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9th Circuit nixes inter partes reviews from FCA's public disclosure bar

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In a recent decision, *United States ex rel. Silbersher v. Valeant Pharmaceuticals Int'l Inc.*[1] ("*Valeant*"), the Ninth Circuit ruled that the False Claims Act's ("FCA") public disclosure bar does not apply to *inter partes* review ("IPR") proceedings — holding that, unlike patent prosecutions, IPRs are not a qualifying channel for disclosures under the bar.

The panel also ruled that the qualifying disclosures the Valeant defendants did identify did "not disclose a combination of facts sufficient to permit a reasonable inference of fraud." The panel's decision reversed a district court's conclusion that the bar did apply, greenlighting the relator's lawsuit to proceed to its merits.

Valeant is one in a string of FCA actions filed by a single patent-lawyer relator, which allege various pharmaceutical companies defrauded the federal government by charging purportedly "inflated" drug prices based on invalid patents that improperly excluded generic competition. *Valeant*, like the relator's other cases, centers on allegations that the defendants obtained a patent through allegedly false and misleading statements to the United States Patent & Trademark Office ("PTO").

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The FCA allows private citizens, referred to as "relators," to bring fraud claims on the government's behalf against those who have allegedly violated the Act's prohibitions.[2] If successful, relators can recover up to thirty percent of the damages.[3] Concerned about potential abuse, Congress enacted the "public disclosure" bar, which precludes relator-brought claims based on certain publicly disclosed information.

As amended, the public disclosure bar requires courts to "dismiss an action or claim ... 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."[4]

As we previously reported,[5] the Ninth Circuit ruled in August 2022 that information disclosed through a patent prosecution is a qualifying disclosure for purposes of the bar.[6] One issue in *Valeant* was a question left open by *Allergan* — whether IPR proceedings also qualify as a public disclosure channel. The panel found first that IPRs "present[ ] many hallmarks of a channel (i) federal administrative hearing," "[b]ut because the government was not 'a party'" to the IPR at issue, it could not be a channel (i) disclosure.

The Court also rejected the Valeant defendants' argument that IPRs, like patent prosecutions, should qualify under channel (ii) as an "other Federal ... hearing," distinguishing IPRs on the grounds that their "primary function [is] not investigative" but instead "adjudicatory." Describing them as a "trial-like federal administrative hearing," the panel contrasted IPRs with the *ex parte* nature of patent prosecutions.

Because the Valeant defendants had identified additional public disclosures that did qualify under the bar — namely the patent prosecution histories for the relevant patents, a Law360 article summarizing the IPR proceeding, and two medical studies — the panel next considered whether these disclosures revealed "substantially the same ... allegations or transactions" as the relator's complaint.

The Ninth Circuit ruled in August 2022 that information disclosed through a patent prosecution is a qualifying disclosure for purposes of the bar.

The relator alleged that Valeant had fraudulently obtained the relevant patents because it (1) knew of two previous studies that rendered the invention obvious but did not disclose those studies to the PTO; and (2) had made claims in a prior patent application

that were the opposite of what it would claim a few years later in a different application.

The parties agreed that none of the qualifying disclosures revealed the precise allegations of fraud; accordingly, the panel considered whether the qualifying disclosures revealed the "facts from which fraud can be inferred." In so doing, the Court applied the X + Y = Z formula used by most circuits in which "Z represents the allegation of fraud and X and Y represent its essential elements" (the misrepresented state of facts and the alleged truth, respectively).

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Although the panel recognized that collectively the qualifying disclosures possibly revealed both X and Y, it found that the disclosures were too "scattered" to fairly disclose the combination of the two. The panel further credits the relator with providing a critical fact necessary for scienter.

On whole, the panel concluded that although the "scattered qualifying public disclosures each contain a piece of the puzzle, none show the full picture," and the relator "filled the gaps by putting together the material elements of the allegedly fraudulent scheme."

Although *Valeant* claims adherence to the framework set forth by *Allergan*, the degree to which the panel required the combination of the transactions to be disclosed represents an additional hurdle for FCA defendants, were it to gain traction. It remains to be seen if the panel's construction of what it means to disclose the "transactions" brings it closer in line with disclosure of the allegations themselves.[7]

Notes

[1] 2023 WL 4940429 (9th Cir. Aug. 3, 2023).

[2] 31 U.S.C. § 3730(b)(1).

[3] 31 U.S.C. §§ 3730(b)(4), (d)(2).

[4] 31 U.S.C. § 3730(e)(4)(A) (2010).

[5] https://bit.ly/45x1FTm

[6] *See United States ex rel. Silbersher v. Allergan, Inc.*, 46 F.4th 991 (9th Cir. 2022).

[7] The opinion is available here: https://bit.ly/3YY9EGq.

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