under the FCA can be stated under the doctrine of promissory fraud, also known as fraud in the inducement. 862 F.3d at 902. The court in *Campie* explained:

> Under this theory, "liability will attach to each claim submitted to the government under a contract, when the contract or extension of the government benefit was originally obtained through false statements or fraudulent conduct." . . . "In other words, subsequent claims are false because of an original fraud (whether a certification or otherwise)."

Id. (quoting *Hendow*, 461 F.3d at 1173). In that case, the relators asserted claims under the FCA against Gilead, a drug manufacturer that produces anti-HIV drug therapies, including the drugs Atripla, Truvada, and Emtriva. *Id*. at 895. All three drugs contain the active ingredient emtricitabine, commonly known as FTC. *Id*. To sell the three drugs, Gilead had to obtain approval from the FDA by filing new drug applications ("NDAs"). *Id*. In its NDA applications, Gilead represented to the FDA that it would source the FTC from specific registered facilities. *Id*. The relators alleged that for approximately sixteen months Gilead bought illicit FTC from an unregistered facility ("Synthetics China") while claiming it had obtained it from one of the approved facilities. *Id*. In addition, the relators alleged that Gilead engaged in misconduct because it used "falsified or concealed data in support of its application" to get Synthetics China approved by the FDA as its source for FTC, including misrepresenting the results of tests Gilead had conducted on batches of FTC obtained from Synthetics China. *Id*.

The relators in *Campie* alleged "that Gilead violated the FCA because it sought payment for its drugs containing FTC either directly or indirectly from government programs, but payment for drugs under these programs is contingent on FDA approval and, "'because the drugs paid for

by the government contained FTC sourced at unregistered facilities, they were not FDA approved and therefore not eligible for payment under the government programs.'" *United States v. Gilead Scis., Inc*. ("*Campie II*"), No. 11-CV-00941-EMC, 2019 WL 5722618, at *2 (N.D. Cal. Nov. 5, 2019) (quoting *Campie*, 862 F.3d at 897). The Ninth Circuit concluded that relators adequately alleged false claims based on factual falsity, implied certification *and* promissory fraud. 862 F.3d at 902-905.

With respect to factual falsity, the court found that the relevant claim was for nonconforming goods, that is, a claim that the defendant "misrepresent[ed] what goods or services that it provided to the Government"). *Id*. at 899 (citing *United States v. Nat'l Wholesalers*, 236 F.2d 944, 950 (9th Cir. 1956); *United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 305 (3d Cir. 2011)). It further concluded that under *Escobar*, "a claim for nonconforming goods is not limited to situations where there is an express specification in a payment contract between a supplier and the government regarding the disputed aspect of the product to be supplied." *Id*. Nonetheless, it found that unless the claimant submitted claims to the government for something that was *worthless* – in which case no false certification is required – "a claim for nonconforming goods must include an intentionally false statement or fraudulent course of conduct that was material to the government's decision to pay." *Id*. at 900 (citing *Nat'l Wholesalers*, 236 F.2d at 950). Applying these principles, the court in *Campie* concluded that the relators had satisfied the falsity requirement on the basis of a factually false certification because "Gilead specifically represented to the FDA that its active ingredients had been manufactured in approved facilities that had been registered" with the FDA. *Id*. at 902.

The Court in *Campie* also found that the doctrine of implied false certification was satisfied under the *Escobar* test. *Id*. at 902-903. The court reasoned that Gilead submitted claims for payment using the drug names Truvada, Emtriva, and Atripla, which refer to specific drugs under the FDA's regulatory regime, thus amounting to a certification that its drugs were manufactured at approved facilities and were not adulterated or misbranded. *Id*. Putting aside the question of materiality, the court found that Gilead's failure to disclose its noncompliance with statutory, regulatory, or contractual requirements made these representations "misleading half-

truths." *Id*. (quoting *Escobar*, 136 S. Ct. at 2000). In reaching this conclusion, the court rejected Gilead's argument that the relators could not allege falsity because "the alleged fraud was directed at the FDA, not the payor agency." *Id*. at 903. The court explained:

