

No. 23-1093

In the Supreme Court of the United States

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

Petitioners,

v.

ZACHARY SILBERSHER, et al.

Respondent.

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

REPLY BRIEF FOR PETITIONERS

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

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

TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	iii
REPLY BRIEF	1
I. THIS COURT SHOULD RESOLVE THE CIRCUIT SPLIT AT THE HEART OF THE FIRST QUESTION PRESENTED.....	3
A. The first question is squarely presented.....	3
B. Under the rule applied in the First, Fifth, Sixth, and Eighth Circuits, the public disclosure bar would apply	5
C. Silbersher’s vehicle arguments are meritless	6
II. THIS COURT SHOULD GRANT CERTIORARI TO ADDRESS WHETHER AN IPR IS A QUALIFYING CHANNEL FOR PUBLIC DISCLOSURE.....	9
A. This Court should grant certiorari to address the Ninth Circuit’s holding that the government is not a “party” to an IPR	9

B.	This Court should grant certiorari to address the Ninth Circuit’s holding that a “hearing” must be “investigative”	11
C.	This question is important	13
	CONCLUSION	14

TABLE OF AUTHORITIES

	Page(s)
Cases:	
<i>Chiaverini v. City of Napoleon, Ohio</i> , 144 S. Ct. 1745 (2024).....	8
<i>Devlin v. Scardelletti</i> , 536 U.S. 1 (2002).....	10
<i>Fin. Oversight & Mgmt. Bd. for P.R. v. Centro de Periodismo Investigativo, Inc.</i> , 598 U.S. 339 (2023).....	6-7
<i>Graham Cty. Soil & Water Conservation Dist. v. U.S. ex rel. Wilson</i> , 559 U.S. 280 (2010).....	1, 8, 12
<i>Oil States Energy Servs., LLC v. Greene’s Energy Grp., LLC</i> , 584 U.S. 325 (2018).....	9
<i>Regents of the Univ. of Minn. v. LSI Corp.</i> , 926 F.3d 1327 (Fed Cir. 2019).....	9
<i>Roberts v. Galen of Va., Inc.</i> , 525 U.S. 249 (1999).....	8
<i>Schindler Elevator Corp. v. U.S. ex rel. Kirk</i> , 563 U.S. 401 (2011).....	8, 12, 13
<i>United States ex rel. Holloway v. Heartland Hospice, Inc.</i> , 960 F.3d 836 (6th Cir. 2020).....	11
<i>United States ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC</i> , 812 F.3d 294 (3d Cir. 2016).....	5

<i>Warner Chappell Music, Inc. v. Nealy</i> , 144 S. Ct. 1135 (2024).....	7
--	---

Statutes & Other Authorities:

Appellant’s Br., <i>Silbersher v. Allergan, Inc.</i> , No. 23-15613 (9th Cir. Aug. 30, 2023)	5, 6, 7
Appellant’s Br., <i>Silbersher v. Valeant Pharms. Int’l</i> , No. 20-16176 (9th Cir. Oct. 22, 2020)	1
Mot. for Indicative Ruling for Post-Judgment Relief, <i>Silbersher v. Allergan Plc.</i> , No. 3:18-cv-03018 (N.D. Cal. Feb. 20, 2024)	4
Reply Br. Mot. for Indicative Ruling for Post- Judgment Relief, <i>Silbersher v. Allergan Plc.</i> , No. 3:18-cv-03018 (N.D. Cal. Mar. 12, 2024)	4
S. Shapiro, K. Geller, et al., <i>Supreme Court Practice</i> (10th ed. 2013)	10, 12, 13
<i>Stitch together</i> , Merriam-Webster (Aug. 25, 2024), http://www.merriam- webster.com/dictionary/stitch%20together	4

REPLY BRIEF

The FCA’s public disclosure bar serves the critical purpose of limiting relators to those envisioned by Congress: “whistle-blowing insiders with genuinely valuable information.” *Graham Cty. Soil & Water Conservation Dist. v. U.S. ex rel. Wilson*, 559 U.S. 280, 294 (2010). But the decision below interprets the public disclosure bar to permit claims brought by a self-described “*outside* relator”¹—even where the allegations were based on documents that were “*all* publicly disclosed.” (App.18a (emphasis added).)

