

**FOR PUBLICATION**

**UNITED STATES COURT OF APPEALS**

**FOR THE NINTH CIRCUIT**

UNITED STATES OF AMERICA,  
EXREL., INSOON LEE,  
Plaintiff-Appellant,

No. 98-56557

v.

D.C. No.  
CV-95-06524-MRP

SMITHKLINE BEECHAM, INC.;  
SMITHKLINE BEECHAM CLINICAL  
LABORATORIES; DOES 1-100,  
Defendants-Appellees.

OPINION

Appeal from the United States District Court  
for the Central District of California  
Mariana R. Pfaelzer, District Judge, Presiding

Argued September 12, 2000  
Submitted March 21, 2001  
Pasadena, California

Filed April 2, 2001

Before: Harry Pregerson, William A. Fletcher, and  
Ronald M. Gould, Circuit Judges.

Opinion by Judge Gould

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**COUNSEL**

Thomas H. Tate and David T. Harney, Harney Law Offices,  
Los Angeles, California, for the plaintiff-appellant.

Thomas H. Lee, II, Frederick G. Herold, and Matthew S. Miner, Dechert Price & Rhoads, Philadelphia, Pennsylvania, and Wayne S. Flick, Latham & Watkins, Los Angeles, California, for the defendants-appellees.

Douglas N. Letter and Sushma Soni, Department of Justice, Washington, D.C., for the amicus curiae.

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## OPINION

GOULD, Circuit Judge:

Insoon Lee ("Lee") appeals a judgment and order dismissing the qui tam action that he brought under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733, against SmithKline Beecham, Inc. ("SmithKline"). We affirm the district court's determination that Lee failed to satisfy the heightened pleading requirements of Federal Rule of Civil Procedure 9(b).

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However, we reverse the district court's decision to dismiss Lee's case with prejudice because we conclude that Lee should have been granted leave to amend his federal FCA and federal "whistleblower" retaliation claims. **1**

We reverse in part and remand.

## FACTS AND PROCEDURAL HISTORY

SmithKline owns and operates regional clinical laboratories, satellite laboratories, draw stations, and patient service centers throughout the United States. At these laboratories, SmithKline personnel test human specimens, including blood, urine, and tissue. Complicated and non-routine tests are performed at SmithKline's National Esoteric Testing Center ("NETC") in Van Nuys, California.

Lee, a supervisor at NETC, filed a complaint on September 29, 1995, asserting claims under the qui tam provisions of the FCA. Lee's allegations centered on SmithKline's handling of control samples.<sup>2</sup> Lee alleged that when test results for control samples fell outside the acceptable standard of error, SmithKline falsified the results and made no attempt to investigate the source of the error, fix the problem, or retest the affected

patient specimens. Lee alleged that because SmithKline billed Medicare for these allegedly worthless tests and falsely certified the payment requests that it sent to the government, SmithKline had violated the FCA. In a separate claim, Lee

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**1** Lee challenges the district court's judgment and order only as they relate to his federal claims. Because we limit our review to issues argued in a party's opening brief, we do not address Lee's state claims. Entm't Research Group, Inc. v. Genesis Creative Group, Inc., 122 F.3d 1211, 1217 (9th Cir. 1997).

**2** As the amicus brief explains, laboratories use control samples with known qualities as a means to verify the accuracy of testing equipment, the technician's performance, and the testing environment. If results for control samples are outside an acceptable range of error, laboratories know that the test is faulty and the results for patient specimens unreliable.

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asserted that SmithKline illegally retaliated against him after he reported the laboratory's wrongful conduct to SmithKline management.

As required under the FCA, Lee served his complaint on the United States, which chose not to intervene in the lawsuit. Lee continued to pursue this action under section 3730(c)(3) of the FCA.

On December 15, 1997, Lee served SmithKline with his complaint. Shortly thereafter, SmithKline moved to dismiss the complaint for, among other reasons, failure to state a claim upon which relief may be granted and failure to plead fraud with particularity. Before the hearing on SmithKline's motion, Lee filed a first amended complaint pursuant to Federal Rule of Civil Procedure 15(a).

SmithKline responded with a second motion to dismiss that again asserted that Lee had not stated a claim or pled fraud with particularity. SmithKline argued that Lee's amended complaint was deficient because it failed to allege (1) that SmithKline certified to the government that its testing complied with certain rules and regulations, or (2) that such compliance was a prerequisite to payment for the tests. SmithKline also argued that Lee's retaliation claims fell short because he failed to allege that SmithKline's retaliatory conduct resulted from the investigation and pursuit of his FCA claims.

