

2022 WL 3652967

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United States Court of Appeals, Ninth Circuit.

UNITED STATES of America; 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 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 Vermont; [State of Washington](#); Commonwealth of Massachusetts; Commonwealth of Virginia; District of Columbia, ex rel Zachary Silbersher, Relator, Plaintiffs-Appellees,

v.

ALLERGAN, INC.; Allergan USA, Inc.; [Allergan Sales, LLC](#); Forest Laboratories Holdings, Ltd.; Adamas Pharma LLC; Adamas Pharmaceuticals, Inc., Defendants-Appellants.

No. 21-15420

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Argued and Submitted January 10,
2022 San Francisco, California

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Filed August 25, 2022

Synopsis

Background: Patent attorney brought qui tam action under False Claims Act (FCA) alleging that pharmaceutical manufacturers fraudulently obtained patents to protect their brand-name drugs from price competition from generic drug competitors. The United States District Court for the Northern District of California, [Joseph C. Spero](#), United States Magistrate Judge, [506 F.Supp.3d 772](#), denied manufacturers' motion to dismiss. Manufacturers appealed.

Holdings: The Court of Appeals, [Gould](#), Circuit Judge, held that:

an ex parte patent prosecution is an “other Federal hearing” under FCA's public disclosure bar, and

attorney's claims were based on information from an “other Federal hearing.”

Reversed and remanded.

Procedural Posture(s): On Appeal; Motion to Dismiss for Failure to State a Claim.

Appeal from the United States District Court for the Northern District of California, [Joseph C. Spero](#), Magistrate Judge, Presiding, D.C. No. 3:18-cv-03018-JCS

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Before: Ronald M. Gould, Mark J. Bennett, and Ryan D. Nelson, Circuit Judges.

OPINION

GOULD, Circuit Judge:

Defendant-Appellants (“Appellants”) challenge the district court’s denial of their motion to dismiss relator Zachary Silbersher’s *qui tam* action. In his *qui tam* action, Silbersher alleged that Appellants violated the False Claims Act (FCA). Silbersher contended that Appellants fraudulently obtained patents on two drugs to combat *Alzheimer’s disease* and, by virtue of these fraudulent patents, prevented generic drug competitors from entering the market. According to Silbersher, preventing generic drug competitors from entering the market permitted Appellants to charge Medicare inflated prices for the two drugs. We have jurisdiction pursuant to 28 U.S.C. § 1292(b), and we reverse the district court’s denial of Appellants’ motion to dismiss and remand.

I. BACKGROUND

A. The FCA

*2 The FCA creates civil liability for “any person who (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or] (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.” 31 U.S.C. § 3729(a)(1). A private person, known as a *qui tam* relator, may bring a civil action under the FCA in the name of the U.S. government. 31 U.S.C. § 3730(b). The government may proceed with the action or decline to take over the action; if the government declines, then the relator can still pursue the action.¹ *Id.* § 3730(b)(4). The FCA incentivizes whistleblowers to come forward by offering successful relators up to thirty percent of the recovery. *Id.* § 3730(d).

“The FCA was enacted in 1863 with the principal goal of stopping the massive frauds perpetrated by large private contractors during the Civil War.” *Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 781, 120

S.Ct. 1858, 146 L.Ed.2d 836 (2000) (cleaned up). When it was originally enacted, “the FCA placed no restriction on the sources from which a *qui tam* relator could acquire information on which to base a lawsuit.” *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 current version of the FCA, though, provides limits on who can bring a *qui tam* action and the sources of information upon which they can base their suit. *See United States ex rel. Bennett v. Biotronik, Inc.*, 876 F.3d 1011, 1013 (9th Cir. 2017) (“[T]he right to bring *qui tam* suits is not absolute,” and “even if the Government does not intervene and take over the action, the FCA still does not allow every relator to bring a suit, but rather contains a series of ‘bars’ to such suit.”). These “bars” to suit are intended to prevent “parasitic” or “opportunistic” *qui tam* actions. *Schindler*, 563 U.S. at 412–13, 131 S.Ct. 1885. Here, the parties dispute the proper interpretation of the FCA’s public disclosure bar.