The importance of this decision is undeniable. Amici catalogue the “disastrous, unintended consequences” that will follow. (WLF Br.3.) If the decision below stands, the bar “will quickly become a dead letter.” (WLF Br.3.) Given the need for the public disclosure bar as a critical “check on parasitic *qui tam* suits,” its weakening will cause “[t]he number of meritless FCA suits . . . to skyrocket.” (WLF Br. 9–10.)

In turn, the main industries targeted by FCA claims, including healthcare and other knowledge-intensive sectors, will face “exponentially expand[ed]” FCA exposure. (WLF Br.13.) Such increased litigation costs—even for defending against meritless claims—could “wreak[] havoc on the healthcare sector and the greater American economy.” (WLF Br.15.)

BIO and PhRMA—two of the largest and most influential biotechnology trade associations—

¹ Appellant’s Br. at 36, *Silbersher v. Valeant Pharms. Int’l*, No. 20-16176 (9th Cir. Oct. 22, 2020), ECF 20 (emphasis added).

emphasize that the Ninth Circuit’s decision “jeopardizes” a core driver of the country’s innovation: “the reliable framework of the U.S. patent system.” (BIO/PhRMA Br.11.) The decision below will create a “new breed” of patent-based FCA claims allowing relators to “quickly spin [patent] invalidation into a qui tam suit seeking hundreds of millions, if not billions, in penalties and damages.” (BIO/PhRMA Br.12, 14.) These incentives will not only encourage unnecessary IPR petitions, but also spark more patent-related FCA claims to be filed in non-specialty courts that “lack [the] expertise” needed “to answer complex patent questions”—like what happened with the Ninth Circuit here. (BIO/PhRMA Br.12.)

The result is a tax on innovation. “[A]ny industry that sells patented products or services to or under federal government programs” will face significant new costs and risks. (BIO/PhRMA Br.16.) Such industries will be forced to increase the “cost of innovative products”; other innovators may “determine that the potential costs exceed the benefits” and opt out altogether. (BIO/PhRMA Br.16.)

Respondent Zachary Silbersher has no answer to these amici. The Brief in Opposition relies instead on a misreading of the decision below—which Silbersher’s own briefing to other courts refutes—and on meritless vehicle arguments.

Certiorari is warranted.

**I. THIS COURT SHOULD RESOLVE THE
CIRCUIT SPLIT AT THE HEART OF THE
FIRST QUESTION PRESENTED.**

**A. The first question is squarely
presented.**

With respect to the first question presented, Silbersher wrongly accuses petitioner of “mischaracteriz[ing]” the decision below, arguing that, when understood correctly, “the Ninth Circuit’s decision does not conflict with precedent from any other circuit.” (Opp.12.)

To the contrary, the petition accurately describes the Ninth Circuit’s sweeping and unprecedented rule that allows relators to avoid the bar by identifying inconsistencies between two disclosures. (*Infra* p.5.)

Silbersher asserts that the Ninth Circuit ruled in his favor because he added “key information” to the mix of “collectively insufficient public disclosures.” (Opp.10.) But Silbersher does not identify *any* non-public information he purportedly uncovered—a failure that is unsurprising given the Ninth Circuit’s acknowledgement that “the relevant documents that are the subject of this appeal were *all* publicly disclosed.” (App.18a.)

Moreover, the Ninth Circuit wrote that Silbersher “filled the gaps by stitching together the material elements of the allegedly fraudulent scheme.” (App.30a.) Silbersher interprets this to mean that he “stitched together the elements of fraud by *supplementing* the . . . public disclosures with additional material allegations.” (Opp.10 (emphasis added).) But “stitch together” means merely to “make (something) out of many different things”—that is, to

combine pre-existing material, not to supplement with anything new. *Stitch together*, Merriam-Webster (Aug. 25, 2024), <http://www.merriam-webster.com/dictionary/stitch%20together>.

Silbersher’s briefing in another pending matter refutes his arguments in the Brief in Opposition. There, Silbersher (correctly) described the broad holding of the decision below:

Valeant recognized that when two separate statements found in different [disclosures] are inconsistent, they do not themselves disclose the contradiction for purposes of . . . the public disclosure bar.²

According to Silbersher, the decision below “determined . . . that piecemeal disclosures” do not trigger the public disclosure bar even if those disclosures “reveal *both* the false statements by defendants *and* the true state of affairs.”³

This Court should recognize and reject Silbersher’s gamesmanship: characterizing an admittedly broad decision as a narrow one to avoid certiorari.

² Reply Br. Mot. for Indicative Ruling for Post-Judgment Relief at 3, *Silbersher v. Allergan Plc*, No. 3:18-cv-03018 (N.D. Cal. Mar. 12, 2024), ECF 204.

