FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

UNITED STATES EX REL. FRANK SOLIS, *Plaintiff-Appellant*, v. MILLENNIUM PHARMACEUTICALS, INC.; SCHERING-PLOUGH CORPORATION; MERCK & CO., *Defendants-Appellees.*	No. 15-16953 D.C. No. 2:09-cv-03010-MCE-EFB OPINION

UNITED STATES EX REL. FRANK SOLIS, *Plaintiff-Appellee*, v. MILLENNIUM PHARMACEUTICALS, INC., *Defendant-Appellant*, and SCHERING-PLOUGH CORPORATION