

No. 23-1093

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

**RESPONDENT ZACHARY SILBERSHER'S
BRIEF IN OPPOSITION**

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BRIEF IN OPPOSITION

The petition presents two questions about a provision of the False Claims Act (FCA) commonly described as the “public disclosure bar.” Neither question comes close to warranting certiorari.

The public disclosure bar requires dismissal of a *qui tam* action, 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).

The first question presented is whether the public disclosure bar applies to *qui tam* relators who “stitch together” public disclosures. Pet. i. The answer to this question does not control the outcome of this case, and the decision below does not implicate any circuit split. This is because the court of appeals did not hold, as petitioners assert, that respondent merely combined qualifying public disclosures to form his allegations. Instead, the court was crystal clear that the qualifying public disclosures “collectively,” Pet. App. 28a, “in combination,” *id.* at 29a, 31a, and “pieced together,” *id.*

at 30a, did not disclose the fraud alleged by respondent. Instead, it was respondent's insights and additional facts that allowed him to allege the elements of fraud. No circuit holds that the public disclosure bar is triggered when, as here, the qualifying public disclosures do not collectively disclose a combination of facts sufficient to permit a reasonable inference of fraud.

Absent a circuit split, the first question presented is plainly not important enough to merit this Court's review. FCA cases represent a small sliver of federal litigation—and the public disclosure bar only compels dismissal of a subset of FCA cases: those in which the government does not intervene, the relator chooses to proceed, the public disclosure bar's criteria are met, the government does not move to dismiss the case itself or oppose dismissal on public disclosure grounds, and the relator does not qualify as an “original source.” And cases involving the specific question presented—*i.e.*, ones in which an alleged fraud is not disclosed in a single source, but is instead disclosed only through some combination of multiple qualifying public sources—comprise only a subset of those. All-in, it would be surprising if the question presented were dispositive more than once a year.

Even if the question were presented, and even if it were important enough to merit this Court's review, this case would be a poor vehicle for deciding it. Before the Court can decide whether respondent merely stitched together public disclosures, it must determine what qualifies as a public disclosure in the first place. In this case, petitioners themselves are trying to smuggle in additional disclosures through their second question presented—and respondent will argue as alternative grounds for affirmance that other sources

the Ninth Circuit counted in petitioners' favor should not have counted. If the Court agrees with respondent about those points, then the premise of the first question clearly will not hold.

The second question presented is a complete nothingburger. Petitioners ask this Court to decide whether statements made during *inter partes* review (IPR) proceedings before the Patent Trial and Appeal Board (PTAB) fall within the scope of the public disclosure bar. This issue is only ever potentially relevant in FCA cases arising out of patent fraud—and then only when an IPR has occurred—which is a vanishingly small sample of cases. Indeed, to our knowledge, this question has only arisen in two cases: this one, and another in the District of New Jersey. In both cases, courts agreed that IPRs are not qualifying public disclosures except when the government is a party to those proceedings (*e.g.*, when a government-owned patent is challenged, or when the government intervenes in an IPR). In any event, even if the Court were to hold that the IPR in this case qualified, the public disclosure bar still would not be triggered because the information disclosed in the IPR involving petitioners' patent does not bridge the gaps in the public disclosures to reveal the alleged fraud. Thus, there is no split, the question is not important enough to merit this Court's review, and the court below reached the correct result.

The bottom line is that the court of appeals applied legal rules that are, if anything, too defendant-friendly—and it nevertheless held that petitioners were not entitled to dismissal at the pleading stage on this affirmative defense. That is a workaday appeal that plainly does not warrant this Court's review.

STATEMENT OF THE CASE

1. Respondent alleges that petitioners knowingly sought and obtained an invalid patent protecting the ulcerative colitis drug Apriso from generic competition so that petitioners could unlawfully maintain a monopoly allowing them to overcharge the government and other payors for the drug. Pet. App. 13a-16a.

Claims 1 and 16 of the offending patent, U.S. Patent No. 8,865,688 (the '688 Patent), claim that it is inventive to take Apriso's active ingredient, mesalamine, without food. Pet. App. 14a. That claim was false when made. In fact, two scientific papers in the journal *Alimentary Pharmacology & Therapeutics* in 2003 and 2005 showed that mesalamine could be taken without food. *Id.* at 15a. These studies are referred to in this litigation as the Brunner and Marakhouski studies. *Ibid.* The patent accordingly never should have issued because the claimed invention was obvious. *See* 35 U.S.C. § 103 (providing that patents may not be obtained for inventions that a person of ordinary skill in the art would deem obvious as of the effective filing date of the claimed invention).