> It is not the distinction between the agencies that matters, but rather the connection between the regulatory omissions and the claim for payment. *See United States ex rel. Petratos v. Genentech Inc*., 855 F.3d 481, 492 (3d Cir. 2017) ("[O]ur focus here should not be whether the alleged fraud deceived the prescribing physicians, but rather whether it affected CMS's payment decision."). As we stated in *Hendow*, "if a false statement is integral to a causal chain leading to payment, it is irrelevant how the federal bureaucracy has apportioned the statements among layers of paperwork." 461 F.3d at 1174. *Hendow* itself involved false statements submitted to the Department of Education where claims were submitted to private lenders. *Id*. at 1169–80; *see also, e.g., United States ex rel. Duxbury v. Ortho Biotech Products, L.P.*, 579 F.3d 13, 29–30 (1st Cir. 2009) (alleging defendant's fraud caused medical providers to submit false claims); *Hutcheson*, 647 F.3d at 378 (similar).

Id.

Finally, the court in *Campie* concluded that the allegations in that case also satisfied the falsity requirement under the doctrine of promissory fraud. *Id*. at 902, 904. The court reasoned that "[b]ecause Gilead committed either factually false or impliedly false certification through its representations to the FDA and labeling of its products . . . each claim was fraudulent even if false representations were not made therein." *Id.* at 904.

In this case, Relator alleges that Defendants misled the Patent Office to obtain the '009 and Went Patents and then used those patents to maintain their monopoly, which then allowed Defendants to charge much higher prices for the drugs than they otherwise could have. The Court concludes that here, as in *Campie*, Defendants' false statements to obtain a government benefit are sufficient to render their later claims false for the purposes of the FCA.

The Court rejects Defendants' assertion, based on *Promega*, No. 03-1447-A (E. D. Va. Sept. 29, 2004), that misrepresentations made to the Patent Office are too "disconnected" from subsequent claims for payment made "years later" to support an FCA claim. Although the court in *Promega* concluded that there was a "disconnect between the alleged misrepresentations to the [Patent Office] and the invoices submitted to the government" "years later" and rejected the relator's argument that "the misrepresentations somehow induced the Government to enter into

contracts with the Defendants," the court did not identify which theory of falsity it was addressing and cited no authority in support of its conclusion. Therefore, that decision does not offer any meaningful guidance here. In any event, the Ninth Circuit appears to have rejected this reasoning, finding in *Hendow* that "the False Claims Act requires 'a causal rather than a temporal connection between fraud and payment[.]'" 461 F.3d at 1174 (quoting *U.S. ex rel. Main v. Oakland City Univ.*, 426 F.3d 914, 916 (7th Cir. 2005) ("*Main*")); *see also Hendow*, 461 F.3d at 1174 ("As the Seventh Circuit rightly noted, the precise logistical details of how the claim is made – with respect to timing, for instance, or the number of stages involved – are immaterial: '[i]f a false statement is integral to a causal chain leading to payment, it is irrelevant how the federal bureaucracy has apportioned the statements among layers of paperwork.'") (quoting *Main*, 461 F.3d at 1174).

Therefore, the Court concludes that Relator has adequately alleged Defendants made false statements under the doctrine of promissory fraud as well as implied certification.[21]

b. Whether Relator Has Alleged Facts Showing Materiality

The FCA defines "materiality" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). Similarly, under common law, "materiality 'look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.'" *Escobar*, 136 S. Ct. at 2002 (quoting 26 R. Lord, Williston on Contracts § 69:12, p. 549 (4th ed. 2003)). In *Escobar*, the Court left open whether the statutory definition in § 3729(b)(4) or common law governs the "materiality" inquiry in FCA cases, concluding that under either, "[t]he materiality standard is demanding." *Id*. The Court explained:

> The False Claims Act is not "an all-purpose antifraud statute," *Allison Engine*, 553 U.S., at 672, 128 S.Ct. 2123 or a vehicle for punishing garden-variety breaches of contract or regulatory violations. A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment. Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's

[21] Because the Court finds that Relator has adequately alleged that Defendants made false statements on these grounds, it does not reach Relator's arguments that the patent applications themselves are false statements, or that their listing of the two drugs in the Orange Book constitute additional false statements.

> noncompliance. Materiality, in addition, cannot be found where noncompliance is minor or insubstantial. *See United States ex rel. Marcus v. Hess*, 317 U.S. 537, 543, 63 S.Ct. 379, 87 L.Ed. 443 (1943) (contractors' misrepresentation that they satisfied a non-collusive bidding requirement for federal program contracts violated the False Claims Act because "[t]he government's money would never have been placed in the joint fund for payment to respondents had its agents known the bids were collusive"); *see also Junius Constr.*, 257 N.Y., at 400, 178 N.E., at 674 (an undisclosed fact was material because "[n]o one can say with reason that the plaintiff would have signed this contract if informed of the likelihood" of the undisclosed fact).