We have previously noted that the public disclosure bar is triggered 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 ‘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) (analyzing the 1986 version of the public disclosure bar). The public disclosure bar seeks to strike a balance between “encourag[ing] suits by whistle-blowers with genuinely valuable information, while discouraging litigation by plaintiffs who have no significant information of their own to contribute.” *United States ex rel. Mateski v. Raytheon Co.*, 816 F.3d 565, 570 (9th Cir. 2016) (analyzing the 1986 version of the public disclosure bar). Stated another way, the public disclosure bar prevents a relator from merely repackaging information enumerated in the public disclosure bar for personal profit by asserting an FCA claim.

B. The Patent Process

To obtain a patent, an inventor applies to the Patent and Trademark Office (PTO). A patent examiner at the PTO then reviews the application and either accepts or rejects the claims and explains why. A patent may only be issued if it would not have been obvious to a person having ordinary skill in the art to which the subject matter pertains. 35 U.S.C. § 103. Patent applications are generally kept confidential. *See* 35 U.S.C. § 122.

The initial patent examination (called a patent prosecution) is an *ex parte* administrative proceeding, and the applicant has “a duty of candor and good faith ... which includes a duty to disclose to the [PTO] all information known to that individual to be material to patentability.” 37 C.F.R. § 1.56(a). No patent should be granted if the application was fraudulent or the “duty of disclosure was violated through bad faith or intentional misconduct.” *Id.*

*3 If an examiner initially rejects an application, the applicant may request further examination or submit a modified application. The applicant may appeal a final rejection to the administrative judges of the Patent Trial and Appeal Board (“PTAB”). The Applicant files a brief in support of their application to the PTAB, the examiner files an answering brief, and the applicant files a reply. The PTAB can hear oral argument. If the PTAB upholds the examiner's rejection, the applicant may appeal to the Federal Circuit or the Eastern District of Virginia. If a patent is granted, a private party can challenge the validity of the patent, but that type of challenge is often an expensive and long process.

C. Silbersher's claims

Silbersher, a patent attorney, brought the present *qui tam* action against Appellants in May 2018. Silbersher alleged that Appellants unlawfully obtained several patents critical to two drugs used to treat Alzheimer's disease, Namenda XR and Namzaric. Silbersher asserted that Appellants, by using these allegedly unlawfully obtained patents, were able to block competitors from producing generic versions of both drugs.² As a result, Medicare paid inflated prices for the drugs. Silbersher estimates that the entry of generic versions of a drug can reduce prices by more than 80%. Medicare reimbursed approximately 5.4 million prescriptions for Namenda XR and Namzaric in 2014 and 2015, costing nearly \$1.5 billion.

The U.S. Department of Justice and all of the states that have analogues to the federal *qui tam* provision, and the District of Columbia, declined to intervene in Silbersher's action. California submitted a statement of interest stating that Silbersher's “suits, if successful, may set an important precedent that would discourage drug companies from taking advantage of the *ex parte* nature of patent proceedings by withholding or misrepresenting material information relating to patentability and thereby significantly reduce the amount governments and insurers pay for important medicines.”

It is salient and potentially controlling that the key factual information underlying Silbersher's complaint was *all* publicly disclosed and much could be found in websites maintained by the PTO and other government agencies. Silbersher has brought two similar FCA suits.³

The district court denied Appellants' motions to dismiss, holding that the public disclosure bar did not apply to Silbersher's allegations and that Silbersher had properly stated claims against Appellants. *See Silbersher v. Allergan Inc.*, 506 F. Supp. 3d 772, 809 (N.D. Cal. 2020). Appellants timely appealed. For the reasons that follow, we reverse and remand.

II. STANDARD OF REVIEW

We review a district court's ruling on a motion to dismiss a FCA action *de novo*. *United States ex rel. Hartpence v. Kinetic Concepts, Inc.*, 792 F.3d 1121, 1126 (9th Cir. 2015) (en banc).

