

Pacemaker Co. Seeks Clarity on Qui Tam Publicity Test

By **Dan McKay**

Law360 (March 24, 2026, 6:51 PM EDT) -- A medical device company is asking the U.S. Supreme Court to weigh in on one of the most fiercely litigated restrictions in the False Claims Act — the bar on qui tam complaints containing allegations already aired in public.



An appeal to the Supreme Court by Biotronik, a German maker of cardiac implants, hinges on the interpretation of the False Claims Act's prohibition on qui tam complaints that are "substantially the same" as allegations that have already been publicly disclosed, as in news reports. (iStock.com/izzetugutmen)

Biotronik Inc., a Germany-based company that makes cardiac implants, contends the Ninth Circuit created a novel test in 2025 that will force defendants to face "parasitic" whistle-blower suits that would be barred in other jurisdictions.

Biotronik's hopes to shed the claims hinge on the interpretation of the FCA's prohibition on qui tam complaints that are "substantially the same" as allegations that have already been publicly disclosed.

In September, the Ninth Circuit revived a fraud lawsuit against Biotronik, finding the whistle-blower complaint about Biotronik's marketing of pacemakers and other devices "provided genuinely new and material information" when evaluated correctly.

In Biotronik's view, that analysis created a novel standard not applied by other courts.

But the Biotronik petition faces an important hurdle, FCA experts say. The company must convince the

high court that there is a genuine circuit split, rather than just developing case law reflecting inherent subjectivity in how judges interpret the word "substantially."

"I do think there's something to the idea that the public disclosure bar is applied inconsistently by different judges," said Tejinder Singh, an appellate lawyer and partner at Sparacino LLC, where his clients include whistle-blowers.

"I don't think the different applications are the result of a circuit split; it's just that the statutory language invites judges to eyeball the similarity and decide if it's enough," he told Law360 Healthcare Authority.

The stakes are high. The public disclosure bar is often an early defense deployed by companies accused of defrauding the government. The prohibition is intended to thwart relators who, say, read a news article and rush to the courthouse to file suit.

Biotronik contends the complaint it now faces — alleging it hired a doctor's family member as part of an illegal scheme to boost sales — mirrors allegations outlined in the New York Times years earlier, and thus runs up against the FCA public disclosure standard.

Pat Naples, a litigator at ArentFox Schiff LLP who often represents healthcare providers, said the Supreme Court hasn't addressed the FCA's public disclosure bar since 2011, in a case that predated the latest version of the statute.

An earlier version of the qui tam prohibition had barred complaints "based upon" an earlier public disclosure. The statute now calls for dismissal of qui tam suits that are "substantially the same" as what's already been made public.

If the high court takes the case, Naples said, "its decision could have substantial ramifications on the FCA landscape, affecting both how many suits get filed and how many survive motions to dismiss."

Erica Blachman Hitchings, a partner at Whistleblower Law Collaborative LLC and former federal prosecutor, said she isn't convinced the Supreme Court needs to review the circuit decision. She said the opinion includes a thorough discussion of the history and purpose of the public disclosure bar.

"The public disclosure bar was designed by Congress to protect the government from parasitic relators ... it shouldn't be used to provide the defense with a get-out-of-jail free card," she said in an interview.

Hiring Relatives

Biotronik makes and sells pacemakers and other devices that monitor and regulate heartbeats. Its marketing practices have come under fire in qui tam complaints and news articles since 2009.

At issue in the current litigation is a 2011 series of articles in the New York Times examining Biotronik's tactics to boost sales. The coverage included allegations that hiring a doctor's relative was widespread industry practice and that Biotronik officials had suggested it while plotting ways to gain sales at a California hospital.

In 2017, Sam Jones Co. LLC launched a qui tam complaint against Biotronik and other defendants, accusing the company of violating anti-kickback and other laws by hiring or paying the relatives of doctors who implanted the devices in patients.

Sam Jones' managing members are two sales representatives who previously worked for Biotronik.

In one case, their suit says, a Biotronik sales representative would recommend the company's devices to his brother, a surgeon who used them for patients at Cedars-Sinai Medical Center in Los Angeles.

The hospital billed Medicare or other government programs for the devices, and the sales representative earned a commission for his brother's business, according to the suit.

