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GUEST COLUMN

2022 year-end review of False Claims Act developments: Ninth Circuit

By Winston Y. Chan

There is rarely a dull year for the False Claims Act (FCA) and last year was no exception. While much attention has been paid to the Supreme Court's consideration of FCA issues this term, two recent enforcement developments in the U.S. Court of Appeals for the Ninth Circuit are also noteworthy.

In *United States ex rel. Hartpence v. Kinetic Concepts, Inc.*, 44 F.4th 838 (9th Cir. 2022), the Ninth Circuit revisited the scienter required under the FCA. The court considered a relator's allegation that a manufacturer of wound care medical devices and its subsidiary fraudulently certified compliance with Medicare payment rules regarding the medical device's use. *Id.* at 841, 844–45. The United States did not intervene. *Id.* at 844–45. The relator alleged that the defendants falsely certified compliance with Medicare reimbursement criteria requiring that the submitted medical records of patients using the devices reflect "progressive wound healing." *Id.* at 841. Specifically, the relator alleged that the defendants manipulated billing codes during "stalled cycles" without healing. *Id.* at 844–45.

The district court granted summary judgment in favor of the defendants, holding that there was insufficient evidence that the defendants' false certifications were material to the Medicare reimbursements or that the defendants had knowingly used the billing codes as alleged. *Id.* at 845. Notably, the district court interpreted the FCA scienter requirement as requiring both knowledge that a representation was material and also knowledge that the representation was false.

Without commenting on the district court's interpretation of the FCA scienter, the Ninth Circuit reversed and held that the relator had produced sufficient evidence to conclude that the defendant knowingly made materially false statements to the government. The court explained that, based on the relator's evidence, a jury could find that the defendants deliberately miscoded claims to conceal them and knew those coded certifications were false. *Id.* at 851. That is because the relator had put forth evidence, in the form of the defendants' internal communications, that suggested deliberate, fraudulent use of billing codes to evade claim appeals and denials. The record reflected that company employees had flagged the billing internally and that Medicare contractors had corrected the billing codes on occasion, yet the defendants had avoided scrutiny of the validity of claim modifiers. *Id.* at 851–52. This, the court held, was "ample evidence to permit a rational trier of fact to conclude that [the defendants] knew that it was a false statement." *Id.*

'In 2022, the Ninth Circuit's notable FCA rulings included one interpretation and application of the FCA's scienter requirement, and another that further set the boundaries of the public disclosure bar.'

Because the FCA's scienter requirement serves as an important limitation on the ability to bring a successful qui tam action, the Ninth Circuit's decision provides a notable interpretation and application of the standard.

Last year, in *United States ex rel. Silbersher v. Allergan, Inc. et al.*, 46 F.4th 991 (9th Cir. 2022), the Ninth Circuit also addressed the bounds of the FCA's public disclosure bar. The public disclosure bar directs the dismissal of an FCA action when "substantially the same allegations or transactions" have already been publicly disclosed, unless the relator is an "original source of the information." 31 U.S.C. § 3730(e)(4)(A). In *Silbersher*, the relator alleged that the defendant drug companies had improperly obtained patents in order to protect their drugs from other competition. *Id.* at 993. These fraudulent patents resulted in less competition, higher drug prices, and, in turn, increased government reimbursement costs. *Id.* The government did not intervene. *Id.* The district court denied the defendants' motion to dismiss, and the defendants appealed.

On appeal, the Ninth Circuit – interpreting, as a matter of first impression, the public disclosure bar as amended in 2010 – reversed and remanded, holding that the district court erred when it concluded that the FCA's public disclosure bar was not triggered. The Ninth Circuit re-stated the three elements of its public disclosure bar test, that "'(1) the disclosure at issue occurred through one of the channels speci-

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fied in the statute; (2) the disclosure was "public"; and (3) the relator's action' is substantially the same as the allegation or transaction publicly disclosed." *Id.* at 996 (citation omitted). Only the first element, the meaning of a "channel" for disclosure under the FCA, was at issue. *Id.*

Under the Act, the channels specified are a "Federal criminal, civil, or administrative hearing in which the Government or its agent is a party." *Id.* § 3730(e)(4)(A)(i). A public patent prosecution, the court concluded, is an "other Federal … hearing." *Id.* at 999 (internal quotation marks omitted). That is because a "patent prosecution is an administrative hearing" in which "inventors submit applications to the [U.S. Patent & Trademark Office (PTO)], an administrative agency" in pursuit of a patent. *Id.* The administrative patent hearing is an "other … Federal hearing" under the FCA because "Congress intended [the Act] to cover a wide array of investigatory processes." *Id.* at 998. The court explained that The court interpreted this breadth from the statutory phrasing applying the public disclosure bar to "a congressional, Government Accountability Office or other Federal" proceedings. *Id.* at 996 (quoting 31 U.S.C. § 3730(e)(4)(A)). The court thus agreed with the defendants that the underlying information in the relator's suit, which sourced from a public patent prosecution, was barred. The Ninth Circuit reversed and remanded the case to the district court for further proceedings. *Id.* at 1000 (internal quotation marks omitted).

Silbersher made clear that, in the Ninth Circuit, the public disclosure bar covers information provided to the PTO during a patent prosecution. Moving forward, a qui tam action based only on materials obtained from PTO-provided records will be barred.

These FCA issues that developed in the Ninth Circuit Court of Appeals last year – and others discussed in Gibson, Dunn & Crutcher LLP's 2022 Year-End False Claims Act Update – have important implications for the scope of FCA liability. We are likely to see them continue to play out in the courts this year.