In 2015, a drug manufacturer called GeneriCo, together with others, initiated an IPR before the PTAB arguing that the '688 Patent was invalid as obvious. Pet. App. 15a. After hearing the arguments from both sides, the PTAB issued a detailed decision (about 15,000 words of technical prose), agreeing that the Brunner and Marakhouski studies rendered claims 1 and 16 of the '688 Patent obvious, and thus canceling those claims. *Ibid.* The government did not intervene in or otherwise present any arguments in the IPR or the ensuing appeal (where the Federal Circuit affirmed the PTAB's decision).

Respondent is a patent attorney with particular expertise in patents relating to drugs and biologics, and he represented GeneriCo in the IPR. Pet. App. 16a. On its own, the IPR and the work behind it did not show that petitioners engaged in fraud. Indeed, most invalid patents aren't the product of fraud on the Patent Office. But in this case, respondent performed an additional investigation and determined that the '688 Patent was an exception from the norm. *Id.* at 16a-17a.

Among other facts, respondent discovered that petitioners had not disclosed the Brunner and Marak-houski studies to the Patent Office while prosecuting the '688 Patent (Pet. App. 17a)—despite petitioners having a “duty of candor and good faith” requiring them to disclose any information that might be material to patentability. 37 C.F.R. § 1.56(a). He further discovered that petitioners likely knew about these studies because some of their own personnel participated in the studies. Pet. App. 15a. Respondent also reviewed petitioners' other statements to the Patent Office—in connection with unrelated patents—and discovered instances where petitioners had made conflicting claims. Thus, respondent discovered that in 2006, while petitioners were prosecuting the application for a different patent—which would become U.S. Patent No. 8,921,344 (the '344 Patent)—petitioners claimed that the more inventive way to take mesal-amine was *with food*, and presented data to that effect. Pet. App. 16a. This was the opposite of what petitioners told the examiner when seeking the '688 Patent. *Ibid.* Petitioners also withheld the data that would have undermined their claim for the patentability of the '344 Patent—even though the '344 Patent and the

'688 Patent shared an inventor, and even though the same attorney prosecuted both applications. *See id.* at 16a-17a.

Respondent's investigation did not end there. He also investigated the importance of the '688 Patent to the market for Apriso, including by determining that other patents protecting Apriso (called the Otterbeck Patents) were so weak that they would not protect Apriso from competition. Pet. App. 16a-17a. He further reviewed market information to determine that generic competitors were ready to enter the market. *Ibid.* And he studied how petitioners used the '688 Patent to block generic competition. *Ibid.* Finally, respondent learned how petitioners' use of the '688 Patent enabled them to overcharge government health care programs for Apriso. *Ibid.*

Based on these facts, respondent brought this FCA action against petitioners, alleging that they knowingly presented and caused others to present false claims to government payors by using fraud to cause the government to buy Apriso when it would have been buying cheaper generics, and to pay more for Apriso than it lawfully should have. Pet. App. 6a, 16a-17a.

2. The district court agreed with petitioners that the public disclosure bar compelled dismissal of this action. Pet. App. 35a. The court held that the IPR disclosed "substantially the same" allegations or transactions as alleged in respondent's complaint (*id.* at 52a), and that respondent did not qualify as an original source of the information in his complaint who could proceed even if the public disclosure bar had been triggered (*id.* at 57a-59a).

3. The Ninth Circuit reversed. Pet. App. 6a. On appeal, the principal dispute was about whether most of the relevant information—the information disclosed in the IPR, the information disclosed on patent prosecution dockets, and the Brunner and Marakhouski studies—fell within the scope of the public disclosure bar at all. Pet. App. 18a-25a. Respondent argued that the answer was “no” as to all of these. *See id.* He also argued that the public sources did not collectively disclose the alleged fraud, and that he qualified as an original source who could proceed even if the public disclosure bar had been triggered.

With respect to the qualifying sources, the Ninth Circuit adopted a rule that was generous to petitioners. Thus, the court held, based on intervening precedent in *United States ex rel. Silbersher v. Allergan*, 46 F.4th 991 (9th Cir. 2022), that information disclosed on patent prosecution dockets falls within the public disclosure bar’s second channel as an “other Federal . . . hearing.” Pet. App. 22a. The court also assumed, without deciding, that the Brunner and Marakhouski studies constitute “news media” and therefore fall within the public disclosure bar’s third channel. *Id.* at 25a.

