Drug Patent Suits' Novel Theory Tests False Claims Act Limits

By **Benjamin Greenblum, Arthur Argall and Patrick Bradley** (January 20, 2022)

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A string of unusual False Claims Act actions could set the federal courts of appeals on a collision course and create risks for patent holders beyond Congress' contemplation.

A single relator, Zachary Silbersher, has brought three qui tam cases pursuing the novel theory that pharmaceutical companies defrauded the government by charging Medicare and Medicaid inflated drug prices based on invalid patents that improperly stalled generic competition.

How did this relator learn of the deficiencies that allegedly made these patents invalid? Not as a company insider, as in the paradigmatic FCA case, but through information disclosed in federal patent proceedings, including inter partes reviews — challenges to issued patents conducted by the U.S. Patent and Trademark Office's Patent Trial and Appeal Board.

At first blush, this theory appears to be an odd fit for a false claims case: It repackages allegations that were already litigated in public proceedings before a federal agency. But recent disagreement among federal district courts confirms that the picture is not so simple.

Silbersher v. Janssen

Just last month, the U.S. District Court for the District of New Jersey ruled in Silbersher v. Janssen Biotech Inc.[1] that an FCA case stated a claim based on allegations — recycled from IPR proceedings — that the defendants overcharged government payors for products covered by an invalid patent.

The case involves a patent directed to a method of co-administering the prostate cancer treatment Zytiga with prednisone at specific dosages to treat prostate cancer. In particular, the relator alleged that the defendants deceived the USPTO by presenting misleading data about Zytiga's commercial success. These alleged misrepresentations in turn allegedly allowed an invalid patent to block generic competition, increasing the price of Zytiga paid by Medicare and Medicaid.

The defendants' motion to dismiss argued that the FCA's public disclosure bar foreclosed the suit. Because of the FCA's bounties for successful relators, Congress adopted an incentive scheme balancing "adequate incentives for whistle-blowing insiders with genuinely valuable information and discouragement of opportunistic plaintiffs who have no significant information to contribute of their own."[2]

Accordingly, the FCA's public disclosure bar, as amended in 2010, provides a defense against qui tam claims raising "substantially the same allegations" as those that were publicly disclosed in one of three channels:

> (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.[3]

The court held that the public disclosure bar was not triggered because an IPR is not a hearing as defined in channels one and two. As to the first channel, the court found that the government is not a party in an IPR, as such a proceeding is more like private litigation.

The court so concluded notwithstanding the USPTO director's substantive role in IPRs — including the discretion whether to institute in the first place and authority to issue a decision even where the IPR petitioner stops participating — because the USPTO is not "on the same footing as the petitioner and patentholder who are the actual parties to the IPR proceeding."[4]

The court reasoned that if an IPR were deemed a federal hearing under the second channel, the first channel's government-party limitation would be "eviscerate[d]," and Congress' "evident intent [to] narrow" the public disclosure bar would be undermined.[5]

In an attempt to eliminate the surplusage concern, the defendants had proposed construing the first channel to apply to adjudicative hearings and the second to inquisitorial or information-gathering hearings. But the court rejected that interpretation, instead implying a government-party restriction in the second channel, and holding that the public disclosure bar therefore did not apply.

Notably, the court did not indicate that the relator brought to bear any new information about the defendants' alleged fraud that was not disclosed in public hearings and reports during the patent prosecution or ensuing IPR.

After losing their motion to dismiss, the defendants moved the district court to certify an interlocutory appeal.[6] Unless the court grants the motion and the U.S. Court of Appeals for the Third Circuit takes the appeal, the case will proceed to discovery.

Silbersher v. Valeant and Silbersher v. Allergan

A year before Janssen, the U.S. District Court for the Northern District of California reached the opposite result on a substantially similar motion to dismiss.

Silbersher v. Valeant Pharmaceuticals International Inc.[7] centers on allegations that the defendants — Valeant Pharmaceuticals, Salix Pharmaceuticals Ltd. and Dr. Falk Pharma GmBH — obtained a patent directed to the remission of ulcerative colitis and covered the prescription drug Apriso by making false and misleading statements to the USPTO.

