No. 23-1093

IN THE

Supreme Court of the United States

VALEANT PHARMACEUTICALS INT'L, 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

Brief of *Amici Curiae* Biotechnology Innovation Organization and Pharmaceutical Research and Manufacturers of America In Support of Petition for a Writ of Certiorari

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INTEREST OF *AMICI CURIAE*

This brief is submitted on behalf of *Amici* the Biotechnology Innovation Organization ("BIO") and the Pharmaceutical Research and Manufacturers of America ("PhRMA").[1]

BIO is the world's largest biotechnology trade association, representing over 1,000 biotechnology companies, research institutions, state biotechnology centers, and related organizations. Its members engage in pioneering research and the development of biotechnological healthcare, agricultural, environmental, and industrial products. BIO's members spend billions of dollars per year researching and developing biotechnological healthcare, agricultural, environmental, and industrial products that cure diseases, improve food security, create alternative energy sources, and deliver many other benefits.

PhRMA is a trade association that represents the leading biopharmaceutical researchers and biotechnology companies in the United States. Every day, PhRMA's members strive to develop cutting-edge medicines, treatments, and vaccines that save, extend, and improve the lives of countless Americans. PhRMA's members have invested nearly $1 trillion since 2000 in their searches for new treatments and cures. *See* PhRMA, *Research and Development*

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[1] Pursuant to Supreme Court Rule 37.6, *Amici* state that this brief was not authored in whole or in part by counsel for any party. No party and no counsel for any party have made or will make a monetary contribution for the costs of preparing or submitting this brief. *Amici* timely notified all parties of their intent to file this brief under Supreme Court Rule 37.2.

https://phrma.org/policy-issues/Research-and-Development-Policy-Framework (last visited May 7, 2024).

Amici's members rely on the patent laws to provide the incentives that spur research and development needed for the discovery of new drugs, vaccines, and biotechnology products. *Amici* have shared goals of advancing policies that enhance the incentives for innovation and in identifying and removing barriers that impede innovation. *Amici*'s members[2] regularly apply for and obtain patents relating to their pharmaceutical products and defend those patents in inter partes review before the Patent Trial and Appeal Board. The federal government provides reimbursement for the use of *Amici*'s members' pharmaceutical products through the Medicare and Medicaid programs. If allowed to stand, the Ninth Circuit's decision will effectively dismantle the public disclosure bar, ushering in a new wave of parasitic *qui tam* lawsuits. Moreover, the panel's divergence from other circuits will have severe repercussions across the pharmaceutical industry and beyond, disrupting the balance of the patent system and stifling innovation.

SUMMARY OF THE ARGUMENT

The Ninth Circuit's interpretation of the False Claims Act's ("FCA") amended public disclosure bar in the context of inter partes review ("IPR") proceedings

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[2] The member companies of BIO and PhRMA are listed on their websites: https://www.bio.org/bio-member-directory; http://www.phrma.org/about/member-companies.

warrants this Court's review.

Diverging from this Court's established precedent and creating a split with its sister circuits, the Ninth Circuit wrongly held that information in an IPR proceeding is not "publicly disclosed" for purposes of the public disclosure bar because (1) the government is not a "party" to an IPR, and (2) an IPR proceeding is not sufficiently "investigative" to be a "hearing." The Ninth Circuit erred on both issues. Both the Court of Appeals for the Federal Circuit and this Court have made clear that an IPR is a proceeding between the government and a patent owner. And no circuit court, until now, has held that Congress's 2010 amendment to the public disclosure bar altered the plain meaning of the word "hearing" in subsection (ii). Under the Ninth Circuit's rationale, legal blogs published on the internet are sources of public disclosure, but documents publicly submitted to the federal government as part of an IPR proceeding are not. This is not and cannot be the rule.