The Ninth Circuit nevertheless held that IPRs are not qualifying public disclosures because, under *Allergan*, adversarial hearings like IPRs are addressed by the public disclosure bar’s first channel, which applies only to administrative hearings “in which the Government or its agent is a party.” 31 U.S.C. § 3730(e)(4)(A)(i). The court held that in this context, the word “party” is analogous to a “litigant,” not a decision-maker. Pet. App. 24a. Thus, “because the government was not a ‘party’ to the IPR concerning the

'688 Patent, the proceeding [there] was not a channel (i) disclosure." *Id.* at 23a.

Based on these holdings, the Ninth Circuit considered "[t]he prosecution histories of the '344, '688, and Otterbeck Patents," as well as "the Brunner and Marakhouski studies" and a Law360 article discussing the IPR result, in determining whether public sources disclosed substantially the same allegations or transactions as respondent's complaint. Pet. App. 25a.

The court of appeals concluded that the answer was "no." The court explained that it was applying the same legal framework to this question that it had applied before the 2010 amendments, reasoning that Congress had effectively codified the Ninth Circuit's prior standard for determining when public disclosures and a relator's allegations are sufficiently similar to trigger the public disclosure bar. Pet. App. 26a-27a. Reciting a ubiquitous legal test (the so-called X+Y=Z test, originally coined by the D.C. Circuit) that courts have applied for years, the Ninth Circuit "conclude[d] that the qualifying public disclosures here do not collectively disclose a combination of facts sufficient to permit a reasonable inference of fraud." *Id.* at 28a. The court of appeals acknowledged that petitioners had identified some "scattered disclosures" that "when viewed together possibly reveal some of these true and misrepresented facts," but it determined that even together, these disclosures revealed "nothing in combination from which fraud can reasonably be inferred." *Id.* at 29a. Indeed, even "when pieced together," the "scattered qualifying public disclosures . . . fail to present the full picture of fraud." *Id.* at 30a. It was respondent who "filled the gaps by stitching

together the material elements of the allegedly fraudulent scheme” with additional allegations. *Ibid.*

Because the court determined that the public disclosure bar did not apply in the first instance, it declined to reach respondent’s argument that he was an original source. The court also did not reach petitioners’ other pleading-stage defenses. Pet. App. 32a.

4. Petitioners sought rehearing en banc, complaining—as they do here—that the Ninth Circuit held that the public disclosure bar only applies when the alleged fraud was disclosed in a single public source. *See* C.A. Reh’g Pet. 1. Respondent explained that the Ninth Circuit held no such thing, pointing to language in the panel opinion making it clear that the panel deemed the public disclosures collectively insufficient to disclose the fraud alleged in the complaint. *See* C.A. Reh’g Resp. 2.

The Ninth Circuit denied rehearing, issuing an amended opinion making it even more clear that the court of appeals was not, as petitioners suggest, limiting the public disclosure bar to instances in which the relevant disclosures appear in a single source. *See* Pet. App. 5a. Despite petitioners’ vociferous arguments that the panel decision created a circuit split and overturned settled Ninth Circuit precedent, “no judge . . . requested to vote on whether to rehear the matter en banc.” *Ibid.*

5. The petition for a writ of certiorari followed.

REASONS TO DENY THE WRIT**I. The First Question Presented Does Not Warrant Certiorari**

1. Petitioners ask this Court to decide whether a relator can avoid the public disclosure bar by stitching together public disclosures. But the Ninth Circuit did not hold, as petitioners suggest, that the public disclosures in this case collectively disclosed the alleged fraud, and that respondent merely stitched them together. Instead, the Ninth Circuit held that the public disclosures did *not* collectively disclose the fraud, and that respondent added the key information necessary to plead fraud. Pet. App. 30a.

Don't take our word for this. The full paragraph from which petitioners draw the "stitched together" language reads:

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.

Pet. App. 30a (citation omitted). In context, it is quite clear that the Ninth Circuit was *not* saying that the qualifying public disclosures collectively disclosed the alleged fraud. It was saying the opposite. Nor was it even saying that respondent stitched together the public disclosures. It was saying he stitched together the elements of fraud by supplementing the collectively insufficient public disclosures with additional material allegations.

There is more. The court of appeals clarified on three additional occasions that it was evaluating the public disclosures collectively:

- “[T]he qualifying public disclosures here do not *collectively* disclose a combination of facts sufficient to permit a reasonable inference of fraud.” Pet. App. 28a (emphasis added).
- “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.” Pet. App. 29a (emphasis added).
- “[N]o public disclosure here, individually *or in combination*, establishes facts from which fraud could be inferred.” Pet. App. 31a (emphasis added).