³ Mot. for Indicative Ruling for Post-Judgment Relief at 3, *Silbersher v. Allergan Plc.*, No. 3:18-cv-03018 (N.D. Cal. Feb. 20, 2024), ECF 201.

B. Under the rule applied in the First, Fifth, Sixth, and Eighth Circuits, the public disclosure bar would apply.

The Ninth Circuit’s holding splits sharply from the other circuits. It upends the very foundation of public disclosure bar precedent, which had always—and in all other circuits—barred claims when both the “misrepresented state of facts” and “true state of facts” were disclosed. *United States ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 303 (3d Cir. 2016).

The petition went case-by-case through First, Fifth, Sixth, and Eighth Circuit opinions and demonstrated that those circuits would have reached a different outcome on the facts of this case. (Pet.15–18.) Silbersher has no response to these cases; he does not even cite them, much less harmonize them with the decision below.

This conflict with other circuits also defeats Silbersher’s suggestion that this issue is not sufficiently important. Silbersher argued that the first question presented is “not important enough to warrant this Court’s review” only assuming “the absence of a clear circuit split.” (Opp.13–14.) Regardless, notwithstanding the Brief in Opposition’s casting of the decision below as “plainly not important” (Opp.2), Silbersher has elsewhere brandished it as “important precedent” that serves to “bring clarity to [FCA] law.”⁴

⁴ Appellant’s Br. at 27, *Silbersher v. Allergan, Inc.*, No. 23-15613 (9th Cir. Aug. 30, 2023), ECF 12.

C. Silbersher’s vehicle arguments are meritless.

Silbersher also contends that “this case is a poor vehicle” because there are “multiple questions” that the Court would need to answer before it could resolve the first question presented. (Opp.14.) Specifically, Silbersher believes that “to determine whether respondent merely stitched together qualifying public disclosures, this Court would first have to determine what constitutes a qualifying public disclosure.” (Opp.14.) Not so.

The broad holding that underlies the first question presented—that a relator can avoid the bar by identifying “conflicting positions” in two separate disclosures—does not depend on what those two disclosures are. (App.29a.) As Silbersher himself has emphasized to other courts, the “application of [the decision below] at the pleading stage constitutes a pure question of law,”⁵ and is suitable for resolution by this Court.

Moreover, Silbersher is incorrect that the Court “must” or will “have to” resolve ancillary issues before addressing the question presented. (Opp.14, 15.) Beneath every question that is presented to this Court are countless rulings and assumptions made during the litigation. But the Court generally does not—and certainly is not *required* to—re-decide every case-specific issue underlying a question presented. *See, e.g., Fin. Oversight & Mgmt. Bd. for P.R. v. Centro de Periodismo Investigativo, Inc.*, 598 U.S. 339,

⁵ Appellant’s Br. at 41, *Silbersher v. Allergan, Inc.*, No. 23-15613 (9th Cir. Aug. 30, 2023), ECF 12.

345–46 (2023) (where decision below had assumed an “underlying [legal premise] as a given,” the Court would “assume without deciding” that the premise was correct and “address only” the question presented); *Warner Chappell Music, Inc. v. Nealy*, 144 S. Ct. 1135, 1138–39 (2024) (where question presented “incorporate[d] an assumption,” that underlying assumption was outside the scope of the question presented and “exclude[d] from consideration”).

In any event, contrary to Silbersher’s assertion, the first question presented simply does not require the Court to address whether IPR disclosures or scientific articles qualify as public disclosures. (Opp.14–15.) As Silbersher has acknowledged in briefing in other matters, the decision below held that Silbersher avoided the bar “by comparing two separate patent applications.”⁶ These patent applications, alone, were enough to satisfy the public disclosure bar under the rule applied in other circuits and were the sole basis for the Ninth Circuit’s holding that Silbersher’s allegations were not publicly disclosed. (See App.29a (“Silbersher’s *qui tam* allegations provide a critical fact necessary for scienter: [Petitioners] took conflicting positions in their patent prosecutions.”).)

To the extent that this Court’s ruling would make necessary a determination of whether the other

⁶ Appellant’s Br. at 33, *Silbersher v. Allergan, Inc.*, No. 23-15613 (9th Cir., Aug. 30, 2023), ECF 12.

categories of sources qualify as public disclosures,⁷ the Ninth Circuit would properly decide the issue in the first instance on remand. *See Chiaverini v. City of Napoleon, Ohio*, 144 S. Ct. 1745, 1752 (2024) (parties’ argument was “not now fit for [the Court’s] resolution” when it was “no[t] part of the question we agreed to review” and “the court below did not address the matter”).