The Ninth Circuit also erred in holding that a *qui tam* relator can avoid the public disclosure bar by "stitching together" two or more sources of publicly available information and identifying purported inconsistencies. Circuit after circuit has held that the public disclosure bar applies even if a relator collects from multiple disclosures the information needed to discern alleged fraud. The Ninth Circuit's holding creates a gaping exception to the public disclosure bar that will invite an onslaught of new parasitic FCA suits. Indeed, even the least creative relator will be able to allege that he or she has identified some purported inconsistency between any number of otherwise public documents.

Unless addressed by this Court, the Ninth Circuit's ruling will have significant consequences in the pharmaceutical industry and beyond. The number of IPR proceedings and FCA lawsuits will skyrocket if any run-of-the-mill patent invalidation through an IPR may form the basis of an FCA claim. Such a result would derail the efficient administration of U.S. patent laws. Further, the looming threat of FCA damages will not only increase the litigation burden and costs for all business and industries that sell to the government, but also will disproportionately impact the pharmaceutical industry, discourage critical investments in research and development, and alter the incentives for parties to resolve IPR proceedings through settlement or other alternatives. Last, the Ninth Circuit's decision will foster an environment where legal counsel in IPR proceedings could prioritize personal gain over client interests, positioning themselves to benefit from potential follow-on FCA cases.

The Ninth Circuit's marked divergence from established principles and this Court's precedents, and the profound implications of its holding, necessitate review by this Court. Only this Court can realign the application of the public disclosure bar with its original purpose and ensure that the patent system continues to function as a cornerstone of innovation rather than a source of opportunistic FCA litigation.

ARGUMENT

I. THE COURT SHOULD GRANT CERTIORARI TO ADDRESS THE NINTH CIRCUIT'S DIVERGENT AND ERRONEOUS INTERPRETATION OF THE PUBLIC DISCLOSURE BAR

A. The Ninth Circuit's Holding that IPR Is Not a Qualifying Channel for Public Disclosure Under Either Channel (i) or (ii) Is Error and Warrants Review

The Court should grant certiorari to address the Ninth Circuit's erroneous holding that information publicly disclosed during an IPR is not "publicly disclosed" under either channel (i) or (ii) of the amended public disclosure bar. *Amici* agree with Petitioner that the Ninth Circuit erred in concluding that the public disclosure bar does not preclude Respondent's claim. Pet. 25-34.

The panel held that an IPR does not qualify as a channel for public disclosure under 31 U.S.C. § 3730(e)(4)(A)(i) because an IPR is a "trial-like, adversary proceeding" between the patent holder and the petitioner where the government is not a "party." App. 12a. The panel's holding, however, is contrary to holdings of both this Court and the Federal Circuit that emphasize the nature of an IPR as a proceeding between the federal government and the patent holder. *See Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 584 U.S. 325, 343 (2018) ("[IPR] remains a matter involving public rights, one 'between the government and others[.]'" (quoting *Ex parte Bakelite Corp.*, 279 U.S. 438, 451 (1929));

Regents of the Univ. of Minn. v. LSI Corp., 926 F.3d 1327, 1339 (Fed. Cir. 2019) ("IPR is in key respects a proceeding between the government and the patent owner."); Pet. 25-28.

Moreover, several features of an IPR make clear that it is fundamentally different from an adversarial proceeding in which the government functions as a disinterested umpire calling balls and strikes. The Patent and Trademark Office ("PTO") has the sole authority to institute an IPR and may decline to institute an IPR in its unreviewable discretion. *See* 35 U.S.C. § 314(d); 37 C.F.R. § 42.108(c). This Court has highlighted the PTO's unique ability in this respect, observing that it makes IPR "less like a judicial proceeding and more like a specialized agency proceeding." *Cuozzo Speed Techs., LLC v. Lee*, 579 U.S. 261, 279 (2016). This Court in *Cuozzo* expressly rejected the argument that Congress created IPR proceedings as a "trial, adjudicatory in nature" and a "surrogate for court proceedings." *Id.* at 277-78. Additionally, the Patent Trial and Appeal Board ("PTAB") has discretion to "proceed to a final written decision" even if no petitioner remains to prosecute the case, 35 U.S.C. § 317(a), and has the right to participate in any appeal of an IPR to the Federal Circuit to "defend its decision—even if the private challengers drop out." *Cuozzo*, 579 U.S. at 279; *see* 35 U.S.C. § 143. These methods of active participation in an IPR are not the powers of a neutral arbiter, but those of a "party." *See LSI Corp.*, 926 F.3d at 1339. The Ninth Circuit's decision is squarely at odds with holdings of this Court and of the Federal Circuit.

