No. _____

In the Supreme Court of the United States

VALEANT PHARMACEUTICALS INTERNATIONAL, INC., et al.
Petitioners,
v.

ZACHARY SILBERSHER AND **DR. FALK PHARMA GMBH**,
Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

WILLIAM R. PETERSON
MORGAN, LEWIS & BOCKIUS LLP
1000 LOUISIANA ST.
Suite 4000
Houston, TX 77002

MOEZ M. KABA
Counsel Of Record
PADRAIC FORAN
MICHAEL H. TODISCO
HUESTON HENNIGAN LLP
523 West 6th Street
Suite 400
Los Angeles, CA 90014
(213) 788-4340
mkaba@hueston.com

Counsel for Petitioners

QUESTIONS PRESENTED

The False Claims Act's public disclosure bar plays the critical role of preventing "parasitic" qui tam lawsuits filed by plaintiffs who "learn of the fraud through public channels." *Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 294, 296 n.16 (2010). These public channels include "a Federal . . . administrative hearing in which the Government . . . is a party" and a "Federal report, hearing, audit, or investigation." 31 U.S.C. § 3730(e)(4)(A)(i)–(ii).

The questions presented are:

1. Whether a relator can avoid the public disclosure bar by "stitching together" public disclosures.

2. Whether inter partes review (IPR)—which this Court and the Federal Circuit have described as a hearing between the federal government and the patent owner—constitutes a channel for public disclosure, either because: (i) the government is a "party" to IPRs, or (ii) an IPR is a "Federal . . . hearing."

PARTIES TO THE PROCEEDING

The Petitioners, collectively referred to as "Valeant," are Valeant Pharmaceuticals International (now known as Bausch Health Americas, Inc.), Valeant Pharmaceuticals International, Inc. (now known as Bausch Health Companies Inc.), Salix Pharmaceuticals, Ltd., and Salix Pharmaceuticals, Inc. In the proceedings below, the Petitioners were the defendants-appellees.

Respondent Zachary Silbersher was the relator-plaintiff-appellant in the proceedings below.

Respondent Dr. Falk Pharma GmbH was a defendant-appellee in the proceedings below.

CORPORATE DISCLOSURE STATEMENT

Bausch Health Americas, Inc. (formerly known as Valeant Pharmaceuticals International), Salix Pharmaceuticals, Ltd., and Salix Pharmaceuticals, Inc., are wholly owned indirect subsidiaries of Bausch Health Companies Inc. (formerly known as Valeant Pharmaceuticals International, Inc.), which is a publicly held company. No public company owns 10% or more of Bausch Health Companies Inc.'s stock.

STATEMENT OF RELATED PROCEEDINGS

This case arises from and is related to the following proceedings in the United States Court of Appeals for the Ninth Circuit and the United States District Court for the Northern District of California:

- *Silbersher v. Valeant Pharms. Int'l, Inc.*, et al., No. 20-16176, United States Court of Appeals for the Ninth Circuit. Judgment entered Aug. 3, 2023, and amended Jan. 5, 2024.
- *Silbersher v. Valeant Pharms. Int'l, Inc.*, et al., No. 20-16256, United States Court of Appeals for the Ninth Circuit. Judgment entered Aug. 3, 2023.
- *Silbersher v. Valeant Pharms. Int'l, Inc.*, et al., No. 3:18–CV–01496, United States District Court for the Northern District of California. Judgment entered May 11, 2020.
- *Silbersher v. Valeant Pharms. Int'l, Inc.*, et al., No. 3:18–CV–01496, United States District Court for the Northern District of California. Opinion issued on May 7, 2020.

There are no other proceedings in state or federal trial or appellate courts directly related to this case within the meaning of this Court's Rule 14.1(b)(iii).

TABLE OF CONTENTS

TABLE OF APPENDICES

TABLE OF AUTHORITIES

Cases: **Page(s)**

Statutes

Regulations

Other materials:

PETITION FOR A WRIT OF CERTIORARI

Valeant respectfully petitions this Court for a writ of certiorari to review the judgment in this case of the United States Court of Appeals for the Ninth Circuit.

OPINIONS BELOW

The Ninth Circuit's opinion is reported at 89 F.4th 1154 and reprinted in Petitioners' Appendix ("App.") at 1a–32a. The Ninth Circuit's opinion amended and superseded its earlier opinion, which is reported at 76 F.4th 843. The district court's order granting Valeant's motion to dismiss is reported at 445 F. Supp. 3d 393 and reprinted at App. 33a–61a.

JURISDICTION

The court of appeals entered judgment on January 5, 2024. This Court has jurisdiction under 28 U.S.C. § 1254.

STATUTORY PROVISIONS INVOLVED

Section 3730(e)(4) of the False Claims Act ("FCA"), 31 U.S.C. § 3730(e)(4), provides, in relevant part:

(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 [(ii)] 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.

INTRODUCTION

This petition involves the Ninth Circuit's novel interpretation of an important and frequently litigated provision of federal law that this Court has not yet had the opportunity to address: the 2010 amendments to the False Claims Act's public disclosure bar. As this Court has explained, the balance struck by the public disclosure bar is a central variable, perhaps even *the* central variable, in determining both the "volume and efficacy" of FCA qui tam litigation. *Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 294 (2010). In the decision below, the Ninth Circuit interpreted the amended public disclosure bar in a way that conflicts with several other courts of appeals and that threatens to upend long-standing precedent. This petition thus presents issues of nationwide importance relating to a provision at the heart of a critical federal statute.

First, the Ninth Circuit has created a circuit split by holding that a relator can avoid the public disclosure bar by "stitching together" public disclosures. (App. 29a.) According to the Ninth Circuit, the relator "provide[d] a critical fact necessary for scienter" by identifying "conflicting positions" contained in two separate disclosures. (App. 29a–30a.) This holding creates an irreconcilable conflict with the First, Fifth, Sixth, and Eighth Circuits—all of whom have explicitly held that the public disclosure bar applies even if relevant information is spread across multiple disclosures. *See, e.g.*, *Dingle v. Bioport Corp.*, 388 F.3d 209, 214 (6th Cir. 2004) ("The fact that the [disclosed]

information comes from different disclosures is irrelevant.").

Second, the Ninth Circuit held that information publicly disclosed during an IPR is not "publicly disclosed" under either subsection (i) or subsection (ii) of the amended bar. (App. 23a–24a (citing 31 U.S.C. § 3730(4)(A)).) In rejecting each of these subsections, the Ninth Circuit deviated from its sister circuits on vital questions of law.

As for subsection (i), the Ninth Circuit held that IPRs are "not a channel (i) disclosure" because "the government [is] not a 'party' to [an] IPR proceeding." (App. 23a.) But this rationale conflicts directly with Federal Circuit precedent and the holding of this Court, both of which squarely provide that an IPR is "a proceeding between the government and patent owner." *Regents of the Univ. of Minn. v. LSI Corp.*, 926 F.3d 1327, 1339 (Fed. Cir. 2019); *accord Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 584 U.S. 325, 343 (2018) (holding that IPR is "a matter involving public rights, one between the government and others" (quotation omitted)).

As for subsection (ii), the opinion below held that the 2010 amendments to the public disclosure bar changed the meaning of "report, hearing, audit, or investigation"—all of which appeared in the same form and same order in the pre-amendment statute—such that these four nouns now refer only to proceedings whose "primary function [is] investigative." (App. 24a.) Thus, although acknowledging an IPR is indisputably a "hearing" under the plain meaning of that term, the Ninth Circuit held that an IPR is not a "hearing" as defined

in amended subsection (ii) because it is not sufficiently "investigative." (App. 22a, 24a.) Every other circuit to encounter similar arguments has rejected them. As those courts have noted, the 2010 amendments left the sources for public disclosure "largely unaltered," so have continued to interpret the nouns contained in subsection (ii) according to their broad, plain language. *United States ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 302 & n.9 (3d Cir. 2016).

The stark facts of this case crystallize the potential ramifications of the Ninth Circuit's ruling. There was no factual dispute that the "relevant documents . . . were *all* publicly disclosed." (App. 18a (emphasis added).) As the district court explained, the plaintiff in this case is a patent lawyer who "seized upon a favorable patent decision in a case he litigated and added the new punchline of a false claim." (App. 53a.) His "knowledge of defendants' conduct" rested "entirely on . . . public documents" and the patent "decision . . . in favor of his client." (App. 48a.) Given the purely public nature of the documents at issue, the district court observed: "Anyone in the world could have filed this case. . . . My grandmother could have filed this case."[1]

As the district court correctly held, Silbersher's claims are "the quintessence of the opportunistic and 'parasitic' lawsuit Congress has always intended to bar." (App. 53a.) The holding below opens the

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[1] Hannah Albarazi, *'My Grandmother Could Have Filed This,' Valeant Judge Says*, Law360 (Aug. 8, 2019), https://www.law360.com/articles/1186843/print?section=california.

floodgates to qui tams based on publicly disclosed information and provides a roadmap to generate FCA claims based on publicly available IPR proceedings. This Court should grant review to address this troubling trend, resolve a circuit split, and clarify the scope of this critical federal statute.

STATEMENT OF THE CASE

I. Statutory Background

The FCA's public disclosure bar is central to achieving the False Claims Act's "general purpose of encouraging genuine whistleblower actions while snuffing out parasitic suits." *United States ex rel. Holloway v. Heartland Hospice, Inc.*, 960 F.3d 836, 851 (6th Cir. 2020). The bar generally prohibits qui tam claims when "substantially the same allegations or transactions" have already been disclosed through any of three channels:

> (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.

31 U.S.C. § 3730(e)(4)(A).

If the public disclosure bar is triggered, the relator's complaint must be dismissed unless the relator is an "original source" of the disclosure. *Id.* § 3730(e)(4)(B). A relator may qualify as an original source by showing that he "voluntarily disclosed" information to the government prior to its public disclosure or that he possesses "knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions." *Id.*

The current version of the public disclosure bar was passed in 2010 as a short and unexplained insert to the Patient Protection and Affordable Care Act, 124

Stat. 119 (2010). As relevant here, the 2010 amendments revised the language of what is now subsections (i) and (ii) of the bar. Before 2010, the predecessor to subsection (i) applied to disclosures made in any "criminal, civil, or administrative hearing." 31 U.S.C. § 3730(e)(4)(A) (1986). Now, subsection (i) applies to "*Federal* criminal, civil, or administrative hearing[s] *in which the Government or its agent is party*." 31 U.S.C. § 3730(e)(4)(A)(i) (2022) (italics added). Similarly, the predecessor to subsection (ii) applied to disclosures made in a "congressional, administrative, or [GAO] report, hearing, audit, or investigation." 31 U.S.C. § 3730(e)(4)(A) (1986). Now, subsection (ii) applies to disclosures "in a congressional, [GAO], or other *Federal* report, hearing, audit, or investigation." 31 U.S.C. § 3730(e)(4)(A)(i) (2022) (italics added).

II. Factual and Procedural Background

Valeant manufactures and markets pharmaceutical products. (App. 6a.) One such medication manufactured by Valeant is called Apriso®, which is prescribed to treat ulcerative colitis. (App. 13a.) The government pays for Apriso® through Medicare and Medicaid. (App. 13a.) Respondent Zachary Silbersher, the qui tam relator, contends that because of these government payments, Valeant certified to the government that "Apriso's price was fair and reasonable." (App. 17a).

Like most pharmaceutical companies, Valeant holds several U.S. patents. (App. 13a–14a.) Two of these patents are relevant to Silbersher's claims: U.S. Patent No. 8,865,688 ("the '688 Patent"), which covers Apriso®, and U.S. Patent No. 8,921,344 ("the '344

Patent"), which covers certain other medications containing the same active ingredient contained in Apriso®. (App. 16a.)

Patents can include several "claims," "each treated as a distinct invention." (App. 14a n.6.) A patent claim is valid only if it would not have been obvious to a person of ordinary skill in the art at the time of the invention. 35 U.S.C. § 103 (2013). Some claims of the '688 Patent involve administering Apriso's® active ingredient without food. (App. 14a.) Based on his review of public patent prosecution materials, Silbersher alleged that in the earlier application for the '344 Patent, Valeant represented "it was *obvious* that [Apriso's® active ingredient] was effective without food." (App. 16a.)

Silbersher is a patent attorney. (App. 16a.) He was never "an employee or other insider of Valeant." (App. 48a.) Rather, Silbersher encountered Valeant when, in 2015, his client Generico, LLC filed a challenge to Valeant's '688 Patent. (App. 16a.) Serving as Generico's lead lawyer, Silbersher sought to invalidate two of the sixteen claims in the '688 Patent through a petition for inter partes review, or "IPR." (App. 14a n.6, 16a.)

IPR is an "administrative process that authorize[s] the PTO to reconsider and cancel patent claims that were wrongly issued." *Oil States*, 584 U.S. at 330. When conducting an IPR, the PTO generally applies "the same statutory requirements that the PTO consider[s] when granting the patent" during the initial patent prosecution. *Id.* at 336. Many of the ordinary rules of litigation, including basic standing requirements, do not apply during an IPR. "Any

person other than the patent owner can file a petition for inter partes review." *Id.* at 331. In assessing an IPR petition, the Director of the PTO has "final and nonappealable" discretion to decide "whether to institute [the requested IPR]." *Id.* (quotation omitted). And even if the IPR petitioner settles with the patentholder, the Director can continue the proceedings and "issue a final written decision." *Id.* (citing 35 U.S.C. § 317(a)). Given IPR's structural features, this Court has held that IPR is a "matter involving public rights, one between the government and others." *Id.* at 344.

During the IPR on the '688 Patent, Silbersher argued on behalf of his client that the two at-issue claims were invalid as obvious in light of prior art. He asserted that "two published medical studies" and other Valeant "press releases" had previously established that Apriso's® active ingredient was effective without food. (App. 15a–16a.) In May 2017, the PTO concluded that the challenged claims of the '688 Patent were unpatentable as obvious. (App. 16a.) The PTO reasoned that the relevant prior art made it sufficiently obvious to administer Apriso's® active ingredient "without food." *Generico, LLC v. Dr. Falk Pharma GmbH*, No. IPR2016–00297, 2017 WL 2211672, at *15 (P.T.A.B. May 19, 2017).

