

First Circuit Dismisses FCA Claim For Failure To Plead Fraud With Particularity And Denies Further Amendments Of Complaint

December 23, 2013

On December 6, 2013, in *U.S. ex rel. Helen Ge, M.D. v. Takeda Pharmaceutical Company Limited* (No. 13-1088), the First Circuit Court of Appeals affirmed the dismissal of Dr. Helen Ge's *qui tam* actions against her former employer, Takeda Pharmaceutical Company (Takeda). Ge claimed that Takeda terminated her employment when.....

On December 6, 2013, in *U.S. ex rel. Helen Ge, M.D. v. Takeda Pharmaceutical Company Limited* (No. 13-1088), the First Circuit Court of Appeals affirmed the dismissal of Dr. Helen Ge's *qui tam* actions against her former employer, Takeda Pharmaceutical Company (Takeda). Ge claimed that Takeda terminated her employment when she complained about improper reporting of "adverse events" related to several drugs that Takeda sold. The court dismissed her *qui tam* actions, which she brought under the federal False Claims Act (FCA), on the basis that Ge failed to plead fraud with particularity. The court also affirmed the denial of Ge's requests to amend her complaints.

Background

Specifically, in her two *qui tam* actions, Ge alleged that Takeda had failed to adequately disclose risks associated with four of its drugs. She further alleged that as a result of this failure to disclose risks, patients and physicians submitted false claims for government payment through Medicare, Medicaid, or other programs.

Ge amended her complaints twice over the course of approximately two years. Takeda then filed a motion to dismiss, and the district court in Massachusetts dismissed Ge's actions under Federal Rule of Civil Procedure 9(b) for failing to plead fraud with particularity. Ge proposed to amend her complaints for a third time in her opposition to the motion to dismiss and for a fourth time after the court entered judgment, but the court

declined to allow either amendment. Ge then appealed the district court's dismissal of her claims and denial of her requests to amend to the First Circuit.

The First Circuit Decision

In affirming the dismissal, the First Circuit relied on the Rule 9(b) standard of particularity for pleading fraud, stating that plaintiffs (or "relators" in *qui tam* actions) are "required to set forth with particularity the 'who, what, when, where, and how' of the alleged fraud." Particularly, in a *qui tam* action in which the defendant is alleged to have induced others to file false claims with the government, the relator must provide details identifying the particular false claims, such as the dates, contents, numbers, amounts, goods or services billed, and the individuals who billed them.

Ge, as the court of appeals observed, alleged not that the defendant had submitted false claims itself but that it had induced the submission of false claims by others. In such a case, the court held, the relator must do more than merely allege facts related to alleged misconduct; rather, the relator must allege facts sufficient to establish that false claims were submitted for government payment as a result of the alleged misconduct. Ge had provided only the aggregate expenditure data of the government for one of the four drugs, without identifying the entities who submitted claims, the government program that paid them, the times or amounts of claims, or the circumstances of the claims. As a result, the court determined that Ge had alleged "next to no facts in support of the proposition that Takeda's alleged misconduct resulted in the submission of false claims or false statements material to false claims for government payment."

The First Circuit declined to adopt the "per se" rule that Ge had proposed, according to which it would have necessarily followed that false claims and/or material false information were filed whenever the relator made sufficient allegations of misconduct. Instead, the court held that Ge's claims failed because she had not alleged sufficient facts to show that some subset of the claims for government payment were rendered false by any alleged misconduct, and observed that she had pled even less of a basis for her theory that all claims submitted were false because of any alleged misconduct.

Accordingly, the court affirmed dismissal of the *qui tam* actions, ruling that her claims under all theories she presented failed under Rule 9(b).

Requests To Amend Her Complaint

The First Circuit affirmed the lower court's denial of both Ge's third (pre-judgment) and fourth (post-judgment) requests to amend her complaints to cure any defects, noting that the lower court had allowed her two previous requests to amend. Further, on the motion to dismiss, the lower court considered, *arguendo*, the material that Dr. Ge sought to amend into her complaints through her third request. With regard to her fourth request to amend, the First Circuit noted that to allow that amendment would permit a plaintiff or relator to pursue a case to judgment and, if he or she loses, then reopen the case and amend the

complaint to take into consideration the court's decision. For those reasons, the First Circuit affirmed the denials of the requests to amend.

Key Takeaways

The First Circuit's decision in *ex rel. Ge* reinforces Rule 9(b)'s requirement that a plaintiff (or relator) plead fraud with particularity, and further that a *qui tam* relator sufficiently allege not just that the defendant engaged in misconduct, but also that the defendant's alleged misconduct resulted in the submission of false claims to the government.

Appropriately, the court of appeals affirmed the lower court's dismissal of a complaint in which the relator had identified neither the specific false claims under the FCA, nor the times, amounts, and circumstances of those claims. In addition, the court's ruling serves as a reminder that even the liberal standard for amendment of pleadings is not without limit.

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