The same is true of Silbersher’s argument that he may qualify as an “original source”—another issue that the Ninth Circuit “did not reach.” (Opp.17.) It is outside the question presented and would be remanded by this Court to the Ninth Circuit, just as this Court has done in prior public disclosure bar cases. *See Graham Cty.*, 559 U.S. at 301 (“Whether respondent can qualify as an ‘original source’ . . . is one of many issues that remain open on remand.”); *Schindler Elevator Corp. v. U.S. ex rel. Kirk*, 563 U.S. 401, 415 n.8 (2011) (“That [original source] question is not before us, and we do not decide it.”); *see also Roberts v. Galen of Va., Inc.*, 525 U.S. 249, 253 (1999) (declining to address “two alternative grounds for the affirmance of the decision below” that were outside the question presented).

* * *

As Silbersher himself has acknowledged in other proceedings, the decision below radically narrows the public disclosure bar. Amici confirm the

⁷ The Ninth Circuit “assumed without deciding” that scientific studies qualified. (Opp.16). The issue of whether patent applications qualified was decided by a prior Ninth Circuit panel. (Opp.15.)

importance of the decision, and the issue warrants certiorari.

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

This Court should also grant certiorari to review the Ninth Circuit's holdings that IPRs are not a channel for disclosure under either subsection (i) or (ii) of public disclosure bar. (App.22a–25a.) Both holdings are erroneous and independently worthy of review.

A. This Court should grant certiorari to address the Ninth Circuit's holding that the government is not a “party” to an IPR.

The Ninth Circuit held that IPR disclosures do not qualify as public disclosures under subsection (i) because “the government [is] not a ‘party’ to [an] IPR.” (App.23a.) The holding cannot be reconciled with the precedents of this Court and the Federal Circuit, which hold “that IPR is in key respects a proceeding between the government and the patent owner.” *Regents of the Univ. of Minn. V. LSI Corp.*, 926 F.3d 1327, 1339 (Fed Cir. 2019); *Oil States Energy Servs., LLC v. Greene’s Energy Grp., LLC*, 584 U.S. 325, 343 (2018) (IPR is a matter “between the government and others”).

The Brief in Opposition primarily raises what it acknowledges are “merits arguments,” asserting that the IPR precedents from this Court and Federal Circuit do not explicitly hold “that the government is

a *party* to IPRs” for purposes of the FCA. (Opp.22, 25.) Silbersher then cites *other* non-FCA cases that he contends support his view that the government is *not* a party to IPR. (Opp.22.)

While Silbersher’s reading of those cases is incorrect, that is ultimately beside the point. These arguments are properly left to the merits stage, and the Ninth Circuit did not rely on (or even cite) the cases cited by Silbersher. In fact, despite basing its holding on the “procedural features” and “function” of IPR, the Ninth Circuit did not cite to *a single* precedent analyzing the nature of IPR. (See App.20a–25a.) This failure to address—or even acknowledge—these cases is a strong indicator in favor of certiorari. Cf. S. Shapiro, K. Geller, et al., *Supreme Court Practice* 251 (10th ed. 2013) (“When the decision of the court of appeals clearly fails to apply prior Supreme Court decisions because of error or oversight, the Court usually grants certiorari.”).

In any event, the cases Silbersher cites did not address—much less decide—whether the government is a “party” to IPRs for purposes of the FCA’s public disclosure bar. Silbersher simply seizes on the appearance of the word “party” in those cases. (Opp.22–23.) But “[t]he label ‘party’ does not indicate an absolute characteristic, but rather a conclusion about the applicability of various procedural rules that may differ based on context.” *Devlin v. Scardelletti*, 536 U.S. 1, 10 (2002).

Given that the core question under the public disclosure bar is whether the government is in a position to learn of the alleged fraud, in this context, the government need not fully or exclusively control

the litigation to be a “party.” *See generally United States ex rel. Holloway v. Heartland Hospice, Inc.*, 960 F.3d 836, 845 (6th Cir. 2020) (holding that an FCA relator is the government’s agent—even in FCA cases where the government does not intervene—including because the government nonetheless “receives copies of all pleadings and deposition transcripts” and could move to stay or intervene).