The relator's allegations followed on the PTAB's invalidation of the patent in an IPR; the PTAB concluded that the method disclosed in the patent was obvious in light of earlier publications.[8]

The relator urged that the defendants deceptively obtained their patent by concealing this prior art from the USPTO, thereby improperly extending their ability to exclude generic competition for Apriso, and thus "each and every Apriso prescription covered by Medicare, Medicaid, and other government agencies" was not charged at a "fair and reasonable price."[9]

As in Janssen, the defendants moved to dismiss on the ground that the FCA's public disclosure bar foreclosed the suit.

The district court found that the public disclosure bar applied and granted the motion. The court reasoned that the relator's allegations "about the obviousness of the ... patent, and [the] defendants' allegedly nefarious conduct in obtaining it, were all disclosed in the PTAB proceedings."[10]

The court explained that such proceedings constitute other federal hearings under the plain text of the second channel, which is not limited to federal hearings to which the government is party.[11]

The relator's allegations of fraud were further disclosed in the news media, including in a Law360 **article**[12] summarizing the PTAB's determinations, which the court held also barred the suit under the third channel.[13]

Although the court granted the relator leave to amend his complaint, he opted to appeal the decision to the U.S. Court of Appeals for the Ninth Circuit.[14]

There, Valeant joined a companion qui tam action, Silbersher v. Allergan Inc.[15] In Allergan, a different Northern District of California court held that FCA allegations leveraging publicly disclosed USPTO records did not fall within the public disclosure bar and that the qui tam action alleging that the defendants used their allegedly ill-gotten patents to charge government payors inflated prices could proceed.[16]

The district court then certified, and the Ninth Circuit accepted, the defendants' request to take an interlocutory appeal.[17] Both the Allergan and Valeant appeals are fully briefed. A panel of the Ninth Circuit heard oral argument in Allergan on Jan. 10.[18]

Implications

Although each of these courts wrestled with a question of statutory interpretation — whether IPRs constitute federal hearings or federal reports for purposes of the public disclosure bar — the unintended consequences of the Janssen court's apparent approach could be far-reaching.

If IPRs and patent prosecutions truly fall outside the public disclosure bar, all manner of public information could potentially become fodder for FCA actions. An applicant may make dozens if not hundreds of submissions to the USPTO in connection with any given patent prosecution. The USPTO then publishes selected prosecution materials on its public Patent Application Information Retrieval database.

And the validity of the patent might be litigated anew in an IPR, instigated by any number of petitioners. As illustrated in the Valeant and Janssen decisions, IPRs can breed the types of facts and arguments — that the holder of an issued patent allegedly withheld or misrepresented information material to patentability — that can be copied and pasted into a False Claims Act complaint years later.

To be sure, even the courts that allow such allegations to proceed have not meaningfully questioned whether information disclosed in patent prosecutions and IPRs is public. And because the public disclosure bar is not unqualified — it contains an exception for original sources of information[19] — there is little risk that applying the bar by its terms will shut

out veritable whistleblowers with nonpublic evidence of fraud on the government.

The implications of allowing these qui tam cases do not stop at the public disclosure bar. As the U.S. Court of Appeals for the First Circuit held in the 1995 U.S. v. Rivera decision, the FCA "attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the 'claim for payment.'"[20]

As the U.S. Supreme Court put it in the 2016 Universal Health Services Inc. v. U.S. decision, the FCA "is not an all-purpose antifraud statute."[21]

Yet the connection between a patent holder's allegedly failing to disclose material information to a patent examiner prior to patent issuance, on one hand, and charging government payors allegedly inflated drug prices on the other, is far from tight.

Indeed, a broad range of events, including several prescribed by federal statute, must occur between the fraud and the claim.

The patent holder lists its patent in the U.S. Food and Drug Administration's Orange Book, putative generic competitors challenge the patent in filing abbreviated new drug applications, and the patent holder can then bring infringement suits, staying generic entry for a period of time. The generic drug manufacturer also must get FDA approval for its product and successfully bring it to market.

And then there remain all types of disputed questions about what impact generic entry will actually have on the patent holder's price and market share. The daisy chain of events from a submission to the USPTO in connection with one of what may become multiple patents on a pharmaceutical product to the government's being charged a price that is allegedly not fair and reasonable — as the qui tam complaint in Janssen alleged — is as long as it is twisted.