On May 22, 1998, the district court granted SmithKline's motion and dismissed Lee's case with prejudice for failure to plead fraud with particularity under Federal Rule of Civil Procedure 9(b) and failure to state a claim under Federal Rule of Civil Procedure 12(b)(6). Lee filed a motion for reconsideration which was denied. This appeal follows.

## DISCUSSION

We review de novo both a dismissal for failure to allege facts of fraud with particularity, Wool v. Tandem Computers,

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Inc., 818 F.2d 1433, 1439 (9th Cir. 1987), and a dismissal for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6), Monterey Plaza Hotel, Ltd. v. Local 483, 215 F.3d 923, 926 (9th Cir. 2000). Denial of leave to amend is reviewed for abuse of discretion. Simon v. Value Behavioral Health, Inc., 208 F.3d 1073, 1084 (9th Cir. 2000).

A

Complaints brought under the FCA must fulfill the requirements of Rule 9(b). Bly Magee v. California, 236 F.3d 1014, 1018 (9th Cir. 2001). Lee contends that his qui tam complaint satisfied Rule 9(b)'s heightened pleading requirements. We disagree.

In his first amended complaint, Lee alleged that SmithKline "knowingly . . . changed control numbers [on various tests] to wrongfully represent that the laboratory results fell within an acceptable standard of error." This broad claim had no factual support -- Lee did not specify the types of tests implicated in the alleged fraud, identify the SmithKline employees who performed the tests, or provide any dates, times, or places the tests were conducted.

Rule 9(b) may not require Lee to allege, in detail, all facts supporting each and every instance of false testing over a multi-year period. See Cooper v. Pickett, 137 F.3d 616, 627 (9th Cir. 1998) (Where complaint asserting claims of improper revenue recognition identified (i) some of the specific customers defrauded, (ii) the type of conduct at issue, (iii) the general time frame in which the conduct occurred, and (iv) why the conduct was fraudulent, it was "not fatal to the complaint that it [did] not describe in detail a single spe-

cific transaction . . . by customer, amount, and precise method."). However, Lee's first amended complaint is not "specific enough to give defendants notice of the particular misconduct which is alleged to constitute the fraud charged so that they can defend against the charge and not just deny that

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they have done anything wrong." Neubronner v. Milken, 6 F.3d 666, 671 (9th Cir. 1993) (internal quotation marks and citation omitted). The complaint therefore fails to satisfy Rule 9(b). Moore v. Kayport Package Express, Inc., 885 F.2d 531, 540 (9th Cir. 1989) ("[M]ere conclusory allegations of fraud are insufficient."). We affirm the district court's dismissal of Lee's first amended complaint.

Lee contends that he is entitled to a lenient application of Rule 9(b) because the information supporting his claims is in the possession of SmithKline.<sup>3</sup> Rule 9(b) may be relaxed to permit discovery in a limited class of corporate fraud cases where the evidence of fraud is within a defendant's exclusive possession. Wool, 818 F.2d at 1439; Deutsch v. Flannery, 823 F.2d 1361, 1366 (9th Cir. 1987). However, given that Lee worked as a supervisor at NETC for over twenty years, was knowledgeable about the tests allegedly falsified, and was employed by SmithKline when he filed this action, he cannot fairly allege that SmithKline has sole possession of the facts evidencing an FCA violation. In light of these circumstances, Lee has no legitimate excuse for filing a vague complaint that does not assert particular details to support its allegations of fraud. In any event, the district court properly determined that Lee's claims, as pled, failed to satisfy Rule 9(b).

B

Although we agree that Lee did not comply with Rule 9(b), we hold that the district court erred in denying him leave

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<sup>3</sup> Although Lee did not plead or brief this issue in the district court, we have the power and discretion to consider this argument on appeal. Neal v. Shimoda, 131 F.3d 818, 827 n.11 (9th Cir. 1997) (generally, Ninth Circuit will not consider issue raised for the first time on appeal, but it has discretion to do so). Given our decision in Part B, below, to remand this case so Lee may attempt to comply with Rule 9(b), we believe it is appropriate and in the interest of judicial economy and efficiency to address the issue now rather than awaiting a second appeal raising the same issue about the application of Rule 9(b) in this case.

to amend. A district court's discretion to deny leave to amend a complaint is not absolute. We consistently have held that leave to amend should be granted unless the district court "determines that the pleading could not possibly be cured by the allegation of other facts." Lopez v. Smith, 203 F.3d 1122, 1127 (9th Cir. 2000) (internal quotation marks and citations omitted). This approach is required by Federal Rule of Civil Procedure 15(a) which provides that leave to amend should be freely granted "when justice so requires." See Foman v. Davis, 371 U.S. 178, 182 (1962) (Rule 15(a)'s mandate "is to be heeded.").