Id.

Under this standard, it is not necessary for the government to expressly identify a statutory or regulatory provision as a condition of payment in order to demonstrate materiality, though such express requirements are relevant to materiality. *Id.* Other evidence that may demonstrate materiality includes "evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement." *Id.* "Conversely, if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material." *Id.* In *Escobar*, the Court found that the materiality inquiry is not too fact intensive to allow dismissal of claims on that basis at the pleading stage if an FCA claimant has not pleaded facts to support allegations of materiality. *Id.*, 136 S. Ct. at 2004 n. 6.

Here, Relator has alleged that Defendants' fraudulent conduct in obtaining the Went Patents and the '009 patent and asserting these patents to prevent generics from entering the market have been the basis for the inflated prices that they have charged the Government for their drugs. Because price goes to the "essence of the bargain" between the government and drug manufacturers, the Court finds that Relator has adequately alleged that Defendants' fraud was material for the purposes of his FCA claims. *See Grubea v. Rosicki, Rosicki & Assocs., P.C.*, 318 F. Supp. 3d 680, 701-702 (S.D.N.Y. 2018) (finding that the FCA's materiality requirement was adequately alleged based on allegations that defendant had made claims for inflated expenses

because it was "highly implausible" that the government "would willingly pay inflated expenses"). Moreover, the fact that the government has continued to pay for Allergan's drugs does not demonstrate a lack of materiality because there is no allegation in the FAC that the government was aware of the alleged fraud on the Patent Office when it paid for the drugs.[22]

c. Whether Relator Has Alleged Facts Showing Scienter

Under the FCA, defendants are liable only if they acted "knowingly." 31 U.S.C. § 3729(a)(1)(a) & (b)(1)(A). "Under Rule 9(b), 'circumstances constituting fraud or mistake' must be stated with particularity, but 'malice, intent, knowledge, and other conditions of a person's mind,' including scienter, can be alleged generally." *United States v. Corinthian Colleges*, 655 F.3d 984, 996 (9th Cir. 2011) (quoting Fed.R.Civ.P. 9(b)). The FCA's scienter requirement is not met by "innocent mistakes, mere negligent misrepresentations and differences in interpretations," *id.* (quoting *Hendow*, 461 F.3d at 1174), but instead requires that a Relator allege that the defendant "knew that its statements were false, or that it was deliberately indifferent to or acted with reckless disregard of the truth of the statements." *Id.* (citing *United States ex rel. Hochman v. Nackman*, 145 F.3d 1069, 1074 (9th Cir. 1998)). Relator has met that requirement here.

With respect to the Adamas Defendants, Relator alleges scienter by alleging that Dr. Went and Adamas intentionally submitted a series of declarations intended to mislead the Patent Office with respect to the results of the ME110 Study. *See* FAC ¶¶ 80-83. The Court rejects Adamas's argument that the allegations show a lack of scienter because Dr. Went subsequently submitted a corrected declaration, showing he did not intend to mislead the Patent Office. While that is a possible inference it is not the only plausible inference that can be drawn from the allegations in the FAC. Drawing all reasonable inferences in favor of Relator, there is at least a plausible inference the Dr. Went and Adamas did, in fact, intend to mislead the Patent Office.

[22] To the extent Defendants rely on the fact that the Government continues to pay for these drugs even after receiving notice of Relator's claims, the Court does not rely on that information. Although the Government is on notice of Relator's *allegations* its continued payment for these drugs could be for any number of reasons. As there may be factual questions related to the reasons for the Government's continued payment for these drugs, this is an issue that is not suitable for determination at the pleading stage. For the same reason, the Court rejects Defendants' reliance on the fact that the Government declined to join in this action to establish a lack of materiality.