III. DISCUSSION

*4 Appellants argue that Silbersher's claims fail because the public disclosure bar prevents his action. The public disclosure bar was first adopted in 1986, *Schindler*, 563 U.S. at 412, 131 S.Ct. 1885,⁴ and it was last modified in 2010. Our Circuit has not yet analyzed the revised public disclosure bar, and so the issues before us are of first impression. Today, we reaffirm that essential elements of the test for triggering the public disclosure bar we used in *Solis*: that “(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. *See* 885 F.3d at 626.⁵ Only the first element is at issue here.⁶

The language of the statute is always where we begin; if the statute is clear, we go no further. *See Hartpence*, 792 F.3d at 1128. The current version of the public disclosure bar contains three “prongs” that each require federal courts to dismiss a claim if it has already been publicly disclosed. The public disclosure bar now states that:

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).

Appellants contend that three portions of the public disclosure bar block Silbersher's claims: (1) Appellants contend that Silbersher's claims are based on information publicly disclosed in an "other Federal ... hearing" under prong (ii); (2) Appellants contend that Silbersher's claims are based on information publicly disclosed in an "other Federal report" under prong (ii); and (3) Appellants contend that Silbersher's claims are based on information publicly disclosed "from the news media" under prong (iii). Any one of Appellants' claims, if valid, is sufficient to invoke the public disclosure bar and warrant reversal of the district court's ruling.

*5 We inform our analysis with two broad principles that the Supreme Court has used to analyze the public disclosure bar. First, the 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.'" *Schindler*, 563 U.S. at 408, 131 S.Ct. 1885 (quoting *Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 290, 293 n.12, 130 S.Ct. 1396, 176 L.Ed.2d 225 (2010)). Second, the Supreme Court has commended the idea that there is a "broad scope of the FCA's public disclosure bar." *Id.* While both of these comments related to the previous version of the public disclosure bar, both are helpful in guiding our analysis.

We next address the statutory language of the public disclosure bar, see *Wilson*, 559 U.S. at 286, 130 S.Ct. 1396, beginning with Appellants' argument that a patent prosecution is an "other Federal ... hearing" under prong (ii). A patent prosecution is an administrative hearing. Analyzing the 1986 version of the public disclosure bar, we defined a "hearing" as a "proceeding" that also "encompasses publicly-filed documents" submitted as part of the proceeding. *A-1 Ambulance Serv., Inc. v. California*, 202 F.3d 1238, 1244

(9th Cir. 2000). Although *A-1 Ambulance* examined the 1986 version of the public disclosure bar, see *id.* at 1243, nothing about the changes made to the public disclosure bar in 2010 suggests that "hearing," as defined in the current version of the public disclosure bar, has a different meaning. The government conducts numerous administrative hearings in which a government agency adjudicates the merits of the claim or request. See *id.* at 1243–44; *Administrative Hearing*, Black's Law Dictionary (11th ed. 2019) ("An administrative-agency proceeding in which evidence is offered for argument or trial.").

These definitions make clear that a patent prosecution is an administrative hearing. In patent prosecutions, inventors submit applications to the PTO, an administrative agency, in which they can argue that their claimed inventions are novel and not obvious to a person with ordinary skill in the art. The PTO conducts a proceeding in which it either accepts or rejects the application; and, if the PTO rejects the application, the inventor has the right to appeal.

Our next step is to determine whether, as Appellants argue, a public patent prosecution is a hearing under prong (ii), as an "other Federal ... hearing."

Prong (ii) requires courts to dismiss a claim that has been publicly disclosed "in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation." Section 3730(e)(4)(A)(ii). As we discussed above, a "hearing" in the public disclosure bar means a "proceeding." Two features of prong (ii) help us determine whether an *ex parte* patent prosecution is an "other Federal ... hearing." First, "hearing" is listed as part of a string of four nouns: "report, hearing, audit, or investigation." We take into account the canon of *noscitur a sociis*, whereby "a word is known by the company it keeps." *Yates v. United States*, 574 U.S. 528, 543, 135 S.Ct. 1074, 191 L.Ed.2d 64 (2015). All four nouns apply to a fact-finding or investigatory process "to obtain information," see *Schindler*, 563 U.S. at 410, 131 S.Ct. 1885, and together indicate that Congress intended for prong (ii) to cover a wide array of investigatory processes.⁷ This conclusion is reinforced by the fact that prong (ii) begins with Congress and the Government Accountability Office, which often seek to obtain information by way of a hearing, audit, or investigation and issue those findings in a report.