While the appeal of his client's IPR was still pending, Silbersher filed this FCA action in his personal capacity on behalf of the United States and 28 states. (App. 33a.) His core theory was based on the IPR's obviousness finding, alleging that Valeant "wrongfully obtained the '688 Patent by advising the USPTO during patent prosecution" that taking Apriso's® active ingredient "without food was *not*

obvious." (App. 39a.) Silbersher highlighted the purported inconsistency between the '344 and '688 Patent applications: "[T]he '344 Patent application claimed it was *obvious* that [Apriso's® active ingredient] was effective without food—the exact opposite of what Valeant would claim a few years later in the '688 Patent application." (App. 16a.)

Silbersher spun this patent-law issue into an FCA claim by theorizing that Valeant used the '688 Patent to prevent generic competition from entering the market. (App. 14a.) Silbersher asserted that because of the allegedly invalid protection provided by the '688 Patent, Valeant was able to "prolong its monopoly and charge an artificially high price for Apriso," including in payments made by Medicare and Medicaid. (App. 16a.) Thus, Silbersher concluded, Valeant had "committed fraud when it knowingly overcharged the government and certified to Medicare and Medicaid that Apriso's price was fair and reasonable." (App. 17a.)

After the United States and all 28 other states declined to intervene, Silbersher's complaint was unsealed. (App. 34a.) Valeant moved to dismiss on several grounds, including the public disclosure bar. (App. 34a.) Silbersher did not dispute that the underpinning of his complaint had been completely disclosed—including during the IPR—but argued that those disclosures did not occur within "enumerated fora" under the amended statute. (App. 54a.) In fact, Silbersher explicitly conceded that the IPR decision standing alone "would bar his suit" if it qualified as a public disclosure. (App. 56a.)

Closely adhering to this Court's precedents, the district court held that an IPR was a qualifying "Federal . . . hearing" under subsection (ii). (App. 55a (citing *Schindler Elevator Corp. v. United States ex rel. Kirk*, 563 U.S. 401, 408 (2011).) As the district court noted, "hearing" for purposes of the public disclosure bar had long been interpreted to be "synonymous with 'proceeding'"—of which an IPR plainly was one. (App. 54a.)

The district court also highlighted that Silbersher was "a far cry from the quintessential whistleblower contemplated by the FCA." (App. 47a.) "He is, or was, a lawyer at a law firm, and does not allege that he was ever an employee or other insider of [Valeant]." (App. 48a.) "In effect, Silbersher simply seized upon a favorable patent decision in a case he litigated and added the new punchline of a false claim"—"the quintessence of the opportunistic and 'parasitic' lawsuit Congress has always intended to bar." (App. 53.)

The Ninth Circuit reversed. The decision began by holding that none of the extensive public disclosures made during the IPR would be considered "public" because IPRs do "not constitute a disclosure occurring within a specified channel." (App. 25a.) Without citing this Court's *Oil States* decision (or any Federal Circuit authority discussing the nature of IPR), the decision below characterized IPR as a "trial-like, adversarial hearing . . . between a patent owner and a patent challenger" in which the government merely serves as neutral adjudicator. (App. 22a.) As a result, the decision held, subsection (i) is inapplicable "because the government was not a 'party' to the IPR proceeding." (App. 23a.)

With respect to subsection (ii), the Ninth Circuit then held that the 2010 Amendments to subsection (i) in effect also narrowed the meaning of "hearing" in subsection (ii). The opinion reasoned that to "conclude that an adversarial, adjudicatory, federal administrative hearing before the PTAB in which the government was not a party nevertheless qualifies under channel (ii) as an 'other Federal . . . hearing' would render the government-as-a-party requirement in channel (i) a nullity." (App. 25a.)

Having held that the case-dispositive IPR disclosures did not qualify as public disclosures, the Ninth Circuit next analyzed whether Silbersher's complaint was "substantially the same" as the disclosures that occurred through the "qualifying" channels. (App. 26a.) In particular, the Ninth Circuit focused on the "prosecution histories" of the '688 and '344 Patents, which qualified as "disclosures in the second channel" (i.e., as "Federal . . . hearing[s]" under subsection (ii)). (App. 26a–27a.)[2]

This portion of the Ninth Circuit's opinion changed over time. The Ninth Circuit's first opinion, published on August 3, 2023, held that where the "misrepresented state of facts" and the "true state of facts" giving rise to an FCA claim were revealed in different public disclosures, the public disclosure bar was not triggered. 76 F.4th 843, 856–57 (9th Cir.

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[2] Because the other "qualifying" disclosures (including certain Valeant-affiliated studies and press coverage of the IPR decision) were not essential to its holding, the opinion "assume[d] without deciding" that those disclosures would qualify under the "news media" channel in subsection (iii). (App. 25a.)

2023), *amended by* 89 F.4th 1154 (9th Cir. 2024). After Valeant petitioned for rehearing en banc, the panel issued an amended and superseding opinion on January 5, 2024. (App. 5a.)

Although the amended opinion deleted certain language expressly stating that disclosures cannot be spread across different documents, it did not otherwise change the relevant analysis. The amended opinion still turned on the perceived "conflicting positions" in the "patent prosecutions of the '344 and '688 Patents." (App. 29a.) According to the opinion, "Silbersher's *qui tam* allegations provide[d] a critical fact necessary for scienter"—i.e., that Valeant "knowingly" submitted a false claim—by observing these discrepancies. (App. 29a.) The opinion further reasoned that the "critical fact" of this discrepancy—a "fact" that, by its very nature, requires a comparison of at least two separate disclosures—was not explicitly revealed in either of the "patent prosecutions [of the '344 or '688 Patents] or in any other disclosure." (App. 29a.) Thus, the opinion concluded, Silbersher avoided the public disclosure bar "by stitching together" the information contained in these separate disclosures. (App. 30a.)

REASONS FOR GRANTING THE PETITION

Both questions presented warrant this Court's review. On each question, the Ninth Circuit has irreconcilably split with the other circuits and has radically—and erroneously—weakened the public disclosure bar. These holdings will have immediate and far-reaching consequences for FCA qui tam litigation.

I. THIS COURT SHOULD GRANT CERTIORARI TO ADDRESS WHETHER A RELATOR CAN AVOID THE BAR BY STITCHING TOGETHER PUBLIC DISCLOSURES

The decision below holds that the public disclosure bar does not apply when a relator "stitch[es] together the material elements" of the alleged fraud by observing "conflicting positions" in public disclosures. (App. 30a, 29a.) This holding not only creates a circuit split on a frequently recurring issue, but also threatens to destabilize the carefully calibrated public disclosure bar.

A. The decision below creates a circuit split with the First, Fifth, Sixth, and Eighth Circuits.

By holding that a relator may avoid the public disclosure bar by identifying an alleged discrepancy between public disclosures, the decision below creates a direct conflict with the First, Fifth, Sixth, and Eighth Circuits. (App. 29a–30a.) Each of those circuits has held that the public disclosure bar applies when a claim is based on combining public

disclosures, irrespective of the relator's ability to "stitch[] together" those different sources or to infer "scienter" by noting purported discrepancies between them. (App. 29a–30a.)

To determine whether the public disclosure bar applies, the First Circuit asks whether "both the misrepresented state of facts and the true state of facts" have "f[ou]nd their way into the public domain." *United States ex rel. Ondis v. City of Woonsocket*, 587 F.3d 49, 54 (1st Cir. 2009). If such facts are publicly disclosed, then "the inference of fraud may be drawn." *Id.* This is true even when those facts are spread across "*separate* disclosures" or "come from different sources." *United States ex rel. Poteet v. Bahler Med., Inc.*, 619 F.3d 104, 110 n.6 (1st Cir. 2010); *see also United States ex rel. Winkelman v. CVS Caremark Corp.*, 827 F.3d 201, 208 (1st Cir. 2016) (explaining that the "misrepresented state of facts" and the "true state of facts" "may originate in different sources").

The First Circuit's analysis would foreclose Silbersher's claims. The Ninth Circuit acknowledged that the prosecution of the '688 Patent revealed the purportedly false state of facts ("that Apriso's effectiveness without food was not obvious") and that the prosecution of the '344 Patent revealed the purportedly true state of facts ("[that] it was obvious that Apriso would be effective without food"). (App. 29a.) Under First Circuit precedent, this is enough for the public disclosure bar to apply to Silbersher's claims (and to require their dismissal unless he could qualify as an original source). Thus, the decision below directly conflicts with the First Circuit by

holding that the bar did not apply because Silbersher "stitch[ed] together" separate disclosures. (App. 30a.)[3]

The Sixth and Eighth Circuits have also long held "that public disclosures contained in different sources, which together provide information that leads to a conclusion of fraud, trigger the public disclosure bar." *United States ex rel. Gilligan v. Medtronic, Inc.*, 403 F.3d 386, 390 (6th Cir. 2005). In analyzing whether the public disclosure bar mandates dismissal, "[t]he fact that the information comes from different disclosures is irrelevant." *United States v. CSL Behring, L.L.C.*, 855 F.3d 935, 944 (8th Cir. 2017) (quoting *Dingle*, 388 F.3d at 214). Those courts "consider 'public disclosures contained in different sources' *as a whole* to determine whether they *collectively* 'provide information that leads to a conclusion of fraud.'" *Id.* (emphases added) (quoting *Gilligan*, 403 F.3d at 390).

Again, these holdings would squarely preclude Silbersher's claims. The decision below recognizes that the public disclosures contained in different sources—the prosecutions of the '344 and '688 Patents—together provide information that leads to a conclusion of fraud. (*See* App. 29a.) The Sixth Circuit would hold that these disclosures thus "trigger the public disclosure bar." *Gilligan*, 403 F.3d at 387. But

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[3] Like other circuits, the First Circuit also holds that "[a] relator's ability to recognize the legal consequences of a publicly disclosed fraudulent transaction does not alter the fact that the material elements of the violation already have been publicly disclosed." *Winkelman*, 827 F.3d at 209. As the district court correctly recognized, that is all that Silbersher alleged here. (App. 48a ("At best, Silbersher . . . simply infer[s] FCA violations from publicly available evidence.").)

under the rule adopted by the Ninth Circuit, because Silbersher allegedly stitched the two public disclosures together, the public disclosure bar did not apply to his claims. (App. 28a–32a.)

The Fifth Circuit has applied this same rule to foreclose arguments nearly identical to those made by Silbersher here. In *United States ex rel. Solomon v. Lockheed Martin Corp.*, the Fifth Circuit considered the combined effect of "three potentially relevant public disclosures" and held that the relator's claim was barred because his claims "*could have* [been] synthesized" from those disclosures. 878 F.3d 139, 145 (5th Cir. 2017). In *Solomon*, the relator asserted that he had identified a purportedly "necessary piece of the puzzle" on a separate government website. *Id.* at 146. Rejecting this argument, the Fifth Circuit explained that the public disclosure bar is not concerned "with the overall probability of someone inferring fraudulent activity from the public disclosures," but rather "whether they *could have* made the inference." *Id.* Such a rule would have been fatal to Silbersher's claims, which at best "synthesized" public disclosures and inferred fraud from them. *Id.* at 145. The Fifth Circuit holds that such a claim is barred, but the Ninth Circuit holds that such a claim may proceed.

The circuit split is stark and undeniable. Under the rule applied in the First, Fifth, Sixth, and Eighth Circuits, the public disclosure bar applies to Silbersher's claims, which (at the very most) merely drew an inference of fraud from a discrepancy between the two public disclosures.

B. The Ninth Circuit's rule incorrectly narrows the public disclosure bar, encourages parasitic claims, and warrants this Court's review.

Review is further warranted because the decision below is wrong. The Ninth Circuit's holding that Silbersher avoided the bar by stitching together public disclosures is inconsistent with the statute's text and structure. (App. 28a–30a.) There is not—and never has there been—a requirement in the statute's text that all public disclosure be contained in a single document. *See* 31 U.S.C. § 3730(e)(4). And in allowing a relator to avoid the public disclosure bar by synthesizing purely public documents, the Ninth Circuit flouted the principle that "the sole 'touchstone' in the statutory text is 'public disclosure.'" *Schindler Elevator Corp. v. United States ex rel. Kirk*, 563 U.S. 401, 410 (2011) (quoting *Graham Cnty.*, 559 U.S. at 292, 301)).

Although the Ninth Circuit's rule would be wrong as applied to any public disclosures, given the specific disclosures central to the Ninth Circuit's holding—the '344 and '688 Patent prosecution histories—the opinion below is even less defensible. Those patent prosecution materials were submitted directly to the PTO during the applications for the '344 and '688 Patents. (App. 13a–14a.) Thus, the purported "conflicting" documents that revealed the alleged fraud were not merely public; they had already been submitted directly to the federal government. (App. 28a–29a.) Such disclosures to the federal government plainly satisfy the public disclosure bar's overriding purpose of "put[ting] the Federal Government on notice of a potential fraud." *Graham Cnty.*, 559 U.S.

at 291; *see also Winkelman*, 827 F.3d at 208–09 ("The ultimate inquiry, of course, is whether the government has received fair notice, prior to the suit, about the potential existence of the fraud.").

Moreover, the Ninth Circuit failed to recognize the important role of the original source exception. (App. 29a–30a.) The statutory scheme supports a broad interpretation of public disclosure because "Congress carefully preserved the rights of the most deserving *qui tam* plaintiffs" through the original source exception. *Graham Cnty*, 559 U.S. at 301. Here, the original source exception is the proper place—if any—to conduct an analysis of a relator's independent "investigations." (App. 16a.) "If a relator's allegations are actually derived from a public disclosure, the relator *might* be able to show that he has 'independent' knowledge of the fraudulent activity and therefore bring himself within . . . the original-source definition." *Glaser v. Wound Care Consultants, Inc.*, 570 F.3d 907, 917 (7th Cir. 2009). But such independent research is irrelevant to determining whether "the allegations in the action and those in the public disclosure are substantially similar." *United States ex rel. Newell v. City of St. Paul, Minn.*, 728 F.3d 791, 797 (8th Cir. 2013).[4]

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[4] In another of his cases, Silbersher has restyled the same theory presented here as an "original source" argument. In that case, Silbersher claimed that he qualified for the exception because he used his "specialized expertise in patent law" to materially add to the public disclosures by "analyzing [a patent] prosecution history." *Silbersher v. Allergan Inc.*, No. 18–CV–03018, 2023 WL 2593777, at *10 (N.D. Cal. Mar. 20, 2023). But even at the original source stage, Silbersher's theory failed. *Id.* at *11 (Continued...)