What's more, the attenuated concept of fraud animating the complaints in Janssen and Valeant is out of step with parallel concepts in patent law. A defendant in an infringement suit might escape liability, for example, by showing that the patent holder obtained its patent through inequitable conduct. But this is no easy feat: The defense requires proof by clear and convincing evidence of specific intent to deceive.[22]

Even evidence of the patent holder's gross negligence in making sloppy presentations or omitting critical information will not cut it.[23] The defense further demands but-for materiality — that is, that the patent examiner would have rejected the application absent the patentee's misrepresentations.[24]

And all this must be pled with particularity, as in a fraud case. There is no reason why it should be easier for a stranger to all the underlying patent proceedings to collect a generous bounty in a qui tam action based on a purported fraud on the USPTO than it is for an infringement defendant to defend a lawsuit on the same theory. Yet Janssen may well be stretched to support that counterintuitive proposition.[25]

Depending on how, and whether, the courts of appeals construe the FCA's public disclosure bar, the many and interesting questions surrounding the theory that patent prosecution submissions to the USPTO can trigger FCA liability for drug sales years in the future could become academic. For now, patent holders will have to wait and see.

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[1] Silbersher v. Janssen Biotech, Inc. , --- F. Supp. 3d. ---, 2021 WL 5980343 (D.N.J. Dec. 17, 2021).

[2] Graham Cty. Soil & Water Conservation Dist. v. United States ex rel. Wilson , 559 U.S. 280, 294 (2010) (internal quotation omitted).

[3] 31 U.S.C. §3730(e)(4)(A).

[4] Janssen, 2021 WL 5980343 at *7 (citing Cuozzo Speed Techs., LLC v. Lee , 579 U.S. 261, 279 (2016)).

[5] Id. at *8 (internal quotation omitted). Congress's intent is only "evident" because there is "no direct legislative history" for the FCA's 2010 amendments to the public disclosure bar. Id. at *6 (quoting U.S. ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC , 812 F.3d 294, 299 (3d Cir. 2016)). How Congress "intended" the public disclosure bar to apply to IPRs, however, is unknowable as IPRs did not exist until 2012, two years after the relevant FCA amendments were enacted.

[6] Mot. To Certify Interlocutory Appeal and for a Stay, Silbersher v. Janssen Biotech, Inc., 19-cv-12107 (Jan. 5, 2022), ECF No. 182.

[7] Silbersher v. Valeant Pharms. Int'l, Inc ., 445 F. Supp. 3d 393 (N.D. Cal. 2020).

[8] Id. at 398–99.

[9] Id. at 399 (internal quotations omitted).

[10] Id. at 404.

[11] Id. at 405–06 ("The PTAB is an adjudicative body within the USPTO that conducts IPR trials and other proceedings before administrative patent judges. This functionality falls squarely within the plain meaning of a federal hearing as used in" the FCA. (citation omitted)). The court did not address whether an IPR is a federal hearing under the first channel by virtue of the Patent Office's significant role in such proceedings.

[12] Matthew Bultman, Part of Apriso Patent Nixed in IPR with Hedge Fund Ties, Law360 (May 19, 2017), https://www.law360.com/articles/926213/part-of-apriso-patent-nixed-in-ipr-with-hedge-fund-ties.

[13] Id. at 406.

[14] Silbersher v. Valeant, Nos. 20-16176, 20-16256 (9th Cir.).

[15] Silbersher v. Allergan, Inc., No. 21-15420 (9th Cir.).

[16] Silbersher v. Allergan, Inc., 506 F. Supp. 3d 772, 797, 820 (N.D. Cal. 2020).

[17] Text Order, Silbersher v. Allergan, Inc., 21-15420 (9th Cir. Mar. 9, 2021), ECF No. 1.

[18] See https://www.ca9.uscourts.gov/media/video/?20220110/21-15420/.

[19] 31 U.S.C. §3730(e)(A)–(B).

[20] United States v. Rivera , 55 F.3d 703, 709 (1st Cir. 1995); see 31 U.S.C. § 3729(a)(1)(A).

[21] Universal Health Servs., Inc. v. United States ex rel. Escobar , 136 S.Ct. 1989, 2003 (2016).

[22] Therasense, Inc. v. Becton, Dickinson & Co ., 649 F.3d 1276, 1290 (Fed. Cir. 2011) (en banc).

[23] Id.

[24] Id. at 1291 ("When an applicant fails to disclose prior art to the PTO, that prior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art.").

[25] The Janssen court declined to apply authority involving inequitable conduct and the related antitrust concept—Walker Process fraud—in deciding the motion to dismiss. 2021 WL 5980343, at *11–12 (rejecting "Defendants' attempt to shoehorn antitrust case law from the Federal Circuit into this case").