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Valeant Ruling May Pave Way For Patent-Based FCA Suits

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In Silbersher v. Valeant Pharmaceuticals International Inc., a generic-drug maker challenged the validity of Valeant's patent before the Patent Trial and Appeal Board and won, with a finding that Valeant got the patent by knowingly misleading the patent examiner.

The generic-drug maker's lawyer then took the same information from the PTAB case and sued Valeant on behalf of the U.S. government under the False Claims Act,[1] claiming that Valeant used the invalid patent to overcharge Medicare for the drug. Valeant now faces potential treble damages for any overcharges, and the lawyer may receive as much as 30% of the recovery.

Until recently, this scenario appeared unrealistic, as courts had rejected attempts to pursue such whistleblower claims based on publicly available information from PTAB proceedings and other publicly available sources.

But the U.S. Court of Appeals for the Ninth Circuit's January decision in Valeant — which it recently refused to rehear en banc and that may be appealed to the U.S. Supreme Court — could open the door to more such cases, at least in California and surrounding states.

The False Claims Act and Its Public Disclosure Bar

The FCA allows a relator — whistleblower — who learns about fraud against the federal government to sue on behalf of the government, and to share a portion of whatever is recovered.

Because the amounts are often large, and the statute allows for treble damages, the rewards can be substantial.

The whistleblower provisions of the statute were meant to encourage those with specific nonpublic information about the false claims to come forward and act on them.

But those provisions were not meant to encourage or reward "parasitic" lawsuits that merely repackaged information about fraud that had already been made public. Thus, a public disclosure bar was added to the statute.

Under the current version,[2] a relator cannot pursue an FCA case if substantially the same allegations or transactions were previously publicly disclosed in a "federal criminal, civil, or administrative hearing

in which the Government or its agent is a party," or in a "federal report, hearing, audit, or investigation."

Relators need not be insiders of the accused company. Qui tam actions have been brought by defendants' customers, suppliers and competitors, or their employees.

However, courts have often been hostile to such actions when brought by "outsiders" who merely scoured publicly available information to piece together a theory of fraud against the government.

For example, in CKD Project LLC v. Fresenius Medical Care Holdings Inc. in 2022,[3] the U.S. Court of Appeals for the Second Circuit held that a would-be whistleblower could not assemble information taken from multiple public U.S. Securities and Exchange Commission filings and turn it into an FCA case.

Patent-Based FCA Cases

In recent years, some relators have brought FCA cases based on companies' filing of allegedly fraudulent applications to obtain patents that were subsequently declared invalid, and then charging the U.S. government an allegedly inflated price for the patented product.

The theory is that the patent holder has misled the government by certifying that the price charged for the product is fair and reasonable, when in truth the later-invalidated patent, at least temporarily, prevented other companies from selling the patented product and thus pushing prices down as a result of market competition.

This theory has sometimes been invoked in cases involving pharmaceutical companies, though usually without success.

In Amphastar Pharmaceuticals Inc. v. Aventis Pharma SA in the Ninth Circuit in 2017,[4] for example, generic-drug maker Amphastar first obtained a judgment that Aventis had engaged in inequitable conduct by deliberately using material false statements and omissions to mislead the U.S. Patent and Trademark Office into issuing a patent.

Amphastar then filed an FCA case, alleging that because Aventis knew the patent was unlawfully acquired, it had knowingly overcharged Medicare for the drug.

The Ninth Circuit found that the under the public disclosure bar,[5] Amphastar's prior allegations of fraud in the patent litigation meant that it was barred from pursuing an FCA case on the same grounds.

Similarly, in Silbersher v. Allergan plc, the relator was a patent attorney named Zachary Silbersher, who claimed that a pharmaceutical company had improperly obtained patents for an Alzheimer's drug by presenting inaccurate information during the patent prosecution process, and then charged Medicare inflated prices for the drug.

This time, the U.S. District Court for the Northern District of California applied the updated public disclosure bar, and found that the patent prosecution was not a "federal report, hearing, audit, or investigation" that would trigger the bar.

The Ninth Circuit disagreed, finding that the prosecution process qualified under that provision, and noting that "the key factual information underlying [the relator's] complaint was all publicly disclosed and much could be found in websites maintained by the PTO and other government agencies." It thus

reversed and directed that the case be dismissed.

Silbersher, however, tried again in Valeant.

In that case, Valeant had obtained patents on a drug used to treat bowel disease. A generic-drug maker — the aptly named GeneriCo — represented by Silbersher, filed an inter partes review petition asking the PTAB to invalidate one of the patents as obvious in light of prior published studies.

The PTAB agreed and invalidated the patent.

Silbersher then filed an FCA case against Valeant based on information that he obtained in the IPR proceeding.

Specifically, he claimed that information contained within the file history of a different and earlier Valeant patent application showed that Valeant knew that certain representations it made in the later patent application leading to the patent-at-issue were incorrect, and thus that the patent involved in the later proceeding was obvious.

Under this theory, Valeant knew it was charging Medicare an inflated price for the drug because it was patented, and knew that it was not telling the truth when it certified that the price it was charging Medicare was "fair and reasonable."

The district court found that the case against Valeant was prohibited by the public disclosure bar, because the information on which the false statements claim was based came from a federal hearing: the IPR proceeding. But the Ninth Circuit disagreed.

It first found that an IPR proceeding is not a federal hearing covered by the public disclosure bar provision, because the government is not a party to an IPR proceeding — where PTAB acts more like a court — and because the purpose of an IPR proceeding is not for the government to uncover truth, but rather to resolve a dispute.