The Ninth Circuit also held that an IPR does not qualify for public disclosure under 31 U.S.C.

§ 3730(e)(4)(A)(ii) because an IPR is not a "Federal . . . hearing" under the amended public disclosure bar. App. 24a-25a. There is no dispute that under the Ninth Circuit's pre-2010 case law an IPR would have qualified as a channel (ii) "hearing." *See A-1 Ambulance Serv., Inc. v. California*, 202 F.3d 1238, 1243-44 (9th Cir. 2000). The panel, however, disregarded that precedent, concluding that Congress, without saying so, narrowed the meaning of the word "hearing" in channel (ii) when it amended the public disclosure bar in 2010. App. 24a-25a.

But there is no support in the text of the statute or the history of its amendments for the panel's conclusion that Congress intended to narrow the definition of "hearing." Indeed, the only revision Congress made to the text of channel (ii) in the 2010 amendment was to insert the adjective "Federal" before the phrase "report, hearing, audit, or investigation." *Compare* 31 U.S.C. § 3730(e)(4)(A)(ii) (current language), *with* 31 U.S.C. § 3730(e)(4)(A)(ii) (2006) (pre-amendment language). No other circuit court has subscribed to the Ninth Circuit's unprecedented construction of Congress's 2010 amendment. Pet. 29-30.

If courts can glean anything from the 2010 amendment to the public disclosure bar, it is that Congress sought to narrow the bar to circumstances in which it was reasonable to infer that a disclosure would come to the government's attention. This would explain why Congress added the word "Federal" to both channels (i) and (ii). That targeted revision merely narrowed qualifying channels to those in which the federal government is present. Thus, addition of the "Federal" limitation ensures that

relators can bring *qui tam* suits based on disclosures in public channels that the government is less likely to be monitoring (*e.g.*, state-court litigation or local public hearings). A congressional intent to limit the public disclosure bar to channels the federal government is likely to be monitoring also explains why Congress narrowed channel (i) to criminal, civil, and administrative hearings "in which the Government or its agent is a party." 31 U.S.C. § 3730(e)(4)(A)(i). This qualifying language relieves the government of the burden of trawling civil dockets for potential disclosures of fraud.[3]

If Congress's intent with its 2010 amendment was to narrow channels (i) and (ii) to situations in which the federal government would be expected to see the supposed disclosure, one could not imagine a proceeding more fitting for the public disclosure bar than an IPR. Once a panel of PTAB administrative patent judges or the Director of the PTO—a principal officer of the United States[4]—assesses the merits of a petition and determines whether to institute an IPR, the petitioner and patent holder submit information directly to the PTAB. The PTAB then evaluates the

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[3] Prior to 2010, lower courts uniformly held that any disclosure in any public filing in civil litigation or an administrative hearing triggered the public disclosure bar. *See, e.g.*, *Kennard v. Comstock Res., Inc.*, 363 F.3d 1039, 1042 (10th Cir. 2004) ("[E]very court of appeal to have addressed the question has held that any information disclosed through civil litigation and on file with the clerk's office should be considered a public disclosure . . . for purposes of section 3730(e)(4)(A)." (quoting *United States ex rel. Ramsayer v. Century Healthcare Corp.*, 90 F.3d 1514, 1519 n.3 (10th Cir. 1996)).

[4] Director of the PTO is "appointed by the President, by and with the advice and consent of the Senate." 35 U.S.C. § 3(a)(1).

evidence and the patent holder's original application (which, of course, the patent holder submitted to PTO when the application was filed) and issues a decision on the invention's patentability in light of any new information.