Not only that, the court of appeals amended its opinion in response to petitioners’ rehearing petition—which raised precisely the same objection petitioners raise here—to remove any language that might have suggested a different legal rule.

The Ninth Circuit’s conclusion was correct. All of the public disclosures that the Ninth Circuit considered were completely innocuous. They included, for example, the prosecution histories of the relevant patents—none of which stated that petitioners knowingly withheld information while prosecuting the ’688 Patent, nor revealed the weakness inherent in the Otterbeck Patents. They included the Brunner and Makhouski studies, which themselves are just scientific papers—and say nothing about patent prosecutions or Apriso at all. And they included a Law360 article summarizing the result of the IPR, which itself did not find fraud or even misconduct; it merely found the ’688

Patent invalid. It is accordingly fanciful to say that the fraud alleged here—*i.e.*, petitioners using a fraudulently obtained patent monopoly to overcharge the government for Apriso—had ever been publicly disclosed in any combination of public sources.

At bottom, the Ninth Circuit applied the rule petitioners say is correct to reach the right result. Petitioners are unhappy with how the court of appeals applied that rule to the facts of this case. But even if petitioners' gripes had merit (and they do not), "the misapplication of a properly stated rule of law" is not grounds for certiorari. S. Ct. R. 10. Indeed, to give petitioners any relief, this Court would not only have to determine the correct legal rule (which, if petitioners prevail, would be the very rule the Ninth Circuit itself applied)—but would also have to apply that rule to the complex facts of this case, getting into the nitty-gritty of respondent's allegations and the specific public disclosures petitioners raised. That would be a profligate use of this Court's resources.

2. Freed from petitioners' mischaracterizations of the holding, the Ninth Circuit's decision does not conflict with precedent from any other circuit. No circuit holds that the public disclosure bar is triggered when qualifying public disclosures reveal some, but not all, of the material elements of fraud. On the contrary, the rule in other circuits is that "the public disclosure bar is not implicated—even if one or more of a claim's essential elements are in the public domain—unless the exposed elements, taken together, provide adequate notice that there has been a fraudulent transaction." *United States ex rel. Ibanez v. Bristol-Myers Squibb Co.*, 874 F.3d 905, 918-19 (6th Cir. 2017); *see also Grant on behalf of United States v. Zorn*, 107 F.4th

782, 792-93 (8th Cir. 2024); *United States ex rel. Feingold v. AdminaStar Fed., Inc.*, 324 F.3d 492, 495 (7th Cir. 2003). As the D.C. Circuit explained, the public disclosure bar is not triggered “merely because innocuous information necessary though not sufficient to plaintiff’s suit has already been made public.” *United States ex rel. Springfield Terminal Ry. Co. v. Quinn*, 14 F.3d 645, 657 (D.C. Cir. 1994). That is what the Ninth Circuit held here. The lack of a circuit split is a clear reason to deny certiorari.

3. The question presented is also not important enough to warrant this Court’s review. First, *qui tam* cases comprise a tiny sliver of the federal docket. In fiscal year 2023, for example, relators filed 712 such actions. See U.S. Dep’t of Justice, Fraud Statistics – Overview, at 2 (2024), <https://www.justice.gov/opa/media/1339306/dl?inline>. The prior year, it was 658. *Ibid.* Compare that to the number of cases filed in federal district courts during the 12-month period from March 2023 to March 2024, which was 347,991. See U.S. Courts, Federal Judicial Caseload Statistics, Table C-U.S. District Courts-Civil Federal Judicial Caseload Statistics (Mar. 31, 2024), <https://www.uscourts.gov/file/78648/download>. Even using the high-end number of *qui tam* actions, they account for only about two tenths of a percent of the federal case load.

The number of cases implicating the question presented is smaller still. The issue can only ever arise in FCA cases where *all* of the following conditions are met: (1) the government declines to intervene; (2) the relator chooses to carry the case forward; (3) the allegations of fraud were not publicly disclosed (because disclosures of allegations will necessarily be in a single source); and (4) the alleged fraudulent transactions

were disclosed across multiple qualifying sources that the relator merely “stitched together.” The issue is dispositive only if four additional conditions are met: (5) the plaintiff is not an “original source” who may proceed even if the public disclosure bar has been triggered, 31 U.S.C. § 3730(e)(4)(A); (6) the government does not oppose dismissal on public disclosure grounds, *ibid.*; (7) the government does not seek to dismiss the case on its own initiative, *id.* § 3730(c)(2)(A); and (8) the plaintiff’s complaint otherwise states a claim. That is a vanishingly small universe of cases that does not merit this Court’s attention in the absence of a clear circuit split.

