No. 23-1093

IN THE

Supreme Court of the United States

VALEANT PHARMACEUTICALS INTERNATIONAL, INC., ET AL.,

Petitioners,

v.

ZACHARY SILBERSHER & DR. FALK PHARMA GMBH,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF OF WASHINGTON LEGAL FOUNDATION AS AMICUS CURIAE IN SUPPORT OF PETITIONERS

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QUESTIONS PRESENTED

1. Whether a qui tam relator may avoid the False Claims Act's public-disclosure bar, 31 U.S.C. § 3730(e)(4), by "stitching together" information from disparate public disclosures.

2. Whether information publicly disclosed in the United States Patent and Trademark Office's (PTO's) inter partes review (IPR) proceedings is subject to the bar under §§ 3730(e)(4)(A)(i) or (ii) because IPRs (i) include the government as a "party" or (ii) qualify as a "Federal * * * hearing."

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INTEREST OF AMICUS CURIAE*

Washington Legal Foundation is a nonprofit, public-interest law firm and policy center with supporters nationwide. WLF promotes free enterprise, individual rights, limited government, and the rule of law. WLF often appears as an amicus curiae in important qui tam cases to urge the proper construction of the False Claims Act's public-disclosure bar. *See, e.g.*, *Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280 (2010); *Rockwell Int'l Corp v. United States*, 549 U.S. 457 (2007).

WLF opposes fraud against the United States no matter how it occurs. Yet WLF is concerned that expansive FCA liability in recent decades has spawned abusive litigation against businesses, both large and small, to the detriment of free enterprise, employees, shareholders, and consumers. The decision below furthers this troubling trend.

WLF believes that sound and robust enforcement of the FCA's public-disclosure bar is crucial to ensure that the Act is used only for the dual purposes Congress intended—"encouraging private persons to root out fraud" while "stifling parasitic lawsuits." *Graham Cnty.*, 559 U.S. at 295. The Ninth Circuit's decision, if left to stand, would severely undermine Congress's intent and invite great mischief.

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* No party's counsel authored any part of this brief. No person or entity, other than Washington Legal Foundation and its counsel, contributed money for preparing or submitting this brief. WLF timely notified all counsel of record of its intent to file this brief.

SUMMARY OF ARGUMENT

The FCA has taken on a life of its own in recent years. Enacted during the Civil War, the statute began as an important but limited tool against government procurement fraudsters and wartime opportunists. Today, however, the opportunists are less often the targets of the statute than its would-be private enforcers. *See, e.g.*, *United States ex rel. Holmes v. Northrop Grumman Corp.*, 642 F. App'x 373 (5th Cir. 2016); *United States v. Quest Diagnostics, Inc.*, 734 F.3d 154 (2d Cir. 2013).

Although the FCA bars a qui tam claim if substantially the same allegation or transaction has been publicly disclosed, 31 U.S.C. § 3730(e)(4)(A), opportunistic bounty hunters armed with publicly available information have weaponized the FCA into a vehicle for treble-damages lawsuits over just about anything that arguably touches, even remotely, the federal fisc.

Look no further than this case. As the district court rightly recognized, this qui tam action is "the quintessence of the opportunistic and 'parasitic' lawsuit Congress has always intended to bar." Pet. App. 53a. The relator here is not a true whistleblower with valuable inside information. Rather, Zachary Silbersher is a patent attorney and serial qui tam litigant who has filed similar claims against Janssen in the District of New Jersey, *United States ex rel. Silbersher v. Janssen Biotech, Inc.*, No. 19-cv-12107-KM-ESK (D.N.J. May 3, 2019) and against Allergan in the Northern District of California, *United States ex rel. Silbersher v. Allergan Inc.*, No. 18-cv-03018-JCS (N.D. Cal. May 22, 2018). As here, those law-

suits are based on publicly available information, including materials disclosed in IPR patent proceedings before the PTO's Patent Trial and Appeal Board.

By allowing Silbersher's suit to proceed, the decision below offers an easy roadmap for relators to evade one of Congress's most important limits on FCA claims—the public-disclosure bar. As the petition ably shows, the Ninth Circuit's decision flouts the FCA's text and purpose, splits sharply from other circuits on two vital questions of law, and cries out for this Court's review. We write separately to emphasize why this Court should rigorously enforce the balance of incentives Congress struck in the FCA and to elaborate on why the Ninth Circuit's departure from settled law invites disastrous, unintended consequences.