Thus, in cases such as this one, the federal government has in its immediate possession all the evidence that a hypothetical *qui tam* relator would use to allege a violation of the FCA. Nothing about the 2010 amendment to the public disclosure bar suggests that Congress intended to alter the definition of "hearing" in an effort to authorize *qui tam* suits against defendants who directly provided to the government all the information needed to discern the purported fraud. To hold otherwise suggests that Congress intended for the public disclosure bar to apply to online blogs and other internet sources, *see* 31 U.S.C. § 3730(e)(4)(A)(iii), but not documents submitted directly to the federal government as part of an IPR proceeding. Such a contorted interpretation runs counter to Congress's core purpose in enacting the public disclosure bar: to "strike a balance between encouraging private persons to root out fraud and stifling parasitic lawsuits." *Graham Cnty. Soil & Water Cons. Dist. v. U.S. ex rel. Wilson*, 559 U.S. 280, 295 (2010).

B. The Ninth Circuit's Holding that a Relator Can Evade the Public Disclosure Bar by "Stitching Together" Public Information Is Error and Warrants Review

The Ninth Circuit also created a new and problematic exception to the public disclosure bar when it held that a relator may avoid the bar and

bring an FCA claim simply "by stitching together the material elements of the allegedly fraudulent scheme." App. 30a; *see* Pet. 15-24. No other circuit court has held that a relator can evade the public disclosure bar by reviewing public documents and identifying supposed discrepancies between them. To the contrary, circuit after circuit has held that the public disclosure bar applies when a relator seeks to combine public disclosures. *See United States ex rel. Winkelman v. CVS Caremark Corp.*, 827 F.3d 201, 208 (1st Cir. 2016); *United States ex rel. Solomon v. Lockheed Martin Corp.*, 878 F.3d 139, 144-45 (5th Cir. 2017); *United States ex rel. Gilligan v. Medtronic, Inc.*, 403 F.3d 386, 390 (6th Cir. 2005); *United States ex rel. Lager v. CSL Behring, L.L.C.*, 855 F.3d 935, 944 (8th Cir. 2017); *see also* Pet. 15-18.

The Ninth Circuit's new "stitching together" loophole also undermines congressional intent. As this Court has recognized, "Congress amended the [FCA] to preclude such 'parasitic' *qui tam* actions based on 'evidence or information in the possession of the United States . . . at the time such suit was brought.'" *Schindler Elevator Corp. v. United States ex rel. Kirk*, 563 U.S. 401, 412 (2011) (quoting *Graham Cnty.*, 559 U.S. at 294). Allowing a relator to bring a claim by analyzing publicly available information will "attract those looking to capitalize on fraud already exposed by others," leading to an increase in "parasitic *qui tam* actions." *United States ex rel. Poteet v. Bahler Med., Inc.*, 619 F.3d 104, 107 (1st Cir. 2010).

II. THE NINTH CIRCUIT'S HOLDING WILL HAVE SIGNIFICANT CONSEQUENCES IN THE PHARMACEUTICAL INDUSTRY AND BEYOND

A. The Ninth Circuit's Holding Will Disrupt the Administration of U.S. Patent Laws

Amici's members, and patent holders across many other industries, invest substantial resources in costly research and development, aiming to discover and bring groundbreaking products to market. The viability of such significant investments hinges on a stable and predictable patent system. The Ninth Circuit's decision jeopardizes the reliable framework of the U.S. patent system by failing to meaningfully distinguish between garden-variety patent invalidation and fraud against the government (which carries severe civil penalties and damages) for any patented product sold to the government. Pet. 35-36.

Whenever the PTAB invalidates a patent, it necessarily reaches a different conclusion than the PTO regarding the invention's patentability. And typically, the factual record in an IPR is broader than the information that was before the patent examiner initially. But that does not mean the patent was not originally obtained in good faith. To the contrary, granted patents are presumptively valid precisely because the original examination is presumed to be accurate, and the PTO is presumed to have applied the patent laws properly in the first instance. If the Ninth Circuit's decision stands, then putative relators undoubtedly will infer fraudulent intent from *every* perceived inconsistency or other evidence from the IPR that results in invalidation. The predictable

result of the panel decision is that a relator will sprint to a district courthouse within the Ninth Circuit every time the PTAB invalidates a patent that relates to a product paid for by the federal government, alleging that the patent holder defrauded the government by falsely representing that the price the government paid was "fair and reasonable."