4. Certiorari should also be denied because this case is a poor vehicle for deciding the question. The question was not a focus of the briefing below. Instead, the parties principally focused on which sources qualified as public disclosures. Those questions would remain important if this Court granted certiorari, and would cloud the question presented. After all, to determine whether respondent merely stitched together qualifying public disclosures, this Court would first have to determine what constitutes a qualifying public disclosure. This case raises multiple questions on that front.

First, as explained *infra* in the discussion of the second question presented, the Ninth Circuit correctly determined that the IPR challenging the ’688 Patent was not a qualifying source for public disclosures. Petitioners’ ability to rely on that source is accordingly contingent on this Court granting certiorari on the second question presented *and* concluding that petitioners are correct about it. That alone makes this case a poor vehicle for deciding the first question.

Second, respondent will argue, as alternative grounds for affirmance, that neither the patent prosecution histories nor the Brunner and Marakhouski studies fall within the public disclosure bar’s enumerated channels.

The Ninth Circuit was constrained by circuit precedent to hold that patent prosecution histories constitute “other Federal . . . hearing[s]” under the public disclosure bar’s second channel—but that precedent is clearly wrong on this point. Specifically, it depends on adding text to the statute that narrows the public disclosure bar’s first channel to “adversarial” proceedings (a qualifier that appears nowhere in the statute) so as to exclude patent prosecutions from that channel, and then limiting the second channel to “investigatory” proceedings (another qualifier that appears nowhere in the channel)—and then committing the further error of holding that patent prosecution is an “investigatory” proceeding. *See Allergan*, 46 F.4th at 998. Indeed, petitioners themselves criticize *Allergan*’s reasoning in connection with their second question presented. Pet. 32-33. Thus, they fault the Ninth Circuit for misapplying the canon of *noscitur a sociis* and inserting atextual limitations into the statute. *See ibid.*

There is no need to get into the details at this point of why the Ninth Circuit’s decision in *Allergan* was wrong. What matters for present purposes is that the correctness of that decision will be squarely before the Court if it grants certiorari in this case. That is true *both* because petitioners themselves have called *Allergan*’s reasoning into question, and because, before determining that respondent merely stitched together qualifying public disclosures, this Court must determine what constitutes a qualifying public

disclosure. If patent prosecutions do not qualify, then almost all of the transactions that petitioners claim were included in qualifying public disclosures actually were not—and so the premise of the question presented would not hold.

The inquiry will also be complicated by the fact that petitioners did not make the arguments that the Ninth Circuit adopted in *Allergan* (*i.e.*, that patent prosecutions are an “other Federal . . . hearing” under the second channel). Instead, petitioners argued below that the database containing patent prosecutions is a “Federal report.” Pet’r C.A. Br. 46. The Ninth Circuit did not consider that argument—and so assuming petitioners intend to advance it again, this Court would be the first one to consider it.

Similarly, the Ninth Circuit assumed without deciding that the Brunner and Marakhouski studies, two scientific papers published in the journal *Alimentary Pharmacology & Therapeutics*, constitute “the news media.” That is debatable, to say the least. The phrase “the news media” is undefined, and so takes its ordinary meaning. In ordinary parlance, “the news media” refers to professionals who focus on reporting news to the public. The phrase focuses as much on the content (“news,” *i.e.*, important current events) as it does on the speaker (the professional “media,” as opposed to individuals or businesses that might incidentally discuss current events, but not as their focus). For example, information published in the *New York Times* comes “from the news media” because the New York Times Company is part of “the news media” in ordinary parlance. But nobody would describe a restaurant’s website, a political scientist’s Ph.D.

dissertation, a textbook, or a lawyer's Facebook page as "the news media," even if they discussed current events.

Alimentary Pharmacology & Therapeutics does not fall within the ordinary meaning of "the news media" because the journal does not report "news," *i.e.*, current events, nor hold itself out as doing so. Instead, it publishes peer-reviewed scientific articles on a bi-monthly basis. Moreover, these articles target an extremely niche audience: People who study the effects of drugs on the human gastrointestinal and hepatobiliary systems. It is a fair bet that most people do not even know what the hepato-biliary system is, and do not regard information about drugs' effects on that system to be "newsworthy." The authors of these papers are also not "the media"; they are scientists working in the industry. And the publisher is not a news publisher, but instead an academic publisher that produces books and specialty journals. Because the studies do not fall within the ordinary meaning of "the news media," the Ninth Circuit should not have considered them in its public disclosure bar analysis. And without them, important facts could not have been deemed disclosed (including that the studies existed and were withheld during prosecution of the '688 Patent, and that petitioners participated in the studies).