Although conceding that the "relevant documents * * * were all publicly disclosed," Pet. App. 18a, the Ninth Circuit held that a stranger to the alleged fraud may nonetheless evade the public-disclosure bar by "stitching together" publicly available information gleaned from two or more public sources, including IPR proceedings. But if outsiders to the alleged fraud can become qui tam relators by merely repackaging allegations that were already litigated in public proceedings before a federal agency, then the FCA's public-disclosure bar will quickly become a dead letter.

Congress had good reason to bar qui tam actions that add nothing beyond publicly available information. This case proves the point. The government does not need Silbersher's help to learn about

publicly available information from its own IPR patent proceedings at the PTO. Indeed, if the government believed that petitioners had defrauded it, it would have likely intervened to pursue this action. Instead, it chose not to do so. And when a court as influential as the Ninth Circuit ignores Congress's wishes by blessing qui tam suits based on publicly disclosed information, this Court should not hesitate to intervene.

The Court's intervention is especially needed given the importance to the business community of the questions presented. While the many cases in which the government declines to intervene contribute only a small share of the government's total FCA recovery, those qui tam cases collectively cost businesses hundreds of millions of dollars annually to defend against. And from 2010 to 2019, the average number of qui tam suits filed each year nearly doubled to 665—more than a dozen new cases per week.

Pharmaceutical and biotech companies already face outsized litigation risks from qui tam actions. Indeed, healthcare-related cases now comprise about 70% of all new qui tam actions. Compounding that risk by denying the petition would be bad enough. Yet the Ninth Circuit's categorical rule excluding IPR proceedings poses consequences far beyond the pharmaceutical sector. It threatens to increase exposure to qui tam litigation for any company whose business model hinges on selling patented products to the federal government. In today's vibrant tech-based economy, that would be a calamity.

If left to stand, the decision below will drastically expand the scope of FCA liability well beyond

the bounds that Congress intended. To prevent that from happening, the Court should grant review, vacate the Ninth Circuit's opinion, and clarify that the FCA's public-disclosure bar is not as toothless as the Ninth Circuit thinks.

REASONS FOR GRANTING THE PETITION

I. REVIEW IS NEEDED TO ENSURE THAT THE PUBLIC-DISCLOSURE BAR REMAINS AN EFFECTIVE CHECK AGAINST PARASITIC QUI TAM SUITS.

The scope of the FCA's public-disclosure bar is a vital issue that merits this Court's review. Congress intended the FCA to "strike a balance between encouraging private persons to root out fraud and stifling parasitic lawsuits." *Graham Cnty.*, 559 U.S. at 295. As a crucial part of that balance, the public-disclosure bar forecloses a qui tam claim if substantially the same allegations or transactions have already been publicly disclosed. *See* 31 U.S.C. § 3730(e)(4)(A). As relevant here, the bar requires federal courts to dismiss qui tam claims if the "same allegations or transactions" have already been disclosed in (i) "a Federal criminal, civil, or administrative hearing in which the Government is a party" or (ii) "a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation." 31 U.S.C. §§ 3730(e)(4)(A)(i) & (ii).

To be sure, the public-disclosure bar is not without limits. It exempts relators who qualify as "original source[s]." § 3730(e)(4)(B). And it is always subject to the government's right to intervene even in cases to which the public-disclosure bar applies.

These important qualifications ensure that meritorious qui tam suits can advance on the merits. Congress looks to the courts to maintain this delicate statutory balance. The Ninth Circuit's holding here upends that balance.

Because relators who lack non-public information about the details of a false claim are unlikely to assist the government if it chooses to intervene, the public-disclosure bar encourages true whistleblowers to come forward with useful, non-public facts about fraud. At the same time, by foreclosing follow-on claims, the public-disclosure bar protects against parasitic suits that burden the courts and the economy. In short, Congress created the FCA to encourage individuals with insider knowledge of actual fraud to disclose wrongdoing—*not* to enable those without such knowledge to obtain treble-damages windfalls.