But materiality—the standard for what information an applicant must submit to the PTO—is a judgment call, not an exact science. *See Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1291-93 (Fed. Cir. 2011) (discussing the but-for materiality standard that applies in patent applications). For decades, the Federal Circuit, subject only to this Court's review, has had the authority to define uniform standards for difficult patent-related questions such as materiality or whether an applicant's material misstatement or omission in a patent application was knowing and intentional. 28 U.S.C. § 1295(a)(1); 35 U.S.C. § 141(c); *see, e.g.*, *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40 (1997) (recognizing Federal Circuit's "special expertise" in patent law). Yet under the Ninth Circuit's new breed of FCA claim, it is inevitable that parties will ask courts, in the context of FCA suits, to answer complex patent questions over which they lack such expertise and which Congress has said should be decided by a specialty court. Nothing in the FCA evinces a congressional intent for *qui tam* actions to serve as a side vehicle to litigate materiality, fraud on the PTO, or other patent-related issues that have always been the exclusive province of the Federal Circuit. And significantly, patent law has organically developed its own doctrines to discourage

and punish fraud on the PTO. *See generally Walker Process Equip., Inc v. Food Machinery & Chem. Corp.*, 382 U.S. 172, 176-77 (1965) (*Walker Process* fraud); *Precision Instr. Mfg. Co. v. Auto. Maint. Machinery Co.*, 324 U.S. 806, 814-15 (1945) (inequitable conduct). In this respect, the Ninth Circuit's novel interpretation of the public disclosure bar is a solution in search of a problem.

These concerns are real and pressing. To add perspective: IPR petitioners challenge over a thousand patents each year, and approximately 35% of the petitions result in patents being partially or fully invalidated.[5] Nearly 100 IPR petitions are filed annually against biotech and pharmaceutical patents.[6] If this Court leaves the panel decision unaltered, it will create a blueprint for an untold number of new publicly sourced FCA claims each year, alleging fraud with respect to patented products paid for by the federal government—even under circumstances that would never accede to existing fraud-on-the-PTO doctrines.

Additionally, this historic data does not reflect the reality that, if left to stand, the panel decision will

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[5] *See* U.S. Patent & Trademark Office, *PTAB Trial Statistics FY23*, at 10, available at https://www.uspto.gov/sites/default/files/documents/ptab_aia_fy2023__roundup.pdf (last visited (May 7, 2024).

[6] *See id.* at 4; U.S. Patent & Trademark Office, *PTAB Trial Statistics FY22*, at 4, available at https://www.uspto.gov/sites/default/files/documents/ptab__aia_fy2022_roundup.pdf (last visited May 7, 2024); U.S. Patent & Trademark Office, *PTAB Trial Statistics FY21*, at 4, available at https://www.uspto.gov/sites/default/files/documents/ptab_aia_fy2021__roundup.pdf (last visited May 7, 2024).

incentivize putative relators to initiate a greater number of IPR proceedings. This is not because the relator (or the relator's client) seeks patent invalidation to clear the path for competing products or services in the marketplace, but instead because the relator can quickly spin the invalidation into a *qui tam* suit seeking hundreds of millions, if not billions, in penalties and damages (to which the relator, if successful, would be entitled between 15% and 30%, *see* 31 U.S.C. § 3730(d)). Indeed, the panel decision is all but certain to spawn a cottage industry of professional IPR challengers turned *qui tam* relators.