*6 The second feature of prong (ii) is that all four of these nouns, including hearing, are modified by both "other" and "Federal." An *ex parte* patent prosecution is clearly

“Federal”: the PTO is an agency of the U.S. Department of Commerce. To determine the meaning of “other,” we look to dictionaries. *See id.* at 407–08, 131 S.Ct. 1885 (looking to dictionaries to help determine the meaning of “report” in the public disclosure bar). “Other” means distinct from that just mentioned, different, or additional. *See, e.g., Other*, Merriam-Webster’s Third New International Dictionary, 1598 (2002). “[O]ther Federal” here clearly means Federal reports, hearings, audits, or investigations not from Congress or the Government Accountability Office, a definition that of course includes *ex parte* administrative hearings before the PTO. Congress, then, intended for “other” to be a broader category that includes additional, information-obtaining methods distinct from those already mentioned.

For these reasons we conclude that an *ex parte* patent prosecution is an “other Federal ... hearing” under prong (ii). The use of the adjective “other” shows that Congress wanted to ensure that the public disclosure bar applied to Federal reports, hearings, audits, and investigations in addition to those covered elsewhere in the public disclosure bar. Congress’s addition of the word “Federal” also shows that it intended to cover reports, hearings, audits, and investigations by the legislative and executive branches of government. Our recognition that an *ex parte* patent prosecution is an “other Federal ... hearing” conforms with the Supreme Court’s instruction that the public disclosure bar has a “generally broad scope.” *Schindler*, 563 U.S. at 408, 131 S.Ct. 1885. An *ex parte* patent prosecution fits comfortably within prong (ii).

We are not persuaded by Silbersher’s counterarguments. Silbersher primarily argues 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, including those that would otherwise be captured by the plain language of prong (ii). There is an obvious problem with this approach: It would read much of prong (ii)—that which deals with any “other Federal ... hearing”—seemingly out of existence. Silbersher’s reading runs contrary to the Supreme Court’s instruction that “[i]t is our duty ‘to give effect, if possible, to every clause and word of a statute.’ ” *Duncan v. Walker*, 533 U.S. 167, 174, 121 S.Ct. 2120, 150 L.Ed.2d 251 (2001) (quoting *United States v. Menasche*, 348 U.S. 528, 538–39, 75 S.Ct. 513, 99 L.Ed. 615 (1955)).

Our determination that an *ex parte* patent prosecution is an “other Federal ... hearing” under prong (ii) does not

make prong (i) superfluous. Prong (ii), as we discussed above, is primarily concerned with proceedings to gain information. By contrast, prong (i)’s use of the phrase “Federal criminal, civil, or administrative hearing” 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. The adversarial nature of prong (i) is also supported by Congress’s use of the word “party” to describe the government’s role. *See Party*, Black’s Law Dictionary (11th ed. 2019) (“One by or against whom a lawsuit is brought; anyone who both is directly interested in a lawsuit and has a right to control the proceedings, make a defense, or appeal from an adverse judgment; Litigant”). While there is potential overlap between prong (i) and prong (ii), the Supreme Court, analyzing the 1986 version of the public disclosure bar, noted that “the statute contemplates some redundancy.” *Schindler*, 563 U.S. at 410, 131 S.Ct. 1885; *see also A-I Ambulance*, 202 F.3d at 1245 (“It is unlikely that Congress would have referenced administrative hearings twice in the same sentence, unless it intended to allude to different contexts.”). This guidance did not become suspect after the public disclosure bar was modified in 2010, and we have previously explained that some potential redundancy in the FCA does not justify reading the “statutory language in an overly narrow manner.” *Bennett*, 876 F.3d at 1019. The possibility that some hearings might be encompassed by both prongs (i) and (ii) does not change our analysis.

*7 The nature of patent prosecutions also demonstrates that our interpretation does not render prong (i) superfluous. Here, the PTO granted the patents underlying Silbersher’s claim without Appellants needing to appeal; the patent prosecutions were *ex parte* hearings in which the government was not a party, and they fell under prong (ii). But when the PTO rejects a patent application and the inventor appeals, the appeal could fall under prong (i) but not prong (ii).