The decision below distorts those incentives. Silbersher has simply repackaged allegations that were already litigated in public IPR proceedings before the PTO. He uncovered no new information about the defendants' alleged fraud that was not already disclosed during the patent prosecution and ensuing IPR. As the district court wryly remarked, quite rightly: "Anyone in the world could have filed this case. * * * My grandmother could have filed this case." Pet. 5.

Although no one here disputed that the "relevant documents * * * were all publicly disclosed," Pet. App. 18a, the Ninth Circuit held that a stranger to the alleged fraud may evade the public-disclosure bar by simply "stitching together" publicly available

information from disparate IPR proceedings. That decision, if allowed to stand, will drastically expand the scope of FCA liability well beyond the bounds that Congress fixed.

The Ninth Circuit's novel take on the FCA's public-disclosure bar opens the floodgates for opportunistic litigants to bring parasitic lawsuits based solely on information from two or more public sources, rather than just one. But contrary to the Ninth Circuit's view, the FCA's public-disclosure bar does not contain a "single source" condition. As here, a clever relator can almost always insist that he cobbled together multiple sources of publicly available information to present a "full[er] picture" of the defendant's fraudulent intent. Pet. App. 30a.

That is why other circuits have rejected the Ninth Circuit's view. *See, e.g., United States ex rel. Lager v. CSL Behring, LLC*, 855 F.3d 935, 944 (8th Cir. 2017) ("The fact that the information comes from different disclosures is irrelevant."); *United States ex rel. Winkelman v. CVS Caremark Corp.*, 827 F.3d 201, 208 (1st Cir. 2016) (holding that the "misrepresented state of facts" and the "true state of facts" "may originate in different sources"); *United States ex rel. Gilligan v. Medtronic, Inc.*, 403 F.3d 386, 390 (6th Cir. 2005) ("public disclosures contained in different sources, which together provide information that leads to a conclusion of fraud, trigger the public disclosure bar."). In sharp contrast, the decision below offers an easy roadmap for relators to evade one of Congress's most important limits on FCA claims.

The Ninth Circuit's categorical rule that an IPR proceeding cannot be a channel for a public disclosure fares no better. The panel reasoned under § 37320(e)(4)(A)(i) that the government is not a "party" to IPRs. But both this Court and the Federal Circuit recognize that an IPR is a matter deciding public rights between the government and the patent owner. *See Oil States Energy Servs., LLC v. Greene's Energy Group, LLC*, 584 U.S. 325, 335 (2018) (clarifying that "a patent involves a matter * * * between the government and others"); *Regents of the Univ. of Minnesota v. LSI Corp.*, 926 F.3d 1327, 139 (Fed. Cir. 2019) ("IPR is in key respects a proceeding between the government and the patent owner.").

Likewise, the Ninth Circuit's holding that an IPR is not a "Federal * * * hearing" under § 37320(e)(4)(A)(ii) finds no support in law or logic. Although conceding that an IPR is a "hearing" under the plain meaning of that term, the court held that an IPR is not a hearing as defined in subsection (ii) because its primary function is not "investigative." But no court has ever imposed that requirement, and nothing in § 37320(e)(4)(A)(ii)'s 2010 amendments supports that atextual hurdle.

Properly dismissing qui tam actions by relators like Silbersher, who add no independent information beyond what is already publicly available, honors the careful balance that Congress struck in enacting the FCA. Relators lacking any inside information and who present nothing that materially adds to what was already publicly disclosed should not be allowed to force defendants to face costly discovery and trial. Above all, relators like Silbersher do nothing to aid the government's anti-fraud efforts.

Especially when, as here, the government has declined to intervene, dismissal under these facts advances Congress's purpose and is highly unlikely to leave fraud unpunished.

After all, an insider with genuinely valuable information need not base his qui tam action on publicly disclosed information. On the other hand, an outsider who views qui tam litigation as an attractive business model *must* rely on publicly disclosed information, as he lacks any information of his own. It is no accident, then, that the public-disclosure bar is increasingly under attack by professional relators like Silbersher. *See, e.g., Janssen*, No. 19-cv-12107-KM-ESK (D.N.J. May 3, 2019); *Allergan*, No. 18-cv-03018-JCS (N.D. Cal. May 22, 2018). Cases like this one will become the norm in the Ninth Circuit unless this Court arrests the trend.