Independently, even if the public disclosure bar were triggered here, respondent would qualify as an "original source" who could proceed anyway because he "has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions." 31 U.S.C. § 3730(e)(4)(B). The court of appeals did not reach this issue because it held that the public disclosure bar does not apply at all—but it

provides yet another alternative ground for affirmance, demonstrating the question presented does not control the outcome of this case.

5. Finally, if the Court were to grant certiorari, respondent would argue that a rule limiting the public disclosure bar to instances in which an alleged fraud is disclosed in a single public source is the best reading of the statute.

As relevant here, the FCA provides that the public disclosure bar is triggered when “substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed . . . in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation.” 31 U.S.C. § 3730(e)(4)(A)(ii) (emphasis added). Congress’s use of the word “in” (meaning “within”) followed by the singular article “a” indicates that the disclosure of the allegations or transactions must be contained within a single report, hearing, audit, or investigation—as opposed to being spread across some combination of these sources.

This Court’s recent precedents confirm this reading. In *Niz-Chavez v. Garland*, 593 U.S. 155 (2021), the Court held that when serving “a notice to appear” on a deportable alien, the government must serve the relevant information in a single document, not spread over multiple documents. *See id.* at 161. The Court explained that “[t]o an ordinary reader . . . ‘a’ notice would seem to suggest just that: ‘a’ single document containing the required information, not a mishmash of pieces with some assembly required.” *Ibid.* The Court elaborated that when Congress uses a singular article before a countable noun (like a notice, or a hearing), Congress ordinarily means to refer to a singular

item. *Id.* at 162-63. The Court also rejected countervailing policy arguments, explaining that “there are (at least) two sides to the policy questions before us . . . and no amount of policy-talk can overcome a plain statutory command.” *Id.* at 171.

That reasoning applies equally here. A report, hearing, audit, or investigation—like a notice—is a countable noun, and Congress placed a singular article before it. Had Congress wished, it could easily have used plurals or other language making it clear that the public disclosure bar applies to transactions sprinkled across multiple sources. But Congress didn’t; instead, it defined this channel of public disclosure using plain language that is exclusively singular. It follows that a fraudulent transaction must be disclosed in a single source—“not a mishmash of [sources] with some assembly required.” *Niz-Chavez*, 593 U.S. at 161.

Statutory context does not justify deviating from the plain text’s ordinary meaning. As Senator Grassley explained, when Congress added the public disclosure bar to the statute, it did not intend to bar claims by relators who “must piece together facts exposing a fraud from separate documents.” 145 Cong. Rec. E1546-01 (daily ed. July 14, 1999), 1999 WL 495861, at *E1546-47 (emphasis added). Thus, statements from the most prominent legislative authorities support the argument that unless a fraud is disclosed in a single source, the public disclosure bar is not triggered.

Petitioners may point out that respondent first made this argument below at the rehearing stage. That is true; respondent did not need this argument to win below, and he did not base his presentation on it until petitioners at the rehearing stage falsely accused

the Ninth Circuit of adopting a single-source limitation on the public disclosure bar. At that point, respondent defended that limitation while arguing against rehearing. The fact that the argument made such a late appearance is yet another reason to deny certiorari, because it shows that the question presented is underdeveloped in this case.

II. The Second Question Presented Does Not Warrant Certiorari

The second question presented is whether IPRs fall within the public disclosure bar's enumerated channels, either because the government is a party to IPRs or because an IPR constitutes an "other Federal . . . hearing" under the second channel. Pet. i. This question is not even close to being worthy of certiorari. Only one circuit court (the Ninth Circuit here) has considered the question; and it reached the same result as the District of New Jersey, which decided the only other case involving the question. *See United States v. Janssen Biotech, Inc.*, 576 F. Supp. 3d 212 (D.N.J. 2021). The question is also unimportant, and the result below was correct.

1. The specific question presented, *i.e.*, whether statements in IPRs fall within the scope of the public disclosure bar, has only been adjudicated twice: in this case, and another FCA case in the District of New Jersey. Both courts have agreed that the answer is "no," albeit for slightly different reasons. Here, the Ninth Circuit held that because IPRs are an "adversarial" proceeding, they are addressed by the public disclosure bar's first channel, and therefore can only trigger the public disclosure bar if "the Government or its agent is a party" to the IPR. Pet. App. 23a. The Ninth

Circuit further held that the government was not a party to the IPR relating to the '688 Patent because merely serving as the adjudicator (which is all the PTAB did in the IPR at issue here) does not make the government a “party.” *Id.* at 23a-24a.