These errors threaten to throw the False Claims Act out of balance. The public disclosure bar is central to achieving the FCA's "general purpose of encouraging genuine whistleblower actions while snuffing out parasitic suits." *Holloway*, 960 F.3d at 851. Given its importance to the entire FCA scheme, the public disclosure bar has, for decades, been a point of focus for both this Court and Congress. *Graham Cnty.*, 559 U.S. at 294–95, 302 (describing Congress's attempt to find the "golden mean" for public disclosure rules with amendments to the FCA in 1943, 1986, and 2010); *see also Schindler Elevator*, 563 U.S. at 412–13 (describing the evolution of the public disclosure bar). Silbersher's claims—which were derived exclusively from documents publicly filed in federal patent prosecutions—are the exact type of "parasitic" claims that this Court has recognized as "downright harmful." *Graham Cnty.*, 559 U.S. at 298; *id.* at 294 (noting that, after a 1943 decision allowing a relator to bring a claim "discovered . . . by reading a federal criminal indictment," "Congress promptly reacted" to prevent such "quintessential[ly] parasitic suit[s]").

This Court's attention is even more important because of the frequency with which relators attempt to repackage public disclosures to assert FCA claims. The argument accepted in the decision below—that the bar does not apply when disclosures are spread across multiple documents—has long been attempted

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("Congress did not expand the definition of an original source so broadly as to encompass the type of knowledge that Relator brings to bear in this case.").

by opportunistic relators and long been rejected by courts. In addition to the four circuits that have explicitly rejected this argument (*see supra* section I.A), every other circuit has implicitly rejected it by affirming dismissal based on disclosures spread across multiple sources. *See, e.g.*, *Moore*, 812 F.3d at 303 (holding that the bar was triggered when the "misrepresented state of facts" were disclosed in FOIA documents and the "true state of facts" were disclosed in news articles and emails); *Bellevue v. Universal Health Servs. of Hartgrove, Inc.*, 867 F.3d 712, 719 (7th Cir. 2017) (determining that "the audit report and letters provided a sufficient basis to infer that [defendant] was presenting false information to the government").[5]

The Ninth Circuit's "scienter" reasoning would similarly open the floodgates to meritless qui tam claims. Other than in a rare case where the exact fraud was previously and explicitly alleged, a relator

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[5] *See also United States ex rel. CKD Project, LLC v. Fresenius Med. Care Holdings, Inc.*, No. 21–2117, 2022 WL 17818587, at *3 (2d Cir. Dec. 20, 2022) (bar triggered by disclosures through multiple different SEC filings); *United States ex rel. Jones v. Collegiate Funding Servs., Inc.*, 469 F. App'x 244, 257 (4th Cir. 2012) (bar triggered by disclosures through multiple different SEC filings); *United States ex rel. Reed v. KeyPoint Gov't Sols.*, 923 F.3d 729, 749 (10th Cir. 2019) (bar triggered by combination of disclosures in a lawsuit and separate publicly disclosed matters); *United States ex rel. Osheroff v. Humana Inc.*, 776 F.3d 805, 812–14 (11th Cir. 2015) (bar triggered by disclosures through multiple sources, including prior litigation records in combination with news media); *United States ex rel. Doe v. Staples, Inc.*, 773 F.3d 83, 86–87 (D.C. Cir. 2014) (bar triggered by combined disclosure of misrepresented facts in customs declarations and separate disclosure of true facts in two public reports).

could always assert that he "pieced together" discrepancies in public disclosures to present a more "full picture" of the defendant's alleged scienter. (App. 30a.) But if a relator could avoid the bar by inferring "scienter" from public documents, that would create an exception that swallows the public disclosure rule. Recognizing this, similar "scienter" arguments have been rejected by every other court to consider them. *See, e.g.*, *United States ex rel. Oliver v. Philip Morris USA Inc.*, 826 F.3d 466, 473 (D.C. Cir. 2016) (applying public disclosure bar where relator's "allegation [was] not based on his direct knowledge of [defendant's] scienter or lack thereof," but an "inference drawn from the available facts" (cleaned up)); *Bellevue*, 867 F.3d at 718–19 (rejecting relator's scienter allegations because he lacked "personal knowledge of [defendant's] practices" and therefore had necessarily "infer[red] scienter" from public facts).[6]

The Ninth Circuit has now breathed new life into these moribund theories, which have for decades been invoked by relators seeking to plead around the public disclosure bar. Given the frequency with which these

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[6] *See also Reed*, 923 F.3d at 761 (holding that a relator might avoid the bar when he "brings forth knowledge of scienter *that is not specifically contained in a qualifying public disclosure*") (emphasis added and citation omitted); *Winkelman*, 827 F.3d at 212–13 ("We do not rule out the possibility that furnishing information that a particular defendant is acting 'knowingly' (as opposed to negligently) sometimes may suffice as a material addition to information already publicly disclosed. Here, however, . . . the allegations gleaned from [relator's] experience add nothing significant about [defendant's] knowledge." (citation omitted))

issues arise and the early, dispositive role they play in qui tam cases, this Court's review is warranted.

C. This question is squarely presented and does not require further percolation.

This case presents an ideal vehicle to decide whether a relator can avoid the bar by synthesizing public disclosures. There is no factual dispute that all relevant information underlying Silbersher's complaint was in the public domain. (*See* App. 18a ("The parties do not dispute that the relevant documents that are the subject of this appeal were all publicly disclosed.").) Thus, this petition presents a pure question of law: whether a relator can survive the public disclosure bar by synthesizing public documents. (App. 29a.)

Nor would this issue benefit from additional percolation in the lower courts. As reflected in the summary above, multiple circuits have addressed (and rejected) the same arguments that Silbersher prevailed on here. (*See supra* sections I.A, I.B.) The Ninth Circuit was presented with those conflicting circuit decisions below, including through Valeant's petition for rehearing, but nonetheless split from its sister circuits. (App. 5a ("No further petitions will be entertained.").)

Only this Court can resolve the resulting conflict.

II. THIS COURT SHOULD GRANT CERTIORARI TO ADDRESS WHETHER AN IPR IS A QUALIFYING CHANNEL FOR PUBLIC DISCLOSURE

This case presents another important question of federal law: whether public IPR proceedings constitute a channel for public disclosure. (App. 22a–25a.) It is undisputed that the allegedly fraudulent scheme was fully disclosed during the IPR; in fact, Silbersher conceded that if an IPR is a qualifying disclosure, then his claim is barred. (App. 56a.) Under the precedent of this Court and the rules applied in other circuits, IPRs should qualify as public disclosures under both subsections (i) and (ii). But the Ninth Circuit concluded that neither subsection applied, thus splitting with its sister circuits and erring at each step of its analysis.

A. The Ninth Circuit's holding that the government is not a "party" to IPRs conflicts with the Federal Circuit and this Court.

The opinion below holds that IPRs do not qualify under subsection (i) because "the government [is] not a 'party' to [an] IPR." (App. 23a.) The Ninth Circuit described IPR as an adversarial proceeding between private parties, in which the government acts as a mere "adjudicator" and "not a 'party.'" (App. 12a, 23a.)

The Ninth Circuit's characterization of IPRs conflicts directly with decisions of the Federal Circuit—the court with appellate jurisdiction over IPRs, *see* 35 U.S. Code § 141(c)—which has held "that IPR is in key respects a proceeding between the

government and the patent owner." *LSI Corp.*, 926 F.3d at 1339. In fact, in holding that state and tribal sovereign immunity do not apply in an IPR, the Federal Circuit has described IPR as "nothing like a district court patent trial." *Saint Regis Mohawk Tribe v. Mylan Pharms. Inc.*, 896 F.3d 1322, 1328 (Fed. Cir. 2018). Among other things: (1) it is the Director of the USPTO, "not the private party," who has complete and unreviewable discretion whether to institute an IPR; (2) "even if the petitioner or patent owner elects not to participate during IPR, the Board can continue to a final written decision"; and (3) IPR procedures are "more limited than their civil counterparts." *LSI Corp.*, 926 F.3d at 1339–40. Given these characteristics, an IPR is "more like an agency enforcement action than a civil suit brought by a private party." *Saint Regis*, 896 F.3d at 1327.

Because those cases considered claims of state and tribal sovereign immunity—which cannot "apply to suits brought by the United States"—the correct characterization of the United States's role in IPRs was outcome determinative. *LSI Corp.*, 926 F.3d at 1337. Holding that those sovereign immunity doctrines did not apply, the Federal Circuit ultimately characterized IPRs as "proceedings brought by the United States." *Id.* at 1340; *see also Saint Regis*, 896 F.3d at 1329 ("The Director's important role as a gatekeeper and the Board's authority to proceed in the absence of the parties convinces us that *the USPTO is acting as the United States* in its role as a superior sovereign to reconsider a prior administrative grant." (emphasis added)).

The Federal Circuit's characterization of IPR is correct; it flows directly from this Court's precedents.

In *Oil States*, this Court explained that while IPR "includes some of the features of adversarial litigation, it does not make any binding determination regarding the liability" between the patent owner and the challenger. 584 U.S.at 343 (internal citations and quotation marks omitted). Instead, IPR "remains a matter involving public rights, one between the government and others." *Id.* (internal citations and quotation marks omitted). Similarly, in *Cuozzo Speed Technologies, LLC v. Lee*, 579 U.S. 261 (2016), the Court "carefully examin[ed] the purpose of inter partes review" and rejected the argument that IPR is like a "trial, adjudicatory in nature." *Id.* at 277. Looking at the same characteristics of IPR assessed in the decision below, the Court explained that "inter partes review is less like a judicial proceeding and more like a specialized agency proceeding." *Id.* at 279. The "basic purpose[]" of IPR is simply to "reexamine an earlier agency decision." *Id.*

The decision below is also incorrect because it draws an arbitrary distinction between an initial patent prosecution and the subsequent reconsideration of that patent during an IPR. As the decision recognizes, the Ninth Circuit itself has held that a patent prosecution qualifies as a Federal "hearing" under subsection (ii). (App. 21a.) But in applying a different rule to IPRs, the decision below ignores this Court's guidance that "inter partes review involves the same interests as the determination to grant a patent in the first instance." *Oil States*, 584 U.S. at 337. As in *Oil States*, the only salient difference between a patent prosecution and an IPR—"that [IPR] occurs *after* the patent has

issued"—"does not make a difference here." *Id.* at 337.

B. The Ninth Circuit's holding that IPR is not a "Federal hearing" under subsection (ii) creates a circuit split and warrants review.

The decision below also holds that IPR does not fit within subsection (ii), which prohibits qui tam claims based on disclosures in a "Federal report, hearing, audit, or investigation." 31 U.S.C. § 3730(e)(4)(A)(ii). "Invoking the canon of *noscitur a sociis*," the Ninth Circuit reasoned that the "four nouns" in subsection (ii)—report, hearing, audit, or investigation—are all "fact-finding or investigatory process[es]." (App. 21a.) The opinion below then concluded that IPR does not qualify as a "hearing" under subsection (ii) because its "primary function was not investigative." (App. 24a.)

In applying this extratextual limitation to "Federal hearing," the Ninth Circuit became the first court to rule that the 2010 amendments (silently) changed the meaning of "report, hearing, audit, or investigation"—terms that appear in the *same* form and even the *same* order in both the pre-2010 and post-2010 statutes. (App. 11a.) This analysis of the 2010 amendment creates a circuit split with the First, Third, Fourth, Sixth, and Eleventh Circuits and warrants review by this Court.

1. The decision below splits with the First, Third, Fourth, Sixth, and Eleventh Circuit's analysis of the amended bar.

The Ninth Circuit interpreted the 2010 amendments as abrogating its pre-2010 caselaw interpreting "report, hearing, audit, or investigation" in subsection (ii). (App. 30a–31a.)

The other circuits disagree, holding instead that the 2010 amendments left the sources for public disclosure "largely unaltered," amending subsection (ii) to specify that "only 'Federal' [disclosures] qualify." *Moore*, 812 F.3d at 302 & n.9. The Sixth Circuit has explained that all Congress did in the 2010 amendments was "shr[i]nk" the list of potential disclosures "to exclude [disclosures] associated with state-[level] proceedings"—a "distinction [that] is not relevant" to cases like this one involving indisputably "Federal" reports, hearings, investigations, or audits. *United States ex rel. Rahimi v. Rite Aid Corp.*, 3 F.4th 813, 823 n.2 (6th Cir. 2021). The First, Third, Sixth, and Eleventh Circuits have also held that the 2010 amendments did not impact the core meaning of these sources of disclosure listed in subsection (ii). *See, e.g.*, *United States ex rel. Maur v. Hage-Korban*, 981 F.3d 516, 522 (6th Cir. 2020) (applying the pre-amendment definition of "report" to find that a party's contract with the government was a "Federal Report" under the amended statute); *Moore*, 812 F.3d at 302 (similar); *Winkelman*, 827 F.3d at 206 n.2 ("The [2010] amendments . . . make no difference here: under both versions of the statute, . . . disclosures in

congressional hearings and federal reports, are within the statutory sweep.").[7]

If the Ninth Circuit had adhered to the statutory framework applied by any of these other circuits and interpreted "hearing" consistent with pre-amendment caselaw and the word's plain meaning, it would have affirmed dismissal of Silbersher's suit. The decision below expressly acknowledges that an IPR is a "hearing" in the ordinary sense of the word. (App. 23a (describing IPR as "an administrative hearing").) Likewise, under the pre-amendment bar, courts interpreted "hearing" broadly as "synonymous with 'proceeding.'" *A-1 Ambulance Serv., Inc. v. California*, 202 F.3d 1238, 1244 (9th Cir. 2000). Silbersher himself admitted that his theory hinged on the argument that the meaning of "hearing" changed between the pre- and post-amendment statutes. (App. 54a.) He even conceded that "there would be no case" under the pre-amendment precedent. (App. 47a, 49a.)

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[7] While no circuit has squarely addressed whether federal civil litigation qualifies as a "Federal hearing" under the amended bar, at least two circuits have indicated that it does. *See Osheroff*, 776 F.3d at 812 ("After the 2010 amendments, only information disclosed in federal court proceedings may be considered public disclosures."); *Reed*, 923 F.3d at 742 n.4 (noting that the amended statute includes as "sources" of disclosures, "among other things, news reports, congressional hearings, *prior lawsuits*, and federal audits" (emphasis added) (citing 31 U.S.C. § 3730(e)(4)(A)(i)–(iii)).

2. The Ninth Circuit is wrong that an IPR is not a "Federal hearing."

In limiting subsection (ii) to sources whose "primary function [is] . . . investigative," the opinion below contains at least four fundamental errors of statutory interpretation. (App. 24a.)