In assessing whether leave to amend is proper, courts consider "the presence or absence of undue delay, bad faith, dilatory motive, repeated failure to cure deficiencies by previous amendments, undue prejudice to the opposing party and futility of the proposed amendment." Moore, 885 F.2d at 538 (citations omitted). These factors, however, are not given equal weight. Bonin v. Calderon, 59 F.3d 815, 845 (9th Cir. 1995). "Futility of amendment can, by itself, justify the denial of a motion for leave to amend." Id.

The district court denied Lee leave to amend because it concluded that any amendment would be futile. This conclusion, however, rested on an unduly narrow reading of Lee's first amended complaint. The district court held that Lee's complaint presented a "false certification" FCA case based on SmithKline's alleged failure to comply with certain testing regulations and its alleged acceptance of federal funds during this period of non-compliance. The district court then determined that Lee's false certification claims were foreclosed by the holding of United States ex rel. Hopper v. Anton, 91 F.3d 1261 (9th Cir. 1996).<sup>4</sup>

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<sup>4</sup> In Hopper, we held that "[v]iolations of laws, rules, or regulations alone do not create a cause of action under the FCA. It is the false certification of compliance which creates liability when certification is a prerequisite to obtaining a government benefit." Id. at 1266 (emphasis in original). Stated another way, absent a false certification upon which funding is conditioned, there is no remedy under the FCA.

Citing Hopper, the district court determined that Lee failed to state a claim because he did not allege (1) that SmithKline falsely certified on its HCFA-1500 claim forms<sup>5</sup> that it had

complied with all applicable rules and regulations, and (2) that such certification was a prerequisite for payment. Moreover, because the HCFA-1500 form has no certification language, the district court concluded that Lee would never be able to assert these critical allegations. Based on this analysis, the district court determined that amendment was futile and denied leave to amend. The district court, however, overlooked the allegations, particularly those in paragraph 10 of the first amended complaint, that supported a different theory -- that SmithKline violated the FCA by seeking and receiving payment for medically worthless tests.<sup>6</sup>

The FCA prohibits any person from "knowingly" presenting "a false or fraudulent claim for payment or approval" to the federal government. 31 U.S.C. § 3729(a)(1). A person "knowingly" submits a false claim not only when he or she "has actual knowledge of the information," but also when he or she "acts in deliberate ignorance" or "reckless disregard" of the truth or falsity of the information. *Id.* at § 3729(b)(1)-(3). In an appropriate case, knowingly billing for worthless services or recklessly doing so with deliberate ignorance may be actionable under § 3729, regardless of any false certification conduct. See *United States v. Aerodex, Inc.*, 469 F.2d 1003, 1007-08 (5th Cir. 1972). Indeed, *Hopper* did not address FCA claims based on worthless products or services, and it specifically distinguished such claims from the false certifications at issue in that decision. *Hopper*, 91 F.3d at 1266. Neither false certification nor a showing of government

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<sup>5</sup> Federal law requires clinical laboratories to use HCFA-1500 forms in connection with their Medicare payment requests.

<sup>6</sup> Specifically, paragraph 10 of the first amended complaint asserts, in part, that "[SmithKline] knowingly, unlawfully and wrongfully allowed incorrect laboratory results to be reported to Medicare patients in return for payment by Medicare funds."

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reliance on false certification for payment need be proven if the fraud claim asserts fraud in the provision of goods and services.

Lee's complaint is neither artfully nor adequately pled under Rule 9(b) and we express no view as to whether Lee's claims may have any merit. However, the complaint, vague as it is, may be construed to allege, and at argument was expressly asserted to include, a theory based on worthless ser-

vices fraudulently provided to the government. If, for sake of analysis, we assume that a party to a government contract knowingly or with deliberate ignorance charged the government for worthless services, then there would be fraud on the government that may be pursued under the FCA. Lee may amend his complaint if he has a proper basis for doing so. However, any amended complaint to be considered must meet the heightened pleading requirements of Rule 9(b). Because amendment would not necessarily have been futile, we hold that the district court should have granted Lee leave to amend his FCA claim.

C

Lee also contends that section 3730(h) of the FCA authorizes relief for employees who have been "discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment" as a result of lawfully pursuing an FCA claim. As drafted, Lee's first amended complaint did not allege these statutorily-required elements of a retaliation claim. On this issue as well, Lee may amend his complaint under Federal Rule of Civil Procedure 15(a).

#### CONCLUSION

We reverse the dismissal of Lee's federal claims and remand to allow Lee an opportunity to amend his complaint

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to satisfy the requirements of Federal Rule of Civil Procedure 9(b) and Federal Rule of Civil Procedure 12(b)(6).

REVERSED in part, and REMANDED.

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