FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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; STATE OF	No.20-16176 D.C. No. 3:18-cv-01496-JD OPINION

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

Argued and Submitted June 10, 2022
Portland, Oregon

Filed August 3, 2023

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

Opinion by Judge Sanchez

SUMMARY[**]

False Claims Act

The panel reversed 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 remanded 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

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

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

been publicly disclosed, including in *inter partes* patent review ("IPR") before the Patent and Trademark Office.

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.

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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 anti-inflammatory 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.

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 (1943), provides the paradigmatic example of a "parasitic" *qui tam* suit. Hess brought a *qui tam* action alleging that electricians colluded 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

[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).

$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 (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 (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. Millenium Pharms., Inc.*, 885 F.3d 623, 626 (9th Cir. 2018) (quoting *Mateski*, 816 F.3d at 1570) (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—
>
> (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,

[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).

> 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.

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*

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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).

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

[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 (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.

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.

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 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. *Id.* at *6. The PTAB agreed with GeneriCo and invalidated the '688 Patent as obvious. *Id.* 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

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

GeneriCo "had shown the challenged patent claims would have been 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.

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 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 (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 (2006); *Stone v. INS*, 514 U.S. 386, 397 (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(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 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."

Translating Silbersher's allegations into the formula, X stands for the misrepresented facts—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 Y stands for the alleged truth—it *was* obvious that Apriso can be effectively administered without food and that the Otterbeck Patents were invalidly obtained. The scattered disclosures possibly reveal both X and Y, but never the combination of the two. *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 mathematic terms, the '688 Patent discloses X but not Y. The '344 Patent, meanwhile, has the opposite problem. In that patent prosecution, Valeant claimed it *was* obvious that Apriso would be effective without food. But the '344 Patent application contains no misrepresentation, thus disclosing Y without X. 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. The *Law360* article and the medical studies thus reveal Y and not X.

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. Once again, the Otterbeck Patents disclose X but not Y.

In sum, the scattered qualifying public disclosures each contain a piece of the puzzle, but none shows the full picture. In his *qui tam* action, Silbersher filled the gaps by putting 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.