In sum, the decision below flouts the "golden mean," *Graham Cnty.*, 559 U.S. at 294, that Congress sought to achieve—a balance between incentivizing whistleblowers and discouraging parasitic lawsuits. Only this Court can prevent the Ninth Circuit's novel re-write of the public-disclosure bar from upsetting Congress's delicate statutory framework.

II. THE DECISION BELOW INVITES HARMFUL, UNINTENDED CONSEQUENCES THAT MERIT THIS COURT'S REVIEW.

A. The decision below invites an avalanche of speculative qui tam suits.

Allowing the Ninth Circuit to erode the FCA's public-disclosure bar as a check on parasitic qui tam

suits would give a green light to abusive litigation. The number of meritless FCA suits—increasingly common due to the enticing windfalls that relators can obtain—will skyrocket even more. That may benefit opportunistic relators and their attorneys, but it would hurt everyone else.

Qui tam actions have become "the fastest-growing area of federal litigation." Sean Elameto, *Guarding the Guardians: Accountability in Qui tam Litigation Under The Civil False Claims Act*, 41 Pub. Cont. L.J. 813, 844 (2012). Recent years have seen an explosion in FCA complaints, many of which lack merit and should have been dismissed. From 1990 to 1999, relators filed an average of 274 qui tam complaints each year. *See* U.S. Dep't of Justice, *Fraud Statistics—Overview: Oct. 1, 1986 — Sept. 30, 2021*, https://perma.cc/F9FE-ALZ7. From 2000 to 2009, that number climbed to 373. *Id.* And from 2010 to 2019, the average number of qui tam suits had nearly doubled to 665—more than a dozen new cases per week. *Id.*

As this Court knows well, "extensive discovery and disruption in a lawsuit could allow plaintiffs with weak claims to extort settlements from innocent companies." *Stoneridge Inv. Partners v. Scientific-Atlanta*, 552 U.S. 148, 149 (2008). Armed with publicly available information, prospective relators (and their counsel) have every incentive to doggedly pursue qui tam defendants until they agree to settle, no matter how parasitic, speculative, or unfounded the complaint's allegations may be. Faced with the exponential risk of financial ruin, many of those defendants will have little choice but to settle even

frivolous FCA claims once they survive a motion to dismiss.

Even those qui tam defendants who ultimately prevail on the merits must incur massive litigation costs to clear their names. Against the backdrop of so many meritless claims, the burden and expense of discovery loom much larger in FCA suits than in the typical civil case. *See, e.g.*, *United States ex rel. Barko v. Halliburton Co.*, 954 F.3d 307, 309 (D.C. Cir. 2020) (describing qui tam discovery that included 64 document requests and more than 2.4 million pages of potentially responsive documents). "While accurate data would be nearly impossible to compile, the cost of frivolous *qui tam* cases surely runs into the hundreds of millions of dollars annually." Stephen A. Wood, *A Convincing Case for Judicial Stays of Discovery in False Claims Act Qui tam Litigation*, WLF Legal Backgrounder (May 5, 2017), https://perma.cc/LG4D-44V6. If the decision below is allowed to stand, that burden will increase even more.

While this is reason enough to grant review, FCA plaintiffs' easy ability to shop for a favorable forum is another. The FCA's exceedingly broad venue provision allows suit "in any judicial district in which the defendant, or in the case of multiple defendants, any one defendant can be found, resides, transacts business, or in which any [violation] occurred." 31 U.S.C. § 3732(a). Absent this Court's intervention, the FCA's expansive venue provision will invite parasitic relators to the Ninth Circuit like moths to the flame. Although such forum-shopping is precisely the kind of "opportunistic and parasitic behavior that the FCA seeks to preclude," *Bailey v.*

Shell W. E&P, Inc., 609 F.3d 710, 721 n.3 (5th Cir. 2010), it is the inevitable consequence of persistent conflict among the circuits if this Court denies review.