Our result today does not conflict with our prior holding in *A-I Ambulance*. In *A-I Ambulance*, we held that public agency proceedings were administrative hearings under prong (i). 202 F.3d at 1243–44. However, that decision analyzed the 1986 version of the public disclosure bar; the current version of the public disclosure bar added the government-as-a-party limitation to prong (i) and “other Federal” to prong (ii). Our holding today relies on different language than that which we analyzed in *A-I Ambulance*. Further, *A-I Ambulance* neither held that all public agency

proceedings must be under prong (i) nor that some other type of proceeding could not fall under both prongs (i) and (ii).

Because we hold that Silbersher's claims are based on information publicly disclosed in an "other Federal ... hearing" under prong (ii), we need not reach Appellants' remaining arguments regarding the public disclosure bar.⁸

IV. CONCLUSION

Even though the public disclosure bar is triggered, Silbersher may still bring his *qui tam* action if he is an "original source"

of the information in his complaint. 31 U.S.C. § 3730(e)(4)(A); *Solis*, 885 F.3d at 627. The district court did not reach this issue, see *Silbersher*, 506 F. Supp. 3d at 809 n.17, and we express no view on it. We remand to the district court for further proceedings in light of our holding here.

REVERSED AND REMANDED.

All Citations

--- F.4th ----, 2022 WL 3652967

Footnotes

- 1 Unless the court and the Attorney General give written consent to the dismissal. *Id.* § 3730(b)(1).
- 2 By obtaining different patents protecting different aspects of drugs at different times, a company can extend the period during which it has exclusive rights to produce a drug. Even if a generic manufacturer challenges a patent underlying a drug, the patent owner is entitled to an automatic 30-month FDA stay of approval of the generic drug(s). 21 U.S.C. § 355(j)(5)(B)(iii). As a result, simply listing an existing patent as related to a drug can delay generic competition.
- 3 *Silbersher v. Valeant Pharms. Int'l, Inc.*, 445 F. Supp. 3d 393, 408 (N.D. Cal. 2020), *appeal pending* (granting motion to dismiss Silbersher's claims due to public disclosure bar); *Silbersher, v. Janssen Biotech, Inc.*, 576 F.Supp.3d 212, 232 (D.N.J. 2021) (granting one defendant's motion to dismiss).
- 4 The 1986 version of the public disclosure bar, in full, stated that:

No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.
- 31 U.S.C. § 3730(e)(4)(A) (1986) (footnote omitted).
- 5 *Solis* analyzed the 1986 version of the public disclosure bar. The third element of the *Solis* test mirrored the language in the public disclosure bar in the 1986 version, requiring that a relator's action be "based upon" publicly disclosed allegations. See 885 F.3d at 626. The 2010 version of the public disclosure bar deleted the "based upon" language and replaced it with "substantially the same." As we have previously noted, this change did not materially alter the elements required to meet the public disclosure bar. See *Mateski*, 816 F.3d at 569 n.7, 573 & n.14.
- 6 Silbersher argues that the information upon which he based his *qui tam* action was not "substantially the same" as that which was publicly disclosed. See 31 U.S.C. § 3730(e)(4)(A). Silbersher waived this argument before the district court, so we do not consider it here. See *United States v. Valencia-Lopez*, 971 F.3d 891,

902 n.10 (9th Cir. 2020). And it is not contested that the information underlying his complaint was publicly disclosed.

- 7 See *Report*, Black's Law Dictionary (11th ed. 2019) ("A formal oral or written presentation of facts or a recommendation for action"); *Hearing*, Black's Law Dictionary (11th ed. 2019) ("Any setting in which an affected person presents arguments to a decision-maker"); *Audit*, Black's Law Dictionary (11th ed. 2019) ("A formal examination of an individual's or organization's accounting records, financial situation, or compliance with some other set of standards."); *Investigation*, Black's Law Dictionary (11th ed. 2019) ("The activity of trying to find out the truth about something ... esp.... an authoritative inquiry into certain facts").
- 8 We also need not reach Appellant Allergan's argument that Silbersher failed to plead a false claim because we have reversed on the public disclosure bar, rendering that challenge to the pleading moot.