B. The Ninth Circuit's Holding Will Alter Incentives for Pharmaceutical Companies and Harm Innovation

The panel decision drastically alters incentives for innovators and IPR petitioners in ways that will discourage patent applicants—like the members of *Amici*—from investing in the critical research and development needed to bring new and innovative products to market. As outlined above, the Ninth Circuit's holding invites relators to turn any patent invalidation into a FCA claim even where it has never been proven that the patent was inequitably or fraudulently procured or enforced against competitors. As such, every company, especially in the pharmaceutical industry, will need to evaluate and weigh the expected costs of potential FCA suits prior to investing in new areas of research and development, or pursuing new patents, even where the inventor believes that any accusations of fraud would be without merit.

The potential exposure is significant. A successful

FCA claim requires the defendant to pay a civil penalty "plus 3 times the amount of damages which the Government sustains because of the act of that person." 31 U.S.C. § 3729(a)(1). The civil penalty is adjusted by inflation annually; currently, the penalty is not less than $13,946 and not more than $27,894 *per false claim*. *See* 89 Fed. Reg. 9766 (Feb. 12, 2024) (amending 28 C.F.R. § 85.5). The per-claim civil penalty is mandatory. *See United States v. Killough*, 848 F.2d 1523, 1533 (11th Cir. 1988). This exposure is in addition to the significant time, resources, and legal fees that a company must expend to litigate a complex, multi-year FCA case in federal court.

This case amply demonstrates the magnitude of potential damages and penalties that a relator can gin up following even a single patent invalidation. The operative complaint alleges "thousands" of false claims to the U.S. government—*i.e.*, a distinct false claim every time a government healthcare program paid for Apriso®—and that "the United States is entitled to a maximum penalty of up to $22,363" per violation.[7] *See* Compl., at 33, 38. Respondent also alleges hundreds of millions in treble damages apart from the mandatory civil penalty. According to the operative complaint, the government paid $250 million for Apriso® between 2011 and 2016 at prices that would have been "at least 80%" less absent

[7] The maximum civil penalty per false claim when Respondent filed the operative complaint in 2018 was $22,363. *See* 83 Fed. Reg. 3944 (Jan. 29, 2018) (amending 28 C.F.R. § 85.5).

Petitioner's alleged fraud.[8] Compl., at 6.

Would-be patent applicants cannot afford to ignore the financial implications of this magnitude of exposure, even if those companies have confidence in their patent submissions and a good-faith belief in the presumptive validity of their duly examined and granted patents. After the Ninth Circuit's decision, the cost of innovative products may significantly increase to offset potential litigation expenses. Alternatively, inventors may determine that the potential costs exceed the benefits, resulting in a reduced number of innovative products available to the public.

The consequences of the Ninth Circuit's decision, and its chilling effect on innovation, will be felt in any industry that sells patented products or services to or under federal government programs, including in the pharmaceutical and biotech industries, where the federal government pays for pharmaceutical products through Medicare and Medicaid. According to data

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[8] This case is by no means an outlier. In another parasitic FCA case filed by Respondent that is currently pending at the district court level, Respondent alleges more than 98,000 false claims in connection with a drug called Zytiga and that the government pays almost $1 billion per year for Zytiga at costs purportedly inflated by at least 85%. *See* Second Am. Compl. ¶¶ 7-8, *Silbersher v. Janssen Biotech., Inc. et al.*, No. 19-12017 (D.N.J. June 20, 2019). In Respondent's third such FCA suit (which he is currently seeking to revive under Rules 60(b)(6) and 62.1 in light of the panel decision), he alleges that the federal government overpaid for two drugs by more than $2.5 billion. *See* Am. Compl. ¶ 8, *Silbersher v. Allergan Plc et al.*, No. 3:18cv3018 (N.D. Cal. Jan. 22, 2019); Mot. for Indicative Ruling for Post Judgment Relief, *Silbersher v. Allergan Plc et al.* No. 3:18cv2018 (N.D. Cal. Feb. 20, 2024).

from the Centers for Medicare & Medicaid Services, the federal government accounted for 41% of all prescription drug expenditures in 2019.[9] Members of the pharmaceutical and biotech industries are uniquely exposed to parasitic FCA suits in light of the Ninth Circuit's novel approach both because of the volume of their sales to the government and because virtually all of their products are covered by government healthcare programs.