B. By incentivizing qui tam strike suits, the decision below threatens to drive up healthcare costs.

The healthcare industry has proven to be an especially popular target for unscrupulous relators. Healthcare-related cases now comprise about 70% of all new qui tam actions, with 459 new suits filed in 2020. *See Fraud Statistics, supra.* And healthcare companies paid 90% of all FCA settlements in 2021. *See* Tara Bannow, *Healthcare companies paid 90% of False Claims Act settlements in 2021*, Modern Healthcare (Feb. 1, 2022), https://bit.ly/35mHJbW.

These cases are rarely of any value or interest to the government. Indeed, the government intervenes in only one out of four FCA actions. Eric Topor, *Intervention in False Claims Act Lawsuits*, Bloomberg Law (Apr. 24, 2017), https://perma.cc/R5D7-GCDY**.** The vast majority of the remaining 75% of FCA complaints are meritless. In 2020, for example, all healthcare qui tam actions in which the government declined to intervene yielded only 12% of the total healthcare qui tam recovery. *See Fraud Statistics*, *supra.*

Because the healthcare sector is the main target of would-be relators seeking treble damages under the FCA, the number of qui tam claims in the Ninth Circuit will skyrocket if relators there can obtain a windfall by merely "stitching together" dis-

parate public disclosures to avoid the public-disclosure bar. Likewise, forcing pharmaceutical and biotech companies to defend against an onslaught of new qui tam claims based on publicly available IPR proceedings, rather than on the relator's inside knowledge as a whistleblower, would divert time, capital, and other critical resources from healthcare innovation and improvement. And given the threat of mandatory exclusion from participation in all federal healthcare programs, many defendants will opt to settle these suits regardless of merit.

All this would drive up the already high costs of developing and marketing new therapies that treat, cure, or prevent debilitating and life-threatening diseases and conditions. But it's not just the companies who will pay the price. If the Ninth Circuit's novel view of the FCA's public-disclosure bar is allowed to exponentially expand drug and biotech companies' FCA litigation exposure, the public health will suffer. Patients who depend on life-saving therapies will be harmed the most.

C. Left in place, the decision below would harm the economy far beyond the healthcare sector.

The Ninth Circuit's categorical rule excluding IPR proceedings invites consequences far beyond the pharmaceutical and healthcare sectors. It threatens to increase exposure to qui tam litigation for any company whose business model relies on selling patented goods that might be bought with government funds. That would invite an economic catastrophe.

A recent PTO report found that industries reliant on intellectual property protection account for over 41% of U.S. gross domestic product, employing one-third of the total workforce in 47 million jobs. *See* PTO, *Intellectual property and the U.S. economy: Third edition* (2020), at iii, https://perma.cc/7KXU-RQ2U. Patents are especially critical in the tech sector. A recent study concluded that the chips and processors industry has the largest proportion of companies that rely on patents—"a staggering 51%." Farzana Haque, *Patents: Which Sectors Have the Most?*, Beauhurst (May 11, 2023), https://perma.cc/NG8E-MRW2. These companies are the engine for our digital economy.

Patent rights help to protect and monetize innovations in every sector of the economy. Robust patents attract foreign investment, encourage technology transfer, and drive the growth of knowledge-intensive sectors. But if IPR proceedings become fertile ground for follow-on qui tam complaints in the Ninth Circuit, increased exposure to FCA strike suits would no longer be cabined to the healthcare industry. Indeed, patent-reliant firms across the economy would also face increased FCA exposure. Every patent attorney who prevails in an IPR could become a potential relator in search of a quick qui tam payday.

"If that were the case," the district judge here rightly explained, "you'd just have an industry of people pouring over PTAB decisions * * * trying to find a link to * * * any of the tremendous consumers of patented technology in the government." Transcript of Proceedings (Dkt. 102) at 13:6–14, *United States ex rel. Silbersher v. Valeant Pharms. Int'l,*

Inc., No. 3:18–CV–01496 (N.D. Cal., Aug. 8, 2019). Precisely so. Such a trend very well could overwhelm the PTO with an avalanche of IPR petitions, each one a lottery ticket for an FCA treble-damages windfall. That would not only erode the vibrancy of America's patent system, but it would have disastrous ripple effects across the whole economy.

To prevent the decision below from wreaking havoc on the healthcare sector and the greater American economy, this Court should grant the petition and set things right.

CONCLUSION

The Court should grant the petition.

Respectfully submitted,

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