First, the Ninth Circuit assumed that the 2010 amendments *sub silentio* changed the long-standing meaning of "hearing." (App. 30a.) Under the pre-2010 bar, "hearing" had long been interpreted by courts to refer to *any* proceeding. *A-1*, 202 F.3d at 1245; *see also, e.g.*, *Amphastar Pharms. Inc. v. Aventis Pharma SA*, 856 F.3d 696, 703–05 (9th Cir. 2017) (O'Scannlain, J.) (applying the public disclosure bar to a civil patent infringement lawsuit); *United States ex rel. Paranich v. Sorgnard*, 396 F.3d 326, 334 (3d Cir. 2005) ("[W]e are persuaded that a complaint in a civil action falls into the context of 'criminal, civil, or administrative hearings' and is sufficiently public within the meaning of the Act to constitute a public disclosure.").

When Congress amended the statute in 2010, "it could have reacted to these cases" by narrowing the definitions of the terms in subsection (ii), but instead left each "largely unaltered as a public disclosure source." *Moore*, 812 F.3d at 302. The Ninth Circuit thus erred in concluding that the 2010 amendments changed the meaning of "hearing" without saying so. To the contrary, given the "presumption that Congress [is] aware of prior judicial interpretations" when it amends a federal statute, the fact that Congress did not "provid[e] any modification" to

address the definition of hearing only "enhance[s]" the force of the prior judicial interpretations. *Faragher v. City of Boca Raton*, 524 U.S. 775, 792 (1998).

Second, the Ninth Circuit's flawed "*noscitur a sociis*" analysis duplicates the precise error that this Court has repeatedly cautioned against. (App. 21a.) Both *Schindler Elevator* and *Graham County* reversed circuit court decisions for applying "the *noscitur a sociis* canon only to the immediately surrounding words, to the exclusion of the rest of the statute." *Schindler Elevator*, 563 U.S. at 409. In particular, the Court explained in both cases that the public disclosure bar's inclusion of "news media" is "especially" indicative of the bar's "broad sweep" and must be considered in any *noscitur a sociis* analysis. *Id.* at 408 (cleaned up) (quoting *Graham Cnty.*, 559 U.S. at 290). But just like the lower court in *Schindler Elevator*, the Ninth Circuit's *noscitur a sociis* analysis "did not consider" the importance of the statute's "reference to 'news media'" under subsection (iii). *Id.* at 409. This error alone leads to an incoherent and indefensible statutory scheme—where obscure internet advertisements are within the scope of the bar, but the public and official actions of a federal agency are not. *See Osheroff*, 776 F.3d at 813 (holding that "advertisements [and] websites" fall within subsection (iii)'s "broad sweep").

Third, the Ninth Circuit incorrectly holds that "hearing" in subsection (ii) has a different and far narrower definition than "hearing" in subsection (i). (*See* App. 24a (interpreting "hearing" in subsection (ii) to apply only to hearings whose "primary function [is] . . . investigative").) But it is a

cardinal rule of statutory interpretation that "identical words used in different parts of the same statute are presumed to have the same meaning." *Robers v. United States*, 572 U.S. 639, 643 (2014) (cleaned up).

Fourth, the Ninth Circuit drew the wrong conclusion from the fact that "hearing" appears in both subsections (i) and (ii). As this Court has explained, the fact that certain disclosure sources appear twice in the public disclosure bar "reflect[s] intent to avoid underinclusiveness even at the risk of redundancy." *Schindler Elevator*, 563 U.S. at 408. Rather than follow this Court's straightforward guidance, the Ninth Circuit strained to give the term "hearing" in subsections (i) and (ii) specialized definitions to avoid any overlap. (*See* App. 20a.)

Making matters worse, this error was unforced: The Ninth Circuit did not need to resort to an atextual definition of subsection (ii) to avoid "render[ing]" subsection (i) "a nullity." (App. 25a.) Rather, and as the Ninth Circuit had previously recognized when interpreting the amended public disclosure bar, "there are a number of federal proceedings which are not necessarily public including, for example, hearings before the Consumer Product Safety Commission relating to trade secrets." *United States ex rel. Bennett v. Biotronik, Inc.*, 876 F.3d 1011, 1019 (9th Cir. 2017) (citing 15 U.S.C. § 2055(a)). Thus, read together, subsections (i) and (ii) apply coherently to cover hearings (including non-public hearings) in which the government is a party (subsection (i)) as well as all "other . . . Federal hearing[s]" (subsection (ii)). 18 U.S.C. § 3730(e)(4)(A)(i)–(ii).

The combined effect of these unusual interpretive moves is that the Ninth Circuit lost sight of an even more basic principle: "Congress . . . does not alter the fundamental details of a regulatory regime in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001). But as the district court originally and correctly held, "Silbersher's case assumes just that." (App. 50a.) "It hinges on the proposition that Congress made a major change to the public disclosure bar in a short section inserted into a historic and massive healthcare reform law." (App. 50a.) Even if the Ninth Circuit's opinion was grounded in accepted principles of textual interpretation—and it is not—this would have been an unlikely result: Congress would not have amended the public disclosure bar "such that a qui tam action that would have been an opportunistic lawsuit under prior law is now a good case." (App. 49a.)

C. The Ninth Circuit's holding that IPR disclosures are not public will have substantial ramifications.

A rule providing that the public disclosure bar does not apply to documents disclosed in an IPR—or even to facts contained in an IPR decision published by the federal government—would lead to absurd results. Silbersher explicitly alleged that the IPR decision "confirmed" the fraud he is pursuing here. (App. 40a.) Plainly, "the purpose of a public disclosure" is served when the government "has itself issued documents containing information that substantiates an allegation of fraud." *Glaser*, 570

F.3d at 914 (cleaned up). In ruling to the contrary, the Ninth Circuit offered no explanation as to why Congress would have intended obscure scientific references—which the opinion "assume[d]" were qualifying "news media" disclosures—to be covered by the bar, but that the published order of a federal agency should not be. (App. 25a.) This is the sort of "anomalous result" this Court has refused to countenance. *Graham County*, 559 U.S. at 291 n.9 (rejecting parties' interpretation that would allow "public disclosure status to the most obscure local news report . . . but deny[] public disclosure status to a formal public report of a state government agency").

As explained above, this Court has recognized that an overly narrow public disclosure bar can threaten the integrity of FCA qui tam litigation by instigating "parasitic" and "opportunistic" suits. (*See supra* section I.B, p. 24 (quoting *Graham Cnty*., 559 U.S. at 294).) These concerns are particularly acute as applied to IPR proceedings. The Ninth Circuit's decision could permit an FCA claim to survive a motion to dismiss—allowing a relator to reach the "costly and protracted discovery phase" and unlock an "*in terrorem*" increase in "settlement value"—nearly any time a patent is invalidated in an IPR. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 558 (2007) (cleaned up).

This same FCA theory could be duplicated after nearly any successful IPR. Silbersher alleges that Valeant implicitly made a false claim every time the government paid for Apriso® because Valeant had certified that the price was "fair and reasonable" while knowing that the '688 Patent covered technology that was not patentable. (App. 28a). To

recreate this same allegation in a future case, all that a relator would need to do is allege that the defendant patent-holder knew that one of its patent claims "*was* obvious" and identify some covered product purchased by the government. (App. 27a–28a.) The district court recognized that this dynamic would create a cottage industry of derivative FCA claims arising out of successful IPRs.[8] And it may not stop there: the allure of a potential FCA claim could also distort the incentives of the IPR process, leading opportunistic plaintiffs to flood the PTO with IPR petitions with the hope of manufacturing grounds for a follow-on FCA claim.

These patent-specific issues are not only likely to recur, but are already recurring. Silbersher has already filed FCA suits against multiple other pharmaceutical companies alleging that they "unlawfully obtained several patents" and has sought billions of dollars in damages. *United States v. Allergan, Inc.*, 46 F.4th 991, 995 & n.3 (9th Cir. 2022) (noting two other Silbersher FCA suits). In his case filed against Janssen Biotech and Johnson & Johnson, Silbersher has avoided the public disclosure bar—and engaged in years of discovery—based on

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[8] *See* Transcript of Proceedings (Dkt. 102) at 13:6–14, *Silbersher, et al. v. Valeant Pharms. Int'l, Inc., et al.*, No. 3:18–CV–01496 (N.D. Cal., Aug. 8, 2019) ("If that were the case, you'd just have an industry of people pouring over PTAB decisions for invalidation on obviousness and then trying to find a link to Department of Defense, Department of Energy, DHS, you know, any of the tremendous consumers of patented technology in the government, and then just doing exactly what you said. And they don't have a lick of inside information about what really happened to make this a false claim within the meaning of fraud on the government.")

rote allegations of misconduct derived exclusively from an IPR decision and other public sources. *United States v. Janssen Biotech, Inc.*, 576 F. Supp. 3d 212, 219 (D.N.J. 2021).

D. No vehicle issues prevent the Court from granting certiorari to consider this important question.

This petition is an appropriate vehicle to consider whether an IPR qualifies under the amended bar as a channel for public disclosures. Both applicable subsections are squarely presented in the opinion below. (App. 23a ("[T]he IPR proceeding . . . was not a channel (i) disclosure."); *id.* at 24a ("Valeant also contends that the IPR qualifies under channel (ii) as an 'other Federal . . . hearing.' Again, we disagree.").) Moreover, the relevant inputs to this analysis—the statutory and regulatory characteristics of IPR—do not require any factual development. (*See* App. 11a–13a (analyzing, *e.g.*, 35 U.S.C. §§ 6(a), 102, 103, 122(b) 271(a), 311(a), 311(b), and 316(c) and 37 C.F.R. §§ 1.56(a) and 42.100–42.123).) *See also Saint Regis*, 896 F. 3d at 1328–29 (analyzing 35 U.S.C. §§ 143, 316(d), and 317(a) and 37 C.F.R. §§ 120(a), 42.104(c), 42.108(c), and 42.51).

Nor is any further percolation necessary. As for subsection (i), whether the Government is a "party" to an IPR is not only a pure question of statutory interpretation, but also turns on an issue that has been closely scrutinized by multiple courts, including this Court, in just the past few years: the fundamental nature of IPRs. *See Saint Regis*, 896 F. 3d at 1326–29; *LSI Corp.*, 926 F. 3d at 1338–41; *Oil States*, 584 U.S. at 343; *Cuozzo*, 579 U.S. at 279. In light of these

extensive precedents, further percolation about the characteristics of IPR is unnecessary.

As for subsection (ii), the circuits have noted that Congress's reasons for the 2010 amendments were left largely unexplained. *See Moore*, 812 F.3d at 299 (observing that "no direct legislative history seems to exist" for the 2010 amendments). The Ninth Circuit's novel interpretation of the 2010 amendments only adds to the already substantial uncertainty reflected in the circuits. *See Reed*, 923 F.3d at 744 (responding to relator's argument that "Congress acted specifically to jettison the reasoning used in our pre-2010 cases" by resolving to "continue to apply" the circuit's pre-amendment caselaw "until Congress or the Supreme Court tells us otherwise").

Fourteen years of uncertainty is long enough. The Court should grant certiorari now to provide much-needed guidance about the 2010 amendments.

CONCLUSION

For these reasons, the petition for a writ of certiorari should be granted, on either or both questions presented.

Respectfully submitted,

WILLIAM R. PETERSON
MORGAN, LEWIS & BOCKIUS LLP
1000 LOUISIANA ST.
Suite 4000
Houston, TX 77002

MOEZ M. KABA
Counsel Of Record
PADRAIC FORAN
MICHAEL H. TODISCO
HUESTON HENNIGAN LLP
523 West 6th Street
Suite 400
Los Angeles, CA 90014
(213) 788-4340
mkaba@hueston.com

Counsel for Petitioners

April 4, 2024

APPENDIX

TABLE OF APPENDICES

APPENDIX A — OPINION AND ORDER DENYING REHEARING OF THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT, FILED JANUARY 5, 2024

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 20-16176

D.C. No. 3:18-cv-01496-JD

ORDER AND AMENDED OPINION

ZACHARY SILBERSHER, RELATOR,

Plaintiff-Appellant,

and

UNITED STATES OF AMERICA, EX REL.; STATE OF CALIFORNIA; STATE OF COLORADO; STATE OF CONNECTICUT; STATE OF DELAWARE; STATE OF FLORIDA; STATE OF GEORGIA; STATE OF HAWAII; STATE OF ILLINOIS; STATE OF INDIANA; STATE OF IOWA; STATE OF LOUISIANA; STATE OF MARYLAND; STATE OF MICHIGAN; STATE OF MINNESOTA; STATE OF MONTANA; STATE OF NEVADA; STATE OF NEW HAMPSHIRE; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF NORTH CAROLINA; STATE OF OKLAHOMA; STATE OF RHODE ISLAND; STATE OF TENNESSEE; STATE OF TEXAS;

Appendix A

STATE OF VERMONT; STATE OF WASHINGTON; COMMONWEALTH OF MASSACHUSETTS; COMMONWEALTH OF VIRGINIA; DISTRICT OF COLUMBIA,

Plaintiffs,

v.

VALEANT PHARMACEUTICALS INTERNATIONAL, INC.; VALEANT PHARMACEUTICALS INTERNATIONAL; SALIX PHARMACEUTICALS, LTD.; SALIX PHARMACEUTICALS, INC.; FALK PHARMA GMBH,

Defendants-Appellees.

Appeal from the United States District Court for the Northern District of California.
James Donato, District Judge, Presiding.

June 10, 2022, Argued and Submitted, Portland, Oregon;

January 5, 2024, Filed

Before: Mary M. Schroeder and Gabriel P. Sanchez, Circuit Judges, and John Antoon II,[*] District Judge.

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[*] The Honorable John Antoon II, United States District Judge for the Middle District of Florida, sitting by designation.

Appendix A

Order;
Opinion by Judge Sanchez

SUMMARY[**]

False Claims Act

The panel filed (1) an order denying a petition for panel rehearing and a petition for rehearing en banc; and (2) an amended opinion reversing the district court's dismissal of relator Zachary Silbersher's *qui tam* action under the False Claims Act against Dr. Falk Pharma GmbH and drugmaker Valeant Pharmaceuticals International, Inc., and remanding for further proceedings.

Silbersher alleged that Valeant fraudulently obtained two sets of patents related to a drug and asserted these patents to stifle competition from generic drugmakers. Silbersher further alleged that defendants defrauded the federal government by charging an artificially inflated price for the drug while falsely certifying that its price was fair and reasonable. Dismissing Silbersher's action under the False Claims Act's public disclosure bar, the district court concluded that his allegations had already been publicly disclosed, including in *inter partes* patent review ("IPR") before the Patent and Trademark Office.