The District of New Jersey reached the same conclusion when denying a motion to dismiss on public disclosure grounds. Like the Ninth Circuit here, the court held that “the Government is not a party to the IPR process”; rather, “IPR is a proceeding between a petitioner and patentholder, and is closely akin to a private civil litigation.” *Janssen Biotech*, 576 F. Supp. 3d at 224. The court further held that IPRs are not an “other Federal . . . hearing” within the meaning of the public disclosure bar’s second channel because treating them that way would render Congress’s 2010 amendments (which added a government-party limitation to channel (i)) a nullity. *See id.* at 225. Thus, although the court employed different reasoning than the Ninth Circuit (it did not, for example, limit the first channel to adversarial proceedings and the second channel to investigatory proceedings), it reached the same conclusion.

No other court has decided the specific question presented, and so there simply is no split over it.

Nevertheless, petitioners claim two circuit splits, both of which are illusory. First, petitioners argue that the Federal Circuit and this Court have held that the government *is* a party to IPRs. At the outset, this argument has some preservation problems. As the district court noted, petitioners forfeited this argument there. Pet. App. 54a. The Court should hesitate before granting certiorari on a forfeited contention.

In any event, petitioners must concede that none of the cases they cite arose under the FCA—and so even if they had presented an accurate picture of the law, there would be no split about the interpretation of the FCA, which is the question presented here.

Petitioners’ description of the law is also woefully incomplete. They cherry-pick situations in which courts have stressed the role the government plays (or may potentially play) in IPRs. Thus, they point to decisions highlighting that the Director of the Patent Office decides whether to initiate IPRs, that the Patent Office may intervene if the petitioner abandons an IPR, and that the purpose of IPRs is to reexamine a patent grant, which is an executive power.

Tellingly, however, none of those precedents actually says that the government is a *party* to IPRs. Simultaneously, petitioners ignore controlling precedents that say the opposite—in so many words. In particular, in *Return Mail, Inc. v. United States Postal Service*, 587 U.S. 618, 634 (2019), this Court held that the government cannot itself petition for IPR—but must instead react to petitions filed by non-sovereigns. The Court described the IPR process as “adversarial, adjudicatory proceedings between the ‘person’ who petitioned for review and the patent owner.” *Id.* at 634. But the Court concluded that Congress did not authorize the government “to become a party to” this “adversarial proceeding.” *Ibid.*

Similarly, this Court’s decision in *SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348 (2018), explained that the IPR statute permits “a party” to “seek inter partes review” by filing a petition; but “[t]his language doesn’t authorize the Director [of the Patent Office] to start [IPR] proceedings on his own initiative. Not does it

contemplate a petition that asks the Director to initiate whatever kind of inter partes review he might choose. Instead, . . . Congress chose to structure a process in which it's the petitioner, not the Director, who gets to define the contours of the proceeding." *Id.* at 1355. The Court further explained that when Congress created the IPR procedure, "rather than create (another) agency-led, inquisitorial process for reconsidering patents, Congress opted for a party-directed, adversarial process." *Ibid.* In that sentence, when this Court said "party-directed," it plainly meant *private* parties, not the government.

Indeed, the cases petitioners cite not only never say that the government is a party to IPRs, but in fact distinguish between the government and the parties to an IPR. For example, the Federal Circuit in *St. Regis Mohawk Tribe v. Mylan Pharmaceuticals Inc.*, 896 F.3d 1322, 1329 (Fed. Cir. 2018), noted that the PTAB has the "authority to proceed in the absence of the parties," thus distinguishing the PTAB from the parties to an IPR.

The administrative rules governing trials before the PTAB, codified at 37 C.F.R. Part 42, likewise distinguish between the "parties" to a proceeding, on the one hand, and the "Board," *i.e.*, the government, on the other. For example, the definition of a "party" includes "the petitioner" and "the patent owner," but not the Board or the government. 37 C.F.R. § 42.2. Throughout the rules, references to "parties" plainly refer only to the private parties, distinguishing them from the government.

Petitioners argue next that the Ninth Circuit's decision conflicts with other decisions that would classify IPRs as "other Federal . . . hearings" under the public

disclosure bar's second channel. In support, petitioners contend that other circuits have held that the term "hearings" in the second channel retained its meaning from before the 2010 amendments.