B. This Court should grant certiorari to address the Ninth Circuit’s holding that a “hearing” must be “investigative.”

The decision below also erroneously holds that an IPR is not a “hearing” under subsection (ii) of the bar. (App.24a.) Despite acknowledging that an IPR is a “hearing” in the ordinary sense, the Ninth Circuit held that subsection (ii) is limited to sources whose “primary function [is] . . . investigative.” (App.24a.)

Silbersher does not dispute that the statutory analysis leading to this result contained multiple “fundamental errors of statutory interpretation.” (Pet.31.) In fact, Silbersher affirmatively agrees that the Ninth Circuit’s limitation of subsection (ii) to only “investigatory” sources is “clearly wrong” and “depends on adding text to the statute” to artificially narrow its scope. (Opp.15.)

Silbersher instead argues that, based on an entirely different and tenuous interpretation (relating to “administrative hearings”), the Ninth Circuit’s ultimate result was correct in this case. (Opp.20, 27.)

If anything, Silbersher’s arguments only confirm the need for certiorari to review the Ninth Circuit’s

“clearly wrong” interpretation of subsection (ii) and its misguided understanding of the amended public disclosure bar. (Opp.15.) When even the prevailing party will not defend the statutory interpretation of the decision below, certiorari is warranted. *See* S. Shapiro, K. Geller, et al., *Supreme Court Practice* 268 (10th ed. 2013) (“Importance can arise when the lower court decisions leave the intent and meaning of the statute in a state of confusion.”).

As the petition explained, the Ninth Circuit’s holding that subsection (ii) disclosures must be “investigatory” conflicts with—and is based on a fundamentally different understanding of the amended bar than—the decisions in the other circuits. (*See* Pet.29–30 (showing that none of the First, Third, Fourth, Sixth, and Eleventh have interpreted the amended bar to limit subsection (ii)).)

Silbersher likewise does not dispute that interpreting subsection (ii) to exclude IPRs would mean that the 2010 amendments somehow changed the meaning of “hearing” (App.54a), a radical proposition that conflicts with the interpretation of every other circuit to have addressed the 2010 amendments. In fact, Silbersher appears to assume that *all* pre-amendment public-disclosure cases—including the Court’s two seminal precedents—were rendered irrelevant by the 2010 amendments. He makes no attempt to square the atextual result in this case with this Court’s guidance in *Schindler Elevator* or *Graham County*, including the Court’s repeated admonishments against “construing the statute [too] narrowly” or in a way that is “inconsistent with the plain reading” of the bar’s broad text. *Schindler Elevator*, 563 U.S. at 410. Silbersher cites *Graham*

not at all and *Schindler* just once—and only in support of his argument that “the statutory text changed substantially” since then. (Opp.24.)

C. This question is important.

Silbersher attempts to diminish the importance of the second question presented, calling it “a complete nothing-burger” that will impact only a small number of FCA cases implicating IPRs. (Opp.3, 25.)

As an initial matter, this argument misapprehends the scope of the Ninth Circuit’s decision, which restricts *all* subsection (ii) channels—“report[s], hearing[s], audit[s], and investigation[s]”—to proceedings that are sufficiently “investigative.” (App.24a.) The Ninth Circuit’s decision thus sweeps far beyond IPRs and dramatically narrows the scope of subsection (ii) of the public disclosure bar. (App.21a.)

But even as it relates to IPRs, the question is important. Silbersher contends there is “no reason to think many [lawsuits] are coming” that would implicate the second question presented. (Opp.25.) But Silbersher himself has already filed multiple such claims. (BIO/PhRMA Br.15–16 & n.8.)

And the amici explain that the Ninth Circuit’s outlier decision “is all but certain to spawn a cottage industry of professional IPR challengers turned *qui tam* relators. (BIO/PhRMA Br.14.) When, like here, a “decision below may itself threaten to increase litigation dramatically,” the Court need not stand by to wait for that system-wide threat to play out. S. Shapiro, K. Geller, et al., *Supreme Court Practice* 481 (10th ed. 2013).

Finally, Silbersher argues that the second question presented is not important in *this* case because it is not outcome determinative. (Opp.26.) On this point, Silbersher contradicts himself. He admitted below that, if the IPR constituted a public disclosure, “there would be no case.” (App.56a.)

CONCLUSION

Certiorari should be granted, on either or both questions presented.

Respectfully submitted,

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

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

Counsel for Petitioners

August 27, 2024