[**] This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

Appendix A

The False Claims Act's public disclosure bar, as amended in 2010, applies if (1) the disclosure at issue occurred through one of the channels specified in the statute; (2) the disclosure was public; and (3) the relator's action is substantially the same as the allegation or transaction publicly disclosed. Here, it was undisputed that the relevant documents were publicly disclosed.

Under the first prong of the public disclosure bar, the Act provides for the following three channels. Channel (i) applies if a disclosure was made "in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party," and channel (ii) applies if a disclosure was made "in a congressional, Government Accountability Office, or other Federal Report, hearing, audit, or investigation." Channel (iii) applies if a disclosure was made in the news media.

The panel held that an IPR proceeding in which the Patent and Trademark Office invalidated Valeant's "'688" patent was not a channel (i) disclosure because the government was not a party to that proceeding, and it was not a channel (ii) disclosure because its primary function was not investigative. The panel held that, under *United States ex rel. Silbersher v. Allergan*, 46 F.4th 991 (9th Cir. 2022), the patent prosecution histories of Valeant's patents were qualifying public disclosures under channel (ii). The panel assumed without deciding that a *Law360* article and two published medical studies were channel (iii) disclosures.

The panel held that the "substantially the same" prong of the public disclosure bar, as revised by Congress in its 2010 amendments to the False Claims Act, applies when the publicly disclosed facts are substantially similar to the relator's allegations or transactions. None of the qualifying public disclosures made a direct claim that Valeant committed fraud, nor did they disclose a combination of facts sufficient to permit a reasonable inference of fraud. Accordingly, the public disclosure bar was not triggered.

The panel resolved a cross-appeal in a separately issued memorandum disposition.

ORDER

An Amended Opinion is being filed simultaneously with this Order.

Judges Schroeder, Sanchez, and Antoon have voted to deny the petition for panel rehearing. Fed. R. App. P. 40. Judge Sanchez voted to deny the petition for rehearing en banc, and Judges Schroeder and Antoon recommended denying the same. The full court has been advised of the petitions, and no judge has requested to vote on whether to rehear the matter en banc. Fed. R. App. 35. Accordingly, the parties' petitions for panel rehearing and rehearing en banc, filed September 18, 2023, are **DENIED**. No further petitions will be entertained.

Appendix A

OPINION

SANCHEZ, Circuit Judge:

This appeal presents the question whether the public disclosure bar to the False Claims Act ("FCA") applies to Zachary Silbersher's claims against Dr. Falk Pharma GmbH and drugmaker Valeant Pharmaceuticals International, Inc. (collectively, "Valeant").[1] Silbersher alleges that Valeant fraudulently obtained two sets of patents related to the antiinflammatory drug Apriso and asserted these patents to stifle competition from generic drugmakers. Silbersher further alleges that defendants defrauded the government by charging an artificially inflated price for Apriso while falsely certifying that the drug's price was fair and reasonable. The district court dismissed Silbersher's *qui tam* action under the public disclosure bar. *See* 31 U.S.C. § 3730(e)(4)(A). This case requires us to examine Congress's 2010 amendments to the FCA's public disclosure bar and to determine whether Silbersher's claims are "substantially the same" as information that was publicly disclosed in one of three enumerated channels under the FCA. *See id.* We have jurisdiction pursuant to 28 U.S.C. § 1291, and we reverse.[2]

1. In 2015, Valeant Pharmaceuticals International, Inc., acquired Salix Pharmaceuticals, Ltd., and its wholly owned subsidiary, Salix Pharmaceuticals, Inc. Valeant is now Bausch. We refer to these parties, along with Dr. Falk Pharma GmbH, collectively as "Valeant" because Silbersher raises the same allegations against them all.

2. We resolve Dr. Falk Pharma GmbH's cross-appeal in a separately issued memorandum disposition.

Appendix A

I. BACKGROUND

A. False Claims Act

The False Claims Act imposes civil liability on anyone who "knowingly presents" a "fraudulent claim for payment" to the federal government. 31 U.S.C. § 3729(a)(1)(A); *accord United States ex rel. Mateski v. Raytheon Co.*, 816 F.3d 565, 569 (9th Cir. 2016). Known as "Lincoln's Law," Congress passed the Act at President Lincoln's request to combat fraud by Civil War defense contractors. *See United States ex rel. Bennett v. Biotronik, Inc.*, 876 F.3d 1011, 1013 n.1 (9th Cir. 2017). The Act allows private citizens, referred to as "relators," to bring fraud claims on the government's behalf against those who have violated the Act's prohibitions. *United States ex rel. Silbersher v. Allergan*, 46 F.4th 991, 994 (9th Cir. 2022); *see* 31 U.S.C. § 3730(b)(1).[3] If the government declines to proceed, the relator may prosecute the action and, if successful, recover up to thirty percent of the damages. 31 U.S.C. §§ 3730(b)(4), (d)(2).

The promise of bounty has sometimes incentivized relators to bring dubious claims. The Supreme Court's decision in *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 63 S. Ct. 379, 87 L. Ed. 443 (1943), provides the paradigmatic example of a "parasitic" *qui tam* suit. Hess brought a *qui tam* action alleging that electricians colluded

3. Diligent readers of this Court's opinions may feel a sense of *déjà vu*: we recently wrestled with certain parts of the FCA in another case brought by the same relator. *See United States ex rel. Silbersher v. Allergan*, 46 F.4th 991 (9th Cir. 2022).

to inflate prices by coordinating their bids on government contracts. *Id.* at 539. Before Hess's *qui tam* action, the government had already indicted the electricians for the same scheme and the electricians entered a plea bargain requiring them to pay $54,000 in fines. *Id.* at 545. Spotting an opportunity, Hess copied the government's indictment and brought a *qui tam* action against the electricians seeking hundreds of thousands of dollars in damages. *Id.* The Court allowed Hess's suit to stand, reasoning that the action advanced "one of the purposes for which the [FCA] was passed" because it promised "a net recovery to the government of $150,000, three times as much as the fines imposed in the criminal proceedings." *Id.* at 545.

"*Hess* inspired public outcry over the liberality of the *qui tam* provisions that prompted speedy congressional response." *United States ex rel. Springfield Terminal Ry. v. Quinn*, 14 F.3d 645, 650, 304 U.S. App. D.C. 347 (D.C. Cir. 1994). In 1943, President Roosevelt signed amendments to the FCA that barred *qui tam* claims "based upon evidence or information in the possession" of the federal government. 31 U.S.C. § 232(C) (1945). Congress later determined, however, that this "government knowledge" bar prevented too many relators from bringing potentially meritorious claims. *See Mateski*, 816 F.3d at 570. In 1986, Congress replaced the government knowledge bar with the "public disclosure" bar. 31 U.S.C. § 3730(e)(4)(A) (1986). The change reflected Congress's effort "to encourage suits by whistle-blowers with genuinely valuable information, while discouraging litigation by plaintiffs who have no significant information of their own to contribute." *Mateski*, 816 F.3d at 570.

The 1986 public disclosure bar prevented *qui tam* claims "based upon" public disclosures "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 relator was an "original source" of the disclosure.[4] 31 U.S.C. § 3730(e)(4)(A) (1986); *see Schindler Elevator Corp. v. United States ex rel. Kirk*, 563 U.S. 401, 412, 131 S. Ct. 1885, 179 L. Ed. 2d 825 (2011). The public disclosure bar applied when three conditions were 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 Pharms., Inc.*, 885 F.3d 623, 626 (9th Cir. 2018) (quoting *Mateski*, 816 F.3d at 570) (analyzing the 1986 version of the public disclosure bar).

Congress made important changes to the public disclosure bar in 2010. As amended, the bar precludes *qui tam* actions if:

> substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed—

4. 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) (1986).

> (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.[5]

31 U.S.C. § 3730(e)(4)(A) (2010). We recently concluded in *Allergan* that our three-part test for determining whether the public disclosure bar applies to a *qui tam* action remains good law after the 2010 amendments. *See Allergan*, 46 F.4th at 996.

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5. An original source is:

> an individual who either (i) prior to a public disclosure under [the public disclosure bar] has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or [(ii)] 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)(B) (2010).

The 2010 amendments narrowed the requirements for triggering the public disclosure bar in several important respects. Previously, the public disclosure bar was triggered if the *qui tam* action was based upon information publicly disclosed in *any* "criminal, civil, or administrative hearing." *See* 31 U.S.C. § 3730(e)(4)(A) (1986); *see also A-1 Ambulance Serv., Inc. v. California*, 202 F.3d 1238, 1243-44 (9th Cir. 2000) (applying public disclosure bar to information disclosed in county public bidding proceeding). Now, only a "*Federal* criminal, civil, or administrative hearing" qualifies as a specified channel (i) disclosure. 31 U.S.C. § 3730(e)(4)(A)(i) (2010) (emphasis added); *see also Allergan*, 46 F.4th at 998-99. Likewise, for a "report, hearing, audit, or investigation" to trigger the public disclosure bar under channel (ii), it must now be "Federal." *Compare* 31 U.S.C. § 3730(e)(4)(A) (1986), *with id.* § 3730(e)(4)(A)(ii) (2010). *See also Allergan*, 46 F.4th at 998. Finally, for the public disclosure bar to apply under channel (i), the "Government or its agent" must be "a party" to the "Federal criminal, civil or administrative hearing." *Compare* 31 U.S.C. § 3730(e)(4)(A) (1986), *with id.* § 3730(e)(4)(A)(i) (2010).

B. Patent Prosecution and *Inter Partes* Review

A patent gives its owner the exclusive right to make, use, or sell a patented invention for a limited period. 35 U.S.C. § 271(a). For an invention to be patent-worthy, it must be novel and not obvious to a person with ordinary skill in the relevant art. 35 U.S.C. §§ 102, 103. The process of obtaining a patent is called a patent prosecution. In a patent prosecution, an inventor submits

a patent application to the Patent and Trademark Office ("PTO"), which examines the application before accepting or rejecting it. The PTO's examination is an *ex parte* proceeding. The PTO relies on applicants to exercise good faith and candor about the originality of their purported inventions. *See* 37 C.F.R. § 1.56(a). An inventor who applies for a patent must disclose to the PTO "all information known to that individual to be material to patentability." *Id.* Patent applications are generally made public eighteen months after they are filed. *See* 35 U.S.C. § 122(b).

After a patent has been granted, anyone can challenge its validity by petitioning the PTO to hold *inter partes* review ("IPR") of the patent. 35 U.S.C. § 311(a). IPR is a trial-like proceeding conducted at the Patent Trial and Appeal Board ("PTAB"), an adjudicatory branch of the PTO. *See id.* § 6(a). *See generally id.* §§ 311-19; 37 C.F.R. §§ 42.100-42.123 (2021). In an IPR proceeding, the person challenging the patent argues against the validity of the patent, and the patent owner defends it. The PTAB presides as the adjudicator. 35 U.S.C. § 316(c). Both the challenger and the patent owner may present evidence. *See Genzyme Therapeutic Prods. Ltd. v. Biomarin Pharm. Inc.*, 825 F.3d 1360, 1365-70 (Fed. Cir. 2016). The challenger bears the burden of proving the patent is invalid. 35 U.S.C. § 316(e).

The scope of IPR is limited. Challengers can assert only that the patented invention was obvious or not novel and introduce as evidence only previously granted patents and publications (referred to as "prior art"). *See id.* § 311(b). An IPR does not decide whether an inventor

obtained a patent wrongfully—by committing fraud, for example. *See id.*; *see also Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1288-95 (Fed. Cir. 2011).

C. Factual Background

We now describe the facts as presented in Silbersher's *qui tam* complaint. Valeant manufactures Apriso, a medication prescribed to treat ulcerative colitis. When ingested, Apriso travels through the digestive system and releases its active ingredient, mesalamine. Upon arrival in the colon, mesalamine reduces the inflammation and discomfort caused by ulcerative colitis. Valeant owns a set of patents ("the Otterbeck Patents") for Apriso's delayed-release formula, which maximizes the amount of mesalamine that reaches the colon.

Beginning in 2012, Valeant enforced the Otterbeck Patents to prevent competitors from creating cheaper, generic versions of Apriso. The absence of generic competition allowed Valeant to charge high prices for the drug. A one-month prescription of Apriso retailed for about $600, earning Valeant over $200 million each year. A substantial portion of those proceeds came from the federal government, which paid for Apriso through Medicare and Medicaid.

The Otterbeck Patents rested on shaky ground. Several patents predating the Otterbeck Patents describe similar delayed-release formulas for mesalamine drugs. Viewed against those prior inventions, Apriso simply put a new label on an old pill. In 2012, Lupin, a generic drug

manufacturer, submitted an Abbreviated New Drug Application to the FDA attesting that the Otterbeck Patents were invalid. If the Otterbeck Patents were invalidated, generic competition would drive down Apriso's price. Valeant initiated an infringement action against Lupin to prevent that from happening. Seeing the writing on the wall, Valeant sought to extend its monopoly by applying for a new patent, claiming it had recently discovered that Apriso was effective when taken without food. The PTO initially rejected the application. After several rounds of revisions to the application, Valeant finally succeeded, and the PTO granted Patent No. 8,865,688 ("the '688 Patent") in 2014.[6] Valeant's gambit paid off. Approval of the '688 Patent gave Valeant leverage: even if Lupin successfully invalidated the Otterbeck Patents, it would need to mount a new, separate challenge to the '688 Patent before it could manufacture an Apriso generic. In September 2014, Valeant dismissed its infringement claims against Lupin relating to the Otterbeck Patents, and Lupin agreed to refrain from introducing a generic version of Apriso until 2022, four years after the expiration of the Otterbeck Patents.

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6. The '688 Patent contained sixteen "claims." A patent can include several claims, each treated as a distinct invention and correspondingly a distinct right to exclude others from practicing the invention. *See, e.g., Leeds & Catlin Co. v. Victor Talking Mach. Co.*, 213 U.S. 301, 319, 29 S. Ct. 495, 53 L. Ed. 805, 1909 Dec. Comm'r Pat. 536 (1909). Only the first and sixteenth claims of the '688 Patent are relevant to the present appeal. Our discussion of that patent refers only to those two claims.