Sam Jones Co. sued under the FCA, alleging the government wouldn't have paid for the devices if it knew of the compensation arrangement, which it says violated the Anti-Kickback Statute and Stark Law.

Biotronik won dismissal of the case in district court, arguing the New York Times had already reported on the company's tactics for encouraging doctors to choose its devices.

The False Claims Act generally requires dismissal when "substantially the same allegations or transactions" outlined in a qui tam complaint were publicly disclosed already by the news media, federal audits or other federal proceedings.

The Ninth Circuit revived the Sam Jones suit Sept. 10, finding the allegations weren't similar enough to what had been reported in the New York Times.

"Fairly characterized, the transactions described in Sam Jones's complaint do not merely repeat what the public already knew about Biotronik's tactics to increase its sales," the opinion said.

"When viewed with the appropriate level of generality described by the benchmarks in [other cases], Sam Jones's complaint provided genuinely new and material information," U.S. Circuit Judge Morgan B. Christen said in the opinion.

Circuit Judges Johnnie B. Rawlinson and Anthony D. Johnstone also sat on the panel for the Ninth Circuit.

Circuit Split?

Biotronik contends the Ninth Circuit is now out of step with other circuits, having allowed a whistleblower to add some details to information from a public report and thus survive a dismissal motion.

The company filed a petition with the Supreme Court on March 4, asking the justices to review the decision.

Biotronik says most circuits that have addressed the publicity bar have come up with a test for evaluating qui tam complaints, centering on whether the government already had enough information to investigate the allegations or at least be alerted to the possibility of wrongdoing.

The Ninth Circuit, however, created a much more granular materiality test, requiring an analysis of whether the complaint materially adds new information to what's already public, Biotronik said.

"This test erodes the 'broad scope' that Congress intended the public disclosure bar to have," the company said.

The decision "enables qui tam complaints to survive if they merely fill in the details of an alleged fraud that already has been disclosed or identify federal statutes that allegedly were violated by the publicly disclosed scheme," the company said.

"Percolating Battles"

Singh expressed skepticism about the need for the Supreme Court to step in.

"The Ninth Circuit looked at the public disclosures, looked at the allegations in a complaint, and decided that they weren't sufficiently similar," Singh said. "That's a very fact-intensive inquiry, and not typically the sort of thing the Supreme Court would review."

Opponents of the Biotronik petition may also object to framing the key test as a question of whether the government already had enough information to launch an investigation. The statutory language zeroes in on whether the information is "substantially the same," not the government's capacity to investigate, Singh said.

The Biotronik framing "seems to require courts to engage in a different guessing game about the government's investigative capabilities, resources, and bandwidth based on nothing more than intuition," he said.

FCA attorneys are watching to see whether the Trump administration weighs in.

When a whistleblower sought Supreme Court review of a Sixth Circuit decision on the publicity bar 10 years ago, the justices asked the solicitor general to offer its view, said Naples of ArentFox Schiff.

The government's attorneys at the time said the differences of opinion in lower courts emerged because the public disclosure bar requires "close examination of the relevant facts," not because courts applied

competing legal tests. The petition for Supreme Court review in that case was denied.

"It will be interesting to see whether the court invites the solicitor general to weigh in again, particularly now that a litigant from the other side of the aisle is claiming that a circuit split exists even though the courts say they are applying the same legal standard," Naples said.

Hitchings said the public disclosure bar is at the center of some important FCA legal debates, including intense fights over how to define "news media" as more people share and discover information online.

"I see a lot of percolating battles over that," Hitchings said, making it a potential question of interest to federal appellate courts.

In the Biotronik case, no one disputes that the New York Times qualifies as news media.

Biotronik, its counsel and the counsel for Sam Jones didn't immediately respond to requests for comment.

Biotronik is represented by Steven D. Gordon, Megan Mocho, Timothy J. Taylor and Hannah M. Maloney of Holland & Knight LLP.

Sam Jones Co. is represented by Jeremy L. Friedman of the Law Office of Jeremy L. Friedman and by Mychal Wilson of the Law Offices of Mychal Wilson.

The case is Biotronik Inc. v. U.S. ex rel. Sam Jones Co. LLC, case number 25A866, in the Supreme Court of the United States.

--Additional reporting by Lauren Berg. Editing by Amy Rowe.

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