Threats of this magnitude may also alter the incentives of patentees during IPR proceedings. For example, IPR proceedings are often resolved by settlement or disclaimer (*i.e.*, the patentee consenting to invalidation of a particular claim on a patent). Settlements and disclaimers can provide relief to petitioners, narrow the patentee's claims, and reduce the PTAB's workload. In the wake of the Ninth Circuit's ruling, however, patentees will have to reevaluate whether any potential resolution could be twisted to suggest the patentee has taken "conflicting positions" in its public disclosures.

The Ninth Circuit's novel answers to the questions presented in the Petition for Certiorari not only create a circuit split, Pet. 15-18, 25-30, but also threaten to *de facto* become the controlling law nationwide. A putative relator may file an FCA complaint "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 act

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[9] *See* Office of Inspector General, Dep't of Health & Human Servs., *Drug Spending*, https://oig.hhs.gov/reports-and-publications/featured-topics/drug-spending/ (last visited May 7, 2024).

proscribed by section 3729 occurred." 31 U.S.C. § 3732(a). A significant number of *Amici*'s members reside or, at the very least, do business within the Ninth Circuit. Relators will flock to the district courts in the Ninth Circuit to pursue claims that no other circuit has permitted or would permit.

C. The Ninth Circuit's Holding Will Incentivize Patent Counsel to Become Relators to Garner Personal Gain, Raising Ethical Concerns

The Respondent in this case is an outside patent attorney who brought a *qui tam* action by "stitching together" public information that was available to anyone and that he compiled during his representation of a client. While not a focal point of the panel decision, as trade associations representing pharmaceutical and biotechnology companies, *Amici* are also concerned about the consequences the Ninth Circuit's holding will have on the interests of counsel in IPR proceedings to which *Amici*'s members are regularly parties.

More specifically, if allowed to stand, the panel decision could incentivize counsel during IPR proceedings involving *Amici's* members to position themselves to profit in follow-on FCA cases, potentially leading to a misalignment of interests. As the district court recognized, Respondent's FCA theory raises an "ethical problem" for patent counsel turned relators, who may "keep an eye out for the possibility of a personal bounty under the FCA when the attorney's attention should be focused solely on the client[.]" App. 58a. This would shake the foundation of the attorney-client relationship, where

the interests of the client must be paramount and certainly must come before those of the attorney. *See, e.g.*, ABA Model Rule 1.7(10) ("The lawyer's own interests should not be permitted to have an adverse effect on representation of a client."). Further, incentivizing counsel to stitch together information that they obtain from clients to utilize in follow-on *qui tam* actions may lead to a potential breach of confidentiality obligations, which require information relating to the representation, regardless of its source, to remain confidential even after the attorney-client relationship is over. ABA Model Rule 1.6(a).

For instance, in planning for a future money-making role as a relator in a *qui tam* action, counsel in an IPR will have the incentive to put into the record as much information as may be helpful to support a future FCA theory later, regardless of its impact on the IPR. And counsel for the party challenging a patent will be personally incentivized to avoid a settlement—even one that may well be in the interest of that counsel's client—to have the option to later file a *qui tam* action that might itself yield a settlement and personal payment for the lawyer-*cum*-relator. Similarly, if a relator can avoid the public disclosure bar by identifying purported inconsistencies between public documents, any counsel involved in an underlying patent litigation could use his or her access to confidential information and work product to develop theories for potential *qui tam* actions. Such ethical breaches, while prejudicial to the patent system and susceptible to proliferating FCA proceedings, would be incredibly difficult to detect.

Amici take no position on whether Respondent has breached any ethical duties in this and the other

two *qui tam* actions he has filed against *Amici's* members based on public information. But it is clear that if allowed to stand, the panel decision only would increase the risk of ethical breaches and conflicts of interests by incentivizing other similarly positioned attorneys to utilize confidential information in their self-interest, at times without fully comprehending the implications. App. 58a.

CONCLUSION

This Court should grant certiorari to address the important issues presented in the Petition.

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Respectfully submitted,

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