In 2015, another generic drug manufacturer, GeneriCo LLC, sued to invalidate the '688 Patent. GeneriCo challenged the '688 Patent through IPR, arguing it was obvious that Apriso would be effective without food. As evidence, GeneriCo presented two published medical studies predating Valeant's '688 Patent application ("the Brunner and Marakhouski studies"). *See GeneriCo, LLC v. Dr. Falk Pharma GmbH*, No. IPR2016-00297, 2017 Pat. App. LEXIS 5430, 2017 WL 2211672 (P.T.A.B. May 19, 2017), *aff'd*, 774 F. App'x 665 (Fed. Cir. 2019). The Brunner and Marakhouski studies established that mesalamine drugs were effective when taken without food, undermining Valeant's purported later discovery of the same result. Moreover, Valeant's own head of research co-authored both studies, discrediting Valeant's claim that Apriso's effectiveness without food had been a new discovery. 2017 Pat. App. LEXIS 5430, [WL] at *6. The PTAB agreed with GeneriCo and invalidated the '688 Patent as obvious. 2017 Pat. App. LEXIS 5430, [WL] at *24.[7]

A legal news outlet, *Law360*, published an article describing GeneriCo's successful arguments and the PTAB's decision cancelling the '688 Patent. *See* Matthew Bultman, *Part of Apriso Patent Nixed in IPR with Hedge Fund Ties*, Law360 (May 19, 2017, 4:58 PM EDT), [https://perma.cc/56YR-ET78]. The article stated that GeneriCo "had shown the challenged patent claims would have been

7. The PTAB invalidated "claims 1 and 16 of the '688 patent." *GeneriCo*, LLC, 2017 Pat. App. LEXIS 5430, 2017 WL 2211672 at *24. The other fourteen claims in the '688 Patent were not affected by the PTAB's decision. *Id.*

obvious" by pointing to "a collection of references that included press releases from [Valeant] about clinical drug trials and some academic papers." *Id.* The article did not mention that Valeant's head of research had co-authored the Brunner and Marakhouski studies. *Id.*

Silbersher was GeneriCo's lawyer and led the IPR challenge that resulted in the '688 Patent being invalidated. Silbersher's investigations into Valeant's Apriso-related patents revealed other information that was not disclosed in the IPR proceeding. He discovered that three years before applying for the '688 Patent, Valeant had applied for Patent No. 8,921,344 ("the '344 Patent"). In the '344 Patent application, Valeant claimed it had made an "unexpected finding": taking mesalamine *with food* made the drug more effective. In other words, the '344 Patent application claimed it was *obvious* that mesalamine was effective without food—the exact opposite of what Valeant would claim a few years later in the '688 Patent application.

D. Procedural History

Silbersher brought this FCA case seeking damages from Valeant for making false claims for payment to the federal government. He alleges that Valeant fraudulently obtained the Otterbeck and '688 Patents so that it could prolong its monopoly and charge an "artificially high price" for Apriso. According to Silbersher, Valeant "intentionally withheld material information demonstrating that Valeant's claimed granulated mesalamine formulation would be effective when administered without food."

Silbersher contends that Valeant knew about the Brunner and Marakhouski studies and the earlier '344 Patent application but did not disclose that information to the PTO when applying for the '688 Patent. Similarly, Silbersher alleges that the Otterbeck Patents are invalid because Valeant failed to disclose "at least four prior art patents [that] anticipate all or nearly all of the alleged inventions claimed in the Otterbeck Patents."

Medicare and Medicaid allegedly paid nearly $250 million for Apriso from 2011 to 2016. Silbersher estimates that the government would have paid about eighty percent less if generic manufacturers of Apriso were allowed to enter the market. Silbersher contends that Valeant therefore committed fraud when it knowingly overcharged the government and certified to Medicare and Medicaid that Apriso's price was fair and reasonable.

The district court dismissed Silbersher's *qui tam* action as precluded by the public disclosure bar. Guided by our precedent interpreting the pre-2010 FCA, the district court reasoned that IPR qualifies as an "other Federal . . . hearing" under channel (ii) of the bar. The district court determined that Silbersher's allegations against Valeant had all been disclosed in the IPR that invalidated the '688 Patent. Accordingly, the district court concluded that Silbersher's *qui tam* action was the "quintessence of the opportunistic and 'parasitic' lawsuit Congress has always intended to bar." The court gave Silbersher leave to amend his claims, but Silbersher instead filed this appeal.

II. DISCUSSION

We review the district court's ruling on a motion to dismiss an FCA action de novo. *Allergan*, 46 F.4th at 996. To determine whether Silbersher's *qui tam* action was properly dismissed by the district court under the public disclosure bar, we must assess whether "(1) the disclosure at issue occurred through one of the channels specified in the statute; (2) the disclosure was public; and (3) the relator's action is substantially the same as the allegation or transaction publicly disclosed." *Id.* (internal quotation marks omitted) (quoting *Solis*, 885 F.3d at 626). The parties do not dispute that the relevant documents that are the subject of this appeal were all publicly disclosed. Therefore, our analysis is confined to determining whether the public disclosures in question occurred within one of the channels specified by the FCA, and if so, whether they disclosed "substantially the same allegations or transactions as alleged in" Silbersher's *qui tam* action. 31 U.S.C. § 3730(e)(4)(A).

Valeant points us to four sets of disclosures: (1) the patent prosecution histories of the '344, '688, and Otterbeck Patents; (2) the IPR proceeding in which the PTAB invalidated the '688 Patent; (3) the *Law360* article summarizing the IPR proceeding; and (4) the Brunner and Marakhouski studies. We address first whether these disclosures occurred within a specified channel.

Appendix A

A.

The FCA's public disclosure bar requires federal courts to dismiss *qui tam* suits under certain circumstances where the complaint's allegations closely match information that was publicly disclosed in one of three specified channels. 31 U.S.C. § 3730(e)(4)(A). The full text of the public disclosure bar is repeated below:

> 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.

31 U.S.C. § 3730(e)(4)(A) (2010).

"[T]he Supreme Court has instructed that to determine the meaning of one word in the public disclosure bar, we must consider the provision's entire text, read as an integrated whole." *Allergan*, 46 F.4th at 997 (internal quotation marks omitted) (quoting *Schindler*, 563 U.S. at 408). As we explained in *Allergan*, channels (i) and (ii) focus on two distinct types of federal proceedings. *Id.* at 999. Channel (i) primarily involves adversarial proceedings that are adjudicated on the merits before a neutral tribunal or decisionmaker, whereas channel (ii) primarily involves federal investigatory proceedings. *Id.*

Several textual clues lead us to this conclusion. A "Federal criminal, civil, or administrative hearing in which the Government . . . is a party" contemplates an adjudicatory hearing before a neutral tribunal or decisionmaker. *See Hearing*, Black's Law Dictionary (11th ed. 2019) ("A judicial session, usually open to the public, held for the purpose of deciding issues of fact or law, sometimes with witnesses testifying."); *Administrative Hearing, id.* ("An administrative-agency proceeding in which evidence is offered for argument or trial."). As we observed in *Allergan*, the term "party" describing the government's role in such a hearing contemplates that channel (i) hearings are also adversarial. *Allergan*, 46 F.4th at 999 (noting that channel (i) "suggests a focus on adversarial proceedings because criminal hearings are always adversarial, and civil and administrative hearings are very often adversarial when the government is a party" (citing *Party*, Black's Law Dictionary (11th ed. 2019))).

Conversely, in *Allergan* we concluded that prong (ii) "is primarily concerned with proceedings to gain information." *Id.* A "report, hearing, audit, or investigation" all suggest the "activity of trying to find out the truth about something," whether by "an authoritative inquiry into certain facts, as by a legislative committee, or a systematic examination of some intellectual problem or empirical question." *See Investigation*, Black's Law Dictionary (11th ed. 2019). Invoking the canon of *noscitur a sociis*, we observed that "[a]ll four nouns apply to a fact-finding or investigatory process 'to obtain information,' and together indicate that Congress intended for prong (ii) to cover a wide array of investigatory processes." *Allergan*, 46 F.4th at 998 (emphasis removed) (citation omitted) (quoting *Schindler*, 563 U.S. at 410).

We held in *Allergan* that because a patent prosecution is an *ex parte* proceeding before a federal administrative agency—the PTO—such a proceeding qualifies as an "other Federal . . . hearing" under channel (ii). *Id.* at 998-99. We rejected the contention that "by adding the government-as-a-party language to prong (i) in the 2010 amendment, Congress intended to exclude administrative hearings in which the government was not a party from the public disclosure bar writ large." *Id.* at 998. Such a sweeping argument would seemingly read "other Federal . . . hearing" out of existence from channel (ii), and we noted that the FCA "contemplates some redundancy" between the channels. *Id.* at 999 (quoting *Schindler*, 563 U.S. at 410). We explained that an *ex parte* hearing before the PTO in which the government is not a party falls within channel (ii), "[b]ut when the PTO rejects a patent

application and the inventor appeals, the appeal could fall under prong (i) but not prong (ii)" as an adjudication before the PTAB. *Id.*

This appeal requires us to address certain public disclosures addressed by *Allergan* as well as other disclosures that raise novel questions concerning application of the statutory bar. We turn to the four sets of public disclosures identified by Valeant.

The patent prosecutions involving the '344, '688, and Otterbeck Patents are qualifying public disclosures under channel (ii), as "other Federal . . . hearing[s]." *See id.* at 997-99. A public disclosure "also 'encompasses publicly filed documents' submitted as part of the proceeding." *Id.* at 997 (quoting *A-1 Ambulance Serv.*, 202 F.3d at 1244).

Allergan does not, however, resolve whether the IPR that invalidated the '688 Patent was a disclosure occurring within a specified channel. *See id.* at 999 (observing that an appeal by an inventor before the PTAB "could fall under prong (i) but not prong (ii)" but not reaching the issue). We must therefore determine whether the IPR proceeding falls within channel (i) or channel (ii).

As previously explained, IPR is a trial-like, adversarial hearing conducted before the PTAB between a patent owner and patent challenger. *See* 35 U.S.C. §§ 311-19. Other parties may join in the IPR at the discretion of the PTO. *Id.* § 315(c). The function of IPR is to adjudicate disputes about the patentability of a patented invention under the criteria of novelty and obviousness. *Id.* § 311(b).

The parties may file motions, take discovery, and present evidence and oral testimony at a hearing. *Id.* § 316(a); *see* 37 C.F.R. §§ 42.20-25, 42.51-55, 42.61-42.70. At the conclusion of IPR, the PTAB issues "a final written decision with respect to the patentability of any patent claim challenged by the petitioner." 35 U.S.C. § 318(a); *see* 37 C.F.R. §§ 42.20-25. The PTAB's decision may itself be appealed to the Federal Circuit. *See* 35 U.S.C. § 143.

IPR presents many hallmarks of a channel (i) federal administrative hearing. It is clearly "Federal": the PTAB is an adjudicatory body of the PTO, an agency within the U.S. Department of Commerce. *See* 35 U.S.C. § 6(a); *Allergan*, 46 F.4th at 998. It is an "administrative hearing" in which evidence and argument are presented before a neutral tribunal that adjudicates the merits of a dispute about the patentability of an invention. And it is an adversarial proceeding between two or more parties to the litigation. *See* 35 U.S.C. § 311(a)-(b) (establishing grounds and scope of IPR proceeding); *id.* § 313 (describing patent owner's right to respond); *id.* § 314 (defining basis for instituting IPR); *id.* § 316(a)(5) (establishing parties' ability to take "discovery of relevant evidence"); *id.* § 316(a)(8) (establishing parties' ability to present "factual evidence and expert opinions" to support their arguments); *id.* § 318 ("[T]he [PTAB] shall issue a final written decision with respect to the patentability of any patent claim challenged by the petitioner . . . .").

But because the government was not a "party" to the IPR proceeding concerning the '688 Patent, the proceeding here was not a channel (i) disclosure. *See*

31 U.S.C. § 3730(e)(4)(A)(i). Valeant contends that the government was a party to the IPR because the Director of the PTO is charged with determining whether an IPR should proceed and is permitted to participate in an appeal of a PTAB decision— procedural features that suggest the PTO is acting on behalf of the United States. We disagree. That the Director of the PTO decides whether an IPR should be instituted, *see* 35 U.S.C. § 314(a), and may adjudicate claims raised in the IPR as a member of the PTAB, *see id.* § 6(a), does not transform the PTO into a "party" to the IPR proceeding. A "party" is "[o]ne by or against whom a lawsuit is brought; . . . [a] Litigant." *Party*, Black's Law Dictionary (11th ed. 2019); *see Allergan*, 46 F.4th at 999. The government did not participate as a litigant in the IPR challenging the '688 Patent. *See GeneriCo*, 2017 Pat. App. LEXIS 5430, 2017 WL 2211672, at *1, 3-6, 21 (referring to the "parties" as the petitioner and patent owner).

Valeant also contends that the IPR qualifies under channel (ii) as an "other Federal . . . hearing." Again, we disagree. The IPR's primary function was not investigative in the sense of conducting a "fact-finding or investigatory process 'to obtain information.'" *Allergan*, 46 F.4th at 998 (emphasis removed) (quoting *Schindler*, 563 U.S. at 410). It was adjudicatory—its purpose was to render a decision between Valeant and GeneriCo as to the obviousness or novelty of the '688 Patent through a trial-like federal administrative hearing. Moreover, as we emphasized in *Allergan*, an important demarcation between channel (i) and channel (ii) disclosures is whether the proceeding is *ex parte* or adversarial. *Id.* at 999. Here, the IPR

was without question adversarial. To conclude that an adversarial, adjudicatory, federal administrative hearing before the PTAB in which the government was not a party nevertheless qualifies under channel (ii) as an "other Federal . . . hearing" would render the government-as-a-party requirement in channel (i) a nullity. As *Allergan* noted, "[i]t is our duty to give effect, if possible, to every clause and word of a statute." *Allergan*, 46 F.4th at 999 (alteration in original) (internal quotation marks omitted) (quoting *Duncan v. Walker*, 533 U.S. 167, 174, 121 S. Ct. 2120, 150 L. Ed. 2d 251 (2001)). Accordingly, we conclude that the IPR proceeding invalidating the '688 Patent was not a disclosure occurring in a specified channel.

Finally, Valeant contends that the *Law360* article and Brunner and Marakhouski studies are qualifying "news media" disclosures under channel (iii). *See* 31 U.S.C. § 3730(e)(4)(A)(iii). Silbersher does not meaningfully challenge this argument. We need not resolve Valeant's contention because, as we explain below, the *Law360* article and the Brunner and Marakhouski studies do not disclose "substantially the same . . . allegations or transactions" as Silbersher's claims.

In sum, we hold that the disclosures in the IPR proceeding at issue here did not constitute a disclosure occurring within a specified channel. The prosecution histories of the '344, '688, and Otterbeck Patents were disclosures in the second channel. *See Allergan*, 46 F.4th at 997-99. And we assume without deciding that the *Law360* article and the Brunner and Marakhouski studies were disclosures occurring within the third channel.