This is a real stretch. In essence, petitioners have zoomed out to the highest-possible level of abstraction, and found a handful of cases that stated, in passing, that the text of the second channel remained largely similar after the 2010 amendments as before. That is a far cry from *holding* that IPRs fall within the second channel—or, for that matter, holding that *any* "administrative hearing" *not* covered by the first channel would fall within the catchall for "other Federal . . . hearings" in the second channel. Instead, this Court should treat the statements petitioners cite as what they are: passing observations about the statutory language—not holdings that contradict the decision below.

That is especially clear because the statutory text changed substantially in 2010 in ways that matter here. *First*, before the 2010 amendments, *both* the first and the second channel expressly included "administrative hearings." This Court emphasized that repetition, explaining that "[t]he statute also mentions 'administrative hearings' twice, reflecting intent to avoid underinclusiveness even at the risk of redundancy." *Schindler Elevator Corp. v. United States ex rel. Kirk*, 563 U.S. 401, 408 (2011). In 2010, Congress removed the word "administrative" from the second channel, while leaving it in the first. That change alone suggests that if a proceeding qualifies as an "administrative hearing"—as IPRs clearly do—it should *only* be considered under the first channel, and not under the second channel's catchall for "other Federal . . .

hearings.” *Second*, Congress added a specific limitation that *only* applies to criminal, civil, and administrative hearings: the government or its agent must be a party. To sweep any civil or administrative hearing in which the government is *not* a party into the catchall for “other Federal . . . hearings” would render that limitation a nullity.

But those are merits arguments. The point that matters for present purposes is that none of the circuit decisions petitioners identify in their asserted split have considered and rejected these arguments, or otherwise signaled any disagreement with the Ninth Circuit’s reasoning. Instead, the Ninth Circuit is the first circuit that has had to consider the interplay between the public disclosure bar’s first two channels after the 2010 amendments vis-à-vis administrative hearings. Accordingly, petitioners’ second claimed split is illusory.

2. The second question is also not important enough to merit this Court’s review. In addition to the qualifications set forth *supra* pp.13-14 about why public disclosure bar questions generally are not dispositive, this question is subject to multiple additional limitations: (1) it only applies in FCA cases involving patents (of which there have only ever been a handful); (2) where an IPR has occurred (only two); and (3) where the IPR has disclosed substantially the same allegations or transactions as the relator’s complaint (none). Although we cannot rule out a hypothetical future case in which these conditions are met, petitioners offer no reason to think many are coming.

Petitioners speculate that on a going-forward basis, successful IPRs will precipitate *qui tam* actions. The Court should not credit that speculation. IPRs are

limited to assessing whether a patent was invalid “only on a ground that could be raised under” 35 U.S.C. §§ 102 and 103, which relate to novelty and obviousness, “and only on the basis of prior art consisting of patents or printed publications.” 35 U.S.C. § 311(b). They accordingly *cannot* determine that fraud occurred; they can only determine whether a patent is invalid on specific grounds. As explained *supra*, most invalid patents are not the result of fraud. Moreover, many invalid patents will cause little to no damage to the government. Consequently, the vast majority of IPRs will not result in FCA cases. And unlike petitioners, we don’t need to speculate about this point. The IPR mechanism has existed since 2012—but barely any FCA cases have alleged fraud in connection with patents that were also challenged in an IPR. If, somehow, that trend changes, the resulting litigation will provide this Court with ample additional opportunities to consider this question.

Indeed, the question presented is not even important *in this case*. Even if the IPR involving the ’688 Patent were deemed a qualifying source for public disclosures, it would not change the outcome here. That is because the IPR disclosed, at most, that the ’688 Patent was invalid in light of the Brunner and Marakouski studies. But it did not disclose that petitioners withheld those studies during patent prosecution. Nor did it disclose any information about the Otterbeck Patents. Nor did it discuss the ways petitioners used the ’688 Patent to suppress competition and prop up the price of Apriso. In other words, the IPR also did not disclose substantially the same allegations or transactions as respondent’s complaint. At most, it disclosed

a subset of information clearly insufficient to allege fraud.

3. Finally, the Ninth Circuit reached the correct result. Although the better reasoning is that set forth in the District of New Jersey’s opinion, the Ninth Circuit correctly held that the government is not a party to every IPR, and that IPRs in which the government is not a party do not fall within the public disclosure bar. Instead, because IPRs are “administrative hearings,” they fall only under the public disclosure bar’s first channel—and so when the government is not a party, no qualifying disclosure has occurred.

CONCLUSION

Certiorari should be denied.

Respectfully submitted,

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