With respect to the Allergan Defendants, Relator alleges in the FAC that Forest Laboratories was aware of the teachings of the '553 patent yet intentionally failed to disclose them to the patent examiner when it amended the claims of the '009 patent to include a once-daily administration of memantine because it knew the patent examiner would reject the application if it did. *See* FAC ¶¶ 94. 97. Allergan Defendants point to 37 C.F.R. § 1.56 in support of their contention that Forest had an objectively reasonable belief that it was not required to disclose the '553 patent when it amended the claims, but this is a question that is more appropriately addressed at a later stage of the case and not on the pleadings. With respect to the Went Patents, Relator has also alleged facts that raise a plausible inference that Forest Laboratories acted at least recklessly to the extent that under the timeline alleged in the FAC it was already an exclusive licensee at the time two of the applications were filed and was a real-party-in-interest for those patents when misleading statements about the ME110 study were made to the Patent Office.

Accordingly, the Court finds that Relator has sufficiently alleged scienter as to the Allergan Defendants and the Adamas Defendants.[23]

E. The State Law Claims

In their motions, Defendants contend Relator's State law claims fail because most of the States' false claims statutes contain a public disclosure bar that mimics the one in the federal FCA and therefore the claims Relator asserts under those statutes fail for the same reasons they contend his federal FCA claims are barred. Allergan Motion at 29-30; Adamas Motion at 22-23. The Allergan Defendants further assert that Relator has not alleged in sufficient detail how false claims were submitted to the states in violation of their false claims statutes. Allergan Motion at 30. Next, they argue that the State law claims "suffer from the same defects as the federal claims." Allergan Motion at 30; Adamas Motion at 22-23. Finally, Allergan asserts that Relator's claim under New Mexico law is deficient because under the relevant New Mexico law a private right of action exists only if there has been a determination by the state that there is "substantial evidence that a violation has occurred" and Relator has not alleged that such a determination has been

[23] The Court does not reach the question of whether fraud before the Patent Office is chargeable to all those who subsequently acquire and enforce patents for the purposes of FCA claims.

made. Allergan Motion at 30 (citing *United States ex rel. Cestra v. Cephalon, Inc.*, No. CIV.A. 14-1842, 2015 WL 3498761, at *14 (E.D. Pa. June 3, 2015) (citing N.M. Stat. Ann. § 27-14-7(C)).

For the same reasons the Court rejects Defendants' arguments as to the federal FCA claims, it also rejects their challenges based on the same grounds to the State law claims.

The Court also concludes that Allergan's challenge to the New Mexico claim is premature. Under New Mexico law, if the state declines to take over a qui tam action the person who brought the action "shall have the right to conduct the action if the department determined that there is substantial evidence that a violation of the Medicaid False Claims Act has occurred." N.M. Stat. Ann. § 27-14-7. Yet the statute does not require the state of New Mexico to inform the Court of its determination and Relator is not required to come forward with evidence on a motion on the pleadings. Thus, at least one court has held that whether New Mexico had made a substantial evidence determination was not properly decided on a motion to dismiss because the determination was made after the operative complaint was filed. *See United States. ex rel. King v. Solvay S.A.*, 823 F.Supp.2d 472, 519–21 (S.D.Tex.2011) order vacated in part on recons., No. 06–2662, 2012 WL 1067228 (S.D. Tex. Mar. 28, 2012). In contrast, in *United States ex rel. Cestra v. Cephalon, Inc*., the court concluded that this issue could be resolved on the pleadings because in that case, the motion to dismiss challenged the second amended complaint, which was filed three years after the original complaint. No. CIV.A. 14-1842, 2015 WL 3498761, at *14 (E.D. Pa. June 3, 2015). The court reasoned that under those circumstances, the relator had "had the opportunity to determine and allege in the second amended complaint whether New Mexico issued him a determination of substantial evidence that its FCA statute was violated." *Id.*

Here, the FAC was filed on January 22, 2019. At that point, New Mexico had not yet filed its notice of election to decline intervention. *See* Docket No. 15. Because it is not obvious that Relator had had the opportunity to determine whether New Mexico had issued a substantial evidence determination at the time he filed the FAC, the Court declines to resolve this challenge on the pleadings and rejects Defendants' request to dismiss the New Mexico claim on this basis.

IV. CONCLUSION

For the reasons stated above, the Motions are DENIED. The Court sets a Case Management Conference for **January 15, 2021 at 2:00 p.m**. The parties shall file a joint case management conference statement that includes a proposed schedule for the case no later than **January 8, 2021.**

IT IS SO ORDERED.

Dated: December 11, 2020

JOSEPH C. SPERO
Chief Magistrate Judge

United States District Court
Northern District of California