B.

We next consider whether the qualifying disclosures reveal "substantially the same . . . allegations or transactions" as Silbersher's *qui tam* action. We have not yet interpreted the "substantially the same" prong of the public disclosure bar as revised by Congress in its 2010 amendments to the FCA. *Compare* 31 U.S.C. § 3730(e)(4)(A) (2010), *with id.* (1986). In the previous version of the Act, the public disclosure bar applied when a relator's allegations were "based upon" a prior public disclosure. *See id.* (1986).

Ordinarily, Congress's decision to change "based upon" to "substantially the same as" would indicate the two phrases have different meanings. *See Rumsfeld v. F. for Acad. & Institutional Rts., Inc.*, 547 U.S. 47, 57-58, 126 S. Ct. 1297, 164 L. Ed. 2d 156 (2006); *Stone v. INS*, 514 U.S. 386, 397, 115 S. Ct. 1537, 131 L. Ed. 2d 465 (1995). Here, however, the change aligns with our caselaw interpreting the previous version of the Act. Under the pre-2010 version of the FCA, our circuit interpreted "based upon" to mean "substantially similar to." *See generally Mateski*, 816 F.3d at 573 ("Under our case law, for 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.'" (emphasis added) (quoting *United States ex rel. Meyer v. Horizon Health Corp.*, 565 F.3d 1195, 1199 (9th Cir. 2009))); *see also United States ex rel. Lujan v. Hughes Aircraft Co.*, 243 F.3d 1181, 1189 (9th Cir. 2001). Thus, as we suggested in *Allergan*, we

conclude that Congress re-enacted its prior law in clearer terms by replacing "based upon" with "substantially the same as," leaving our precedent interpreting that phrase undisturbed. *See Allergan*, 46 F.4th at 996 n.5; *Mateski*, 816 F.3d at 569 n.7, 573 n.14.

Guided by our precedent interpreting "based upon," we next ask whether "substantially the same allegations or transactions . . . alleged in [Silbersher's] action or claim were publicly disclosed." 31 U.S.C. § 3730(b)(4)(A). We have recognized a distinction between an "allegation" and a "transaction" for purposes of the public disclosure bar. An allegation refers to a prior "direct claim of fraud," while a "transaction" refers to the disclosure of "facts from which fraud can be inferred." *Mateski*, 816 F.3d at 571 (endorsing the definition adopted in *Springfield Terminal*, 14 F.3d at 653-54).

As the parties acknowledge, none of the public disclosures makes a direct claim that Valeant committed fraud. We instead turn to the broader question: whether the qualifying disclosures reveal "facts from which fraud can be inferred." The *Mateski* court explained that "[I]f X + Y = Z, Z represents the allegation of fraud and X and Y represent its essential elements. In order to disclose [a] 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." *Mateski*, 816 F.3d at 571 (first alteration in original) (quoting *United States ex rel. Found. Aiding the Elderly v. Horizon W., Inc.*, 265 F.3d 1011, 1015 (9th Cir.), *amended on denial of reh'g*, 275 F.3d 1189 (9th Cir. 2001)).

In the *Mateski* formula, the variables X and Y stand for the fundamental elements of fraud: "a misrepresented state of facts and a true state of facts." *Id.* (quoting *Horizon*, 265 F.3d at 1015); *see also Amphastar Pharms. Inc. v. Aventis Pharma SA*, 856 F.3d 696, 704 (9th Cir. 2017) ("If enough of the underlying facts making up the elements of fraud are disclosed, the [public disclosure] bar applies.").

Applying this framework, we conclude that the qualifying public disclosures here do not collectively disclose a combination of facts sufficient to permit a reasonable inference of fraud. To refresh, Silbersher's *qui tam* complaint alleges that (1) Valeant "intentionally withheld material information" demonstrating that Apriso's effectiveness without food was obvious from prior art (the Brunner and Marakhouski studies) when Valeant filed the '688 Patent application; (2) Valeant's claims in the '688 Patent prosecution directly contradicted its claims in the earlier '344 Patent prosecution that taking mesalamine *with food* made the drug more effective; (3) the '688 Patent was invalidly obtained because Valeant was aware that the Otterbeck Patents were themselves invalid based on prior art and vulnerable to challenge; and (4) by fraudulently obtaining the '688 Patent, Valeant prolonged its monopoly of Apriso and charged the government an "artificially high price for the drug," all while falsely certifying that the drug price was "fair and reasonable."

Placing Silbersher's allegations into the *Mateski* format, the misrepresented facts would be Valeant's claim that it was *not obvious* that Apriso would be effective without food, and that the Otterbeck Patents for Apriso's

delayed-release formula were original discoveries. And the alleged truth would be that it *was* obvious that Apriso can be effectively administered without food and that the Otterbeck patents were invalidly obtained. The scattered disclosures when viewed together possibly reveal some of these true and misrepresented facts, but nothing in combination from which fraud can reasonably be inferred. *See Mateski*, F.3d at 571. Valeant claimed in the '688 Patent that Apriso's effectiveness without food was not obvious. Nothing in the prosecution history of that patent, however, reveals the alleged truth—that it *was* obvious. In the '344 patent prosecution, Valeant claimed it *was* obvious that Apriso would be effective without food. But the application contains no misrepresentation. To prove fraud under the FCA, the relator must demonstrate that a person "knowingly present[ed]" a "fraudulent claim for payment" to the federal government. 31 U.S.C. § 3729(a)(1)(A). Silbersher's *qui tam* allegations provide a critical fact necessary for scienter: Falk and Valeant took conflicting positions in their patent prosecutions of the '344 and '688 Patents. Neither of these patent prosecutions, or any other disclosure, reveals that fact.

The *Law360* article states that "two claims in the ['688 Patent] were obvious based on a collection of references that included press releases from [Valeant] about clinical drug trials and some academic papers." But the *Law360* article does not disclose—nor even imply—that Valeant knowingly withheld information when applying for the '688 Patent. Similarly, the Brunner and Marakhouski studies (and Valeant's involvement in those studies) reinforce that Valeant understood the obviousness of Apriso's food-free

effectiveness. The studies do not, however, say anything about Valeant's application for the '688 Patent.

Finally, none of the qualifying disclosures—the '688 and '344 Patents, the *Law360* article, or the scientific studies—makes any mention of the Otterbeck Patents, much less disclose anything about the validity of these patents. Valeant allegedly misrepresented to the PTO that Apriso's delayed-release formula underlying the Otterbeck Patents was an original discovery. The patent prosecutions, however, do not reveal the alleged truth: the patents were invalidly obtained.

In sum, the scattered qualifying public disclosures may each contain a piece of the puzzle, but when pieced together, they fail to present the full picture of fraud. In his *qui tam* action, Silbersher filled the gaps by stitching together the material elements of the allegedly fraudulent scheme. *See Mateski*, 816 F.3d at 571.

Valeant contends that our decision in *Amphastar* should guide us to a different conclusion. In *Amphastar*, we affirmed the dismissal of FCA claims asserted against a drug manufacturer under the 1986 version of the public disclosure bar. *Amphastar*, 856 F.3d at 711. Amphastar, a generic drug manufacturer, filed an application seeking the Food and Drug Administration's approval to market a generic blood thinner. *Id.* at 701. The patent holder, Aventis, sued in federal district court for patent infringement. *Id.* at 701-02. In its amended answer and counterclaim, Amphastar asserted that Aventis had obtained an invalid patent through "misrepresentations," alleged that Aventis

"attempted to maintain or obtain a monopoly" over others, and claimed that Aventis "wrongfully derive[d] income" from this conduct. *Id.* at 704. After Amphastar succeeded in invalidating the patent, it filed a *qui tam* action against Aventis alleging the patentee had "obtained an illegal monopoly" over the drug "and then knowingly overcharged the United States." *Id.* at 702.

In upholding the dismissal of the *qui tam* suit, we grounded our decision on several factors that distinguish it from the present case. There, dismissal was based on the 1986 public disclosure bar, which prevented *qui tam* claims based upon public disclosures "in a criminal, civil, or administrative hearing" and did not require, as now, that the government be a party to the hearing. 31 U.S.C. § 3730(e)(4)(A) (1986); *see Amphastar*, 702 856 F.3d at 702 n.7. The *Amphastar* court also held that the prior public disclosure—the amended answer and counterclaim—"made nearly identical *allegations*" of fraud as the *qui tam* complaint. *Id.* at 704 (emphasis added). Here, no party contends that any public disclosure has made a direct claim of fraud. Finally, we concluded that Amphastar's prior amended answer and counterclaim also revealed sufficient facts from which fraud could be inferred, noting all the material facts had been disclosed in that filing except the claim of overcharging the government. *Id.* at 704-05. Unlike in *Amphastar*, no public disclosure here, individually or in combination, establishes facts from which fraud could be inferred. It is the combination of disclosures and conduct alleged in Silbersher's complaint that bring together the constituent elements of fraud.

We therefore determine that the public disclosure bar is not triggered here. In concluding that prior public disclosures did not reveal "substantially the same" allegations or transactions as described in Silbersher's *qui tam* complaint, we make no statement about the sufficiency of the pleadings. The Federal Rules require fraud to be pleaded with particularity, *see* Fed. R. Civ. P. 9(b), and the district court did not address whether Silbersher's allegations meet that requirement. We remand this case for the district court to consider whether Silbersher's *qui tam* action may proceed.

III. CONCLUSION

We reverse the district court's order dismissing Silbersher's action and remand the case for further proceedings consistent with this opinion.

APPENDIX B — ORDER OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA, FILED MAY 11, 2020

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT
OF CALIFORNIA

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

ZACHARY SILBERSHER, *et al.*,

Plaintiffs,

v.

VALEANT PHARMACEUTICALS
INTERNATIONAL, INC., *et al.*,

Defendants.

May 11, 2020, Decided
May 11, 2020, Filed

ORDER RE MOTION TO DISMISS

Re: Dkt. No. 36

This is a qui tam action under the federal False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733, and the counterpart statutes of twenty-eight states, and the District of Columbia. In a "corrected first amended complaint," Dkt. No. 10 ("CFAC"), plaintiff-relator Zachary Silbersher

alleges that defendants fraudulently obtained U.S. Patent No. 8,865,688 (the "'688 patent"), which allowed them to raise the price for the prescription drug Apriso by wrongfully excluding generic competitors. The false claim is said to be the inflated prices that Medicare, Medicaid and other government agencies paid for Apriso prescriptions.

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

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

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

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

BACKGROUND

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

The patent situation for mesalamine changed in October 2014, when the United States Patent and Trademark Office ("USPTO") issued the '688 patent, which has been assigned to Falk at all times relevant to this case. *Id.* ¶¶ 44, 80-82. The '688 patent relates to the remission of ulcerative colitis. Claim 1 recites a "method of maintaining the remission of ulcerative colitis in a subject comprising administering to the subject a granulated mesalamine formulation . . . once per day in the morning, without food." '688 patent, col. 34, ll. 11-15. The patent's other independent claim, claim 16, is identical

to claim 1, but adds the limitation of "advising the subject that granulated mesalamine should not be taken with antacids." *Id.* at col. 35, ll. 5-6.

After the '688 patent was issued, generics manufacturers sued to invalidate it. Dkt. No. 10 ¶¶ 15-16. The key proceedings took place before the Patent Trial and Appeal Board ("PTAB"). The lead plaintiff was GeneriCo, LLC, which filed a petition in December 2015 for inter partes review ("IPR") of the '688 patent. *GeneriCo, LLC v. Dr. Falk Pharma GmbH*, Case IPR2016-00297, 2017 Pat. App. LEXIS 5430, 2017 WL 2211672, at *1 (P.T.A.B. May 19, 2017). IPR was instituted to determine whether claims 1 and 16 were unpatentable as obvious over prior art that was available before the '688 patent application was filed. 2017 Pat. App. LEXIS 5430, [WL] at *3; *see also* 35 U.S.C. § 103(a) (2006).

In May 2017, the PTAB concluded that claims 1 and 16 were unpatentable as obvious.[1] The PTAB construed the '688 patent to address problems with prior mesalamine delivery systems such as "sensitivity to conditions that increase gastric pH and cause premature release of mesalamine (e.g., ingestion of a meal)." *GeneriCo*, 2017 Pat. App. LEXIS 5430, 2017 WL 2211672, at *2 (citation omitted). It determined that the method in the '688 patent was an obvious solution over several publicly available prior art references. These included two press

1. Because the claims were identical save for the antacid advisory and an omission of the article "a" from claim 16, the PTAB confined its discussion to claim 1. *GeneriCo*, 2017 Pat. App. LEXIS 5430, [WL] 2017 WL 2211672, at *3.

releases by Salix, one of which specifically announced the "successful completion" of clinical trials of a granulated mesalamine formulation with an enteric coating, 2017 Pat. App. LEXIS 5430, [WL] at *8, and three academic papers: (1) the "Davis --1985" study by S. S. Davis, *The Design and Evaluation of Controlled Release Systems for the Gastrointestinal Tract*, 2 J. Controlled Release 27-38 (1985); (2) the "Marakhouski" study by Y. Marakhouski, et al., *A Double-Blind Dose-Escalating Trial Comparing Novel Mesalazine Pellets with Mesalazine Tablets in Active Ulcerative Colitis*, 21 Alimentary Pharmacology Therapeutics 133-40 (2005); and (3) the "Brunner" study by M. Brunner, et al., *Gastrointenstinal Transit and Release of 5-Aminosalicylic Acid from ^{153}Sm-Labelled Mesalazine Pellets vs. Tablets in Male Healthy Volunteers*, 17 Alimentary Pharmacology Therapeutics 1163-69 (2003), 2017 Pat. App. LEXIS 5430, [WL] at *3, *8-*9. Davis --1985 discussed the effect of food on stomach pH and gastric emptying in connection with orally administered medications, as well as the positioned release of drugs in the colon, and used the treatment of ulcerative colitis as an example. 2017 Pat. App. LEXIS 5430, [WL] at *8.