It thus said the public disclosure bar does not prevent using information from an IPR proceeding to pursue an FCA claim.

The Ninth Circuit agreed that under Allergan, the public disclosure bar does prevent using information obtained from a patent's file history.

But the court found that the bar still did not apply to Silbersher because, while the file histories of the patents involved in the case "each contain a piece of the puzzle" that would add up to showing a false claim to the government, none of them showed the "full picture." That is, none of the individual prior sources showed both that the Valeant technology was too obvious to be patented and that Valeant knew this.

The fact that a person could have hypothetically reviewed each of those file histories and deduced from them the potential fraud did not, in the court's view, trigger the public disclosure bar. Thus, the case against Valeant could proceed.

In essence, the Valeant decision appears to bless the model of a pure "outsider" analyzing information contained in several separate, publicly available materials, and combining them to support a theory that

an entity is submitting false claims to the government.

Valeant later sought either reconsideration from the panel or en banc review by a larger group of Ninth Circuit judges. It cited decisions from 11 other circuits that, it said, conflicted with the Ninth Circuit's analysis.

On Jan. 5, however, the court denied the request, with no judges voting to grant further review. The court has since stayed the issuance of the mandate while Valeant decides whether to seek review by the Supreme Court.

If Valeant decides not to do so, or if the Supreme Court declines to take the case, the Ninth Circuit's decision will remain the law within its jurisdiction, which contains some of the nation's most active patent dockets.

Meanshile, Silbersher is pursuing a similar FCA lawsuit again Johnson & Johnson affiliate Janssen Biotech Inc. in the U.S. District Court for the District of New Jersey.

The court in that case, like the Ninth Circuit in Valeant, found that an IPR proceeding does not trigger the public disclosure bar, and denied the defendant's motion to dismiss on that basis.

Valeant's Effect on Patent-Based FCA Litigation

If Valeant stands, it will leave several questions remaining.

First, will we see more FCA lawsuits based on allegations that patents were falsely obtained? The Ninth Circuit's decision leaves the door open to such cases, because it holds that information a whistleblower obtains from an IPR proceeding cannot trigger the public disclosure bar.

Thus, a party who pursues an IPR against a patent, or even an outsider who simply reviews the record of such a proceeding along with other information relating to the relevant patent, could identify evidence from multiple sources suggesting that a patent is invalid, and assert that the patent holder knew of the invalidity when it applied for the patent.

If the challenged patent covers a product that the patent holder sells to the federal government, and the patent holder made a certification to the federal government in connection with its proposal regarding the validity of the patent or the reasonableness of the price charged, then the person studying the IPR could pursue an FCA claim.

Even if the information identifying the patent as invalid can be deduced from the file history of related patents, that would not, under the Ninth Circuit's reasoning, preclude an FCA case.

Indeed, under Valeant, the public disclosure bar apply would only apply if all the facts sufficient to demonstrate a knowingly false patent application were contained within a single document or set of documents, such as the file history of the patent-at-issue or a related patent.

Second, will the Ninth Circuit's apparently expansive view of outsider-led FCA cases apply beyond the patent context?

If aggregating information across several different public sources does not trigger the public disclosure

bar and prohibit an FCA whistleblower case, it is not hard to imagine would-be relators scouring various public materials to construct a theory of false representations by healthcare providers, defense contractors or others that do business with the government.

When those materials are not readily available for open-source review, Freedom of Information Act requests could help provide additional pieces to complete the puzzle.

Third, will the Ninth Circuit become a magnet for these kinds of lawsuits?

With circuits across the rest of the country apparently skeptical of the use of aggregated public information to pursue FCA cases, one can imagine relators increasingly looking westward to pursue such claims, just as patent plaintiffs flocked to the U.S. District Court for the Eastern District of Texas before the Supreme Court's 2017 decision in TC Heartland v. Kraft Foods revised the patent venue rules.

Valeant marks a significant development in FCA jurisprudence, particularly regarding the use of publicly available information and patent invalidity claims in qui tam cases. The decision opens new avenues for litigation, and potentially raises the stakes for patent applicants who intend to do business with the government.

It is not hard to imagine FCA whistleblower attorneys teaming up with patent attorneys to scour the patent prosecution histories, or IPR proceeding records, of pharmaceutical companies, medical device makers, defense contractors or other marketing of patented products to federal government buyers, seeking fodder for claims that the patents are invalid, and the patentee knew as much, and then knowingly overcharged the government.

Competitors of such patentees may also seek to double down on attacks on their patents by using information uncovered in IPR proceedings or other patent litigation to launch FCA claims as well.

Court decisions finding that a patentee engaged in inequitable conduct in prosecuting a patent — misrepresenting information to the PTO — could also engender FCA claims.

Companies that sell patented products to the government should thus pay attention to the next steps in Valeant and the ongoing litigation in Janssen, as well as any existing or potential challenges to the validity of any of their relevant patents.

Patent and FCA law have long moved in separate orbits, but we may now be watching those worlds collide.

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[1] 31 U.S.C. §§ 3729-3733.

[2] 31 U.S.C. § 3730(e)(4)(A).

[3] 2022 WL 17818587, at *3 (2d Cir. Dec. 20, 2022).

[4] 856 F.3d 696 (9th Cir. 2017).

[5] The version of the public disclosure bar in place at the time has since been revised.