The PTAB made a detailed analysis of this prior art in the course of invalidating the '688 patent. *See* 2017 Pat. App. LEXIS 5430, [WL] at *8-*19. Among other findings, it noted that the Salix press releases disclosed "the elements recited in the preamble [to the '688 patent] and most of paragraph [a] of claim 1" for the administration of a granulated mesalamine formulation. 2017 Pat. App. LEXIS 5430, [WL] at *9. It determined that the "without food" limitation "is suggested by either Marakhouski

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

The PTAB also found that a person of ordinary skill in the art would have been aware of these teachings and motivated to combine them to obtain the advantages of a granulated mesalamine formulation administered independent of food. 2017 Pat. App. LEXIS 5430, [WL] at *14-*15. Consequently, it concluded that GeneriCo had established that claims 1 and 16 of the '688 patent were unpatentable as obvious. 2017 Pat. App. LEXIS 5430, [WL] at *24.

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

2. The Law360 article meets the standards for admissibility set forth in Federal Rule of Evidence 201(b). The Court takes judicial notice of it solely as an indication of what information was in the

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

Plaintiff-relator Silbersher was deeply involved in GeneriCo's litigation against the '688 patent. He served as a lead counsel for GeneriCo in the PTAB proceedings, and again in defending the decision before the Federal Circuit on GeneriCo's behalf. *GeneriCo*, 2017 Pat. App. LEXIS 5430, 2017 WL 2211672; *Dr. Falk Pharma GmbH*, 774 F. App'x at 666.

The '688 patent litigation is the foundation on which the CFAC is built. The FCA claim is premised on the allegation that defendants wrongfully obtained the '688 patent by advising the USPTO during patent prosecution that "administering the claimed granulated mesalamine formulation without food was *not* obvious." Dkt. No. 10 ¶ 9 (emphasis in original). Silbersher references the patent law doctrine of inequitable conduct, which makes the claims in a patent unenforceable or invalid when the applicant violated the duty of candor during prosecution by deliberately omitting material prior art. *Id.* ¶ 72. He alleges that defendants "withheld" the Brunner and Marakhouski studies from the USPTO to falsely suggest that the advantage of administering the formulation without food was "unexpected," *id.* ¶¶ 14-15, and "because

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public realm at the time. *See Von Saher v. Norton Simon Museum of Art at Pasadena*, 592 F.3d 954, 960 (9th Cir. 2010).

they knew these papers would render the patent invalid as obvious in light of prior art," *id.* ¶ 99. The CFAC has a number of additional allegations about other omissions and inconsistencies in defendants' statements to the USPTO, *see, e.g., id.* ¶¶ 88-98, but the heart of Silbersher's case is that defendants obtained the '688 patent by "willful deceit," as "confirmed" by the PTAB decision, *id.* ¶ 15.

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

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

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

DISCUSSION

I. LEGAL STANDARDS

Rule 8 requires a complaint to provide "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). To meet that rule and survive a Rule 12(b)(6) motion to dismiss, a plaintiff must allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009) (citing *Twombly*, 550 U.S. at 556). The plausibility analysis is "context-specific" and not only invites, but "requires the reviewing court to draw on its judicial experience and common sense." *Id.* at 679.

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

The Court may consider judicially noticeable materials on a motion to dismiss. *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 999 (9th Cir. 2018). "Courts may take judicial notice of publications introduced to indicate what was in the public realm at the time, not whether the contents of those articles were in fact true." *Von Saher v. Norton Simon Museum of Art at Pasadena*, 592 F.3d 954, 960 (9th Cir. 2010). Similarly, "when a court takes judicial notice of another court's opinion [on a Rule 12(b)(6) motion], it may do so not for the truth of the facts recited therein, but for the existence of the opinion, which is not subject to reasonable dispute over its authenticity." *Lee v. City of Los Angeles*, 250 F.3d 668, 690 (9th Cir. 2001) (internal quotation and citation omitted). Defendants filed a request for judicial notice, Dkt. No. 37, which relator did not oppose, Dkt. No. 44.

II. THE FALSE CLAIMS ACT

At heart, the motion to dismiss asks whether Silbersher may bring a qui tam action based on public litigation before

the PTAB, a federal tribunal of administrative judges within the USPTO. The answer depends on the meaning and scope of the public disclosure bar and original source provisions in the FCA in light of amendments Congress made in 2010.

A. Background And Current Law

As many cases have observed, the FCA originated during the Civil War to fight corrupt suppliers who committed fraud against the United States. *See Vermont Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 781-82, 120 S. Ct. 1858, 146 L. Ed. 2d 836 (2000). The FCA imposes civil liability on one who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). It provides two mechanisms of enforcement. The government can bring suit, *id.* § 3730(a), or, as in this case, a private person may file a qui tam action as a relator "for the person and for the United States Government . . . in the name of the Government," *id.* § 3730(b)(1). The FCA incentivizes whistleblower suits by awarding the relator a bounty in the form of a substantial share of the fraudulent payments that are recovered, plus attorney's fees and costs. *Id.* § 3730(d).

The public disclosure bar restricts the information that can be used in a qui tam case to pursue these generous incentives. *Graham Cty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 293-94, 130 S. Ct. 1396, 176 L. Ed. 2d 225 (2010). The basic idea is that if the government already had notice to investigate the

potential fraud, a private action would be "parasitic," and should not be rewarded. *Id.* at 294.

Congress has modified the disclosure bar on several occasions to find "the golden mean between adequate incentives for whistle-blowing insiders with genuinely valuable information and discouragement of opportunistic plaintiffs who have no significant information to contribute of their own." *Id.* (citation omitted). From the enactment of the FCA to World War II, there were no constraints on the sources of information that could be used as the basis of a qui tam action. This period of openness culminated in 1943, when the Supreme Court permitted a relator to recover for a false claim he "discovered" simply by reading a federal criminal indictment. *Id.* (citing *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 63 S. Ct. 379, 87 L. Ed. 443 (1943)). Congress promptly reacted by amending the FCA to prohibit actions "based upon evidence or information in the possession of the United States . . . at the time such suit was brought." *Id.* (citation omitted).

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

of those suits that it deemed unmeritorious or downright harmful." *Id.* (emphasis in original).

Congress amended the disclosure bar again in 2010 in the Patient Protection and Affordable Care Act, the well-known healthcare reform bill. These amendments are the current law, and they govern this case. Silbersher does not allege that defendants made any false claims for payment until July 2012 at the earliest, so the 2010 amendments apply here. *See Hughes Aircraft Co. v. United States ex rel. Schumer*, 520 U.S. 939, 946 n.5, 117 S. Ct. 1871, 138 L. Ed. 2d 135 (1997).

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

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

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

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

B. The CFAC Would Have Been Barred Before 2010

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

This forthright concession is well taken. In a strikingly similar case, the Ninth Circuit affirmed the dismissal of virtually identical FCA claims under the 1986 disclosure bar. *Amphastar Pharmaceuticals Inc. v. Aventis Pharma SA*, 856 F.3d 696, 701 (9th Cir. 2017). A generic drug manufacturer had established in another action that a drug patent was unenforceable because the patentee had engaged in inequitable conduct by withholding material disclosures from the USPTO. *Id.* at 701-02. The generic company subsequently filed a qui tam complaint alleging that the patentee had "obtained an illegal monopoly" over the drug "and then knowingly overcharged the United States." *Id.* at 702. The circuit court affirmed dismissal on the grounds that the material allegations of fraud had been publicly disclosed in the litigation, and so were barred under the 1986 disclosure rules, which applied there. *Id.* at 702 n.7, 711. Silbersher is quite right to recognize that he wouldn't have a leg to stand on before the 2010 amendments.

Silbersher is also a far cry from the quintessential whistleblower plaintiff contemplated by the FCA. The "paradigm qui tam case is one in which an insider at

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

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

At best, Silbersher and the CFAC simply infer FCA violations from publicly available evidence. But a

"relator's ability to recognize the legal consequences of a publicly disclosed fraudulent transaction does not alter the fact that the material elements of the violation already have been publicly disclosed." *Prather*, 847 F.3d at 1105 (citations omitted).

C. The CFAC Is Barred Under Current Law

To be sure, Silbersher would protest that these observations are irrelevant because they are associated with the 1986 disclosure bar, and Congress opened the door to his case in 2010. It is true that precedents construing the pre-2010 FCA are not dispositive, but it also true that the changes in 2010 cannot be construed in a vacuum, as if the long history of the public disclosure bar did not exist. The question is whether the 2010 amendments were an incremental adjustment of the bar, or, as Silbersher argues, a major sea change such that a qui tam action that would have been an opportunistic lawsuit under prior law is now a good case.

As in all statutory interpretation cases, analysis begins with the plain words of the text. *Universal Health Servs., Inc. v. United States ex rel. Escobar*, ___ U.S. ___, 136 S. Ct. 1989, 1999, 195 L. Ed. 2d 348 (2016). The "inquiry must cease if the statutory language is unambiguous" and "the statutory scheme is coherent and consistent." *Schindler Elevator Corp. v. United States ex rel. Kirk*, 563 U.S. 401, 412, 131 S. Ct. 1885, 179 L. Ed. 2d 825 (2011) (citations omitted).

This fundamental rule is supplemented by two other principles of interpretation. The first is that claims of a sea change in the law should be treated with caution. Congress "does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions -- it does not, one might say, hide elephants in mouseholes." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468, 121 S. Ct. 903, 149 L. Ed. 2d 1 (2001). Silbersher's case assumes just that. It hinges on the proposition that Congress made a major change to the public disclosure bar in a short section inserted in a historic and massive healthcare reform law.

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

Appendix B

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

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

These factors warrant dismissal here, just as they did in *Amphastar Pharmaceuticals*. The prior proceeding there for inequitable conduct was held to constitute a

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

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

A good argument can be made that the PTAB decision also foreshadowed the CFAC's inequitable conduct theory, even though inequitable conduct is outside the scope of IPR proceedings. *See* 35 U.S.C. § 311(b). The PTAB highlighted that "Dr. Roland Greinwald is the head of research and development at Falk, with responsibility for

pharmaceutical development and clinical development" and "is a co-author of Marakhouski and Brunner." *GeneriCo*, 2017 Pat. App. LEXIS 5430, 2017 WL 2211672, at *6 (citations omitted). The point of this observation is that the failure to disclose those studies is even more suspect given that a co-author worked at Falk during the patent prosecution stage. Similarly, in concluding that it would have been obvious to a person of ordinary skill in the art to combine the two Salix press releases with the Marakhouski and Brunner studies, the PTAB found that the "evidence further establishes that all four references pertain to a granulated mesalamine formulation that was provided by or licensed from the same company -- Falk (Patent Owner)." 2017 Pat. App. LEXIS 5430, [WL] at *14. The PTAB raised several flags about the possibility of impropriety before the USPTO.

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

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

The point is not well taken. Defendants do not dispute that the first channel in Section 3730(e)(4)(A)(i) is not applicable because the PTAB proceedings were not "a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party." But the second channel in Section 3730(e)(4)(A)(ii) is not subject to the same government-party limitation. This subsection bars the use of substantially similar allegations or transactions disclosed "in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation." This plain text shows that the government need not be a party for the bar to arise in a federal forum. And under the prior version of the FCA, a "'[h]earing' in this context is synonymous with 'proceeding.'" *A-1 Ambulance Serv.*, 202 F.3d at 1244. This construction was not changed by Congress in 2010 and carries over to the amended statute. *See Lamar, Archer & Cofrin, LLP v. Appling*, ___ U.S. ___, 138 S. Ct. 1752, 1762, 201 L. Ed. 2d 102 (2018) (Congress is presumptively aware of a "longstanding judicial interpretation" and retains that meaning if language is not changed in amendments.).

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

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

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

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

D. Silbersher Is Not An Original Source

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

This effectively closes the door to Silbersher as an original source, but since leave to amend will be granted, a few additional points of guidance are warranted. Silbersher says for the first time in his opposition brief that he is an original source because he disclosed the Marakhouski and Brunner studies to the PTAB while representing GeneriCo in the IPR proceedings. In addition to the fact that an argument in a brief is no substitute for an allegation in the CFAC, *see Rothschild Digital Confirmation, LLC v. Skedulo Holdings Inc.*, Case No. 19-cv-2659-JD, 2020 U.S. Dist. LEXIS 47914, 2020 WL 1307016, at *5 (N.D. Cal. Mar. 19, 2020), the point is not of substantive help to him.

Pre-filing information disclosed in the course of a relator's job does not qualify as a "voluntary disclosure" under Section 3730(e)(4)(B)(i). *See Fine*, 72 F.3d at 741; *Prather*, 847 F.3d at 1107-08. To be sure, *Fine* and *Prather* involved government lawyers who were tasked with fraud investigation duties. But Silbersher was engaged in an

equivalent undertaking as the lead counsel for the generic drug manufacturer in the IPR. Silbersher's job was to find and use the Marakhouski and Brunner studies, and the Salix press releases, to attack the '688 patent. He "was no volunteer. He was . . . compelled to disclose the fraud by the very terms of his employment. He no more voluntarily provided information to the government than we, as federal judges voluntarily hear arguments and draft dispositions." *Fine*, 72 F.3d at 743-44. Silbersher did not require the incentive of a qui tam recovery to risk his job or reputation to provide the invalidating prior art to the PTAB. *Id.* at 743 n.3, 745. That's what he was paid to do, and he did it successfully.

Allowing a lawyer to qualify as an original source based on information a client paid him to obtain raises a possible ethical problem as well. It could incentivize lawyers to keep an eye out for the possibility of a personal bounty under the FCA when the attorney's attention should be focused solely on the client under the duties of loyalty and candor. *See id.* at 745 (discussing "perverse incentives" of rewarding government auditors for disclosing fraud under FCA). There is also the issue of why the lawyer should be allowed to appropriate an FCA claim from an underlying case, in lieu of the client who paid for the work. Both would be similarly situated as plaintiffs, and it is hard to see how the lawyer would necessarily have a better claim to the relator role.

Silbersher also might have qualified as an original source under the FCA if he had alleged "knowledge that is independent of and materially adds to the publicly

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

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

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

E. No Government Opposition To Dismissal

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

III. STATE LAW CLAIMS

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

CONCLUSION

The CFAC is dismissed under the public disclosure bar. The Court declines to take up defendants' other arguments for dismissal at this time. Although the efficacy of amendment is not readily apparent, the Court cannot say it would be futile. Silbersher may file an amended complaint consistent with this order by June 15, 2020. No new claims or parties may be added without the Court's prior approval. If this deadline is not feasible in light of the public health situation, the parties may agree on a new date by stipulation. If the parties cannot agree, a

party may ask the Court to extend the deadline. Failure to respond to this order by June 15, 2020, will result in dismissal with prejudice under Rule 41(b). The motion to stay discovery is terminated as moot.

IT IS SO ORDERED.

Dated: May 11, 2020

/s/ James Donato
JAMES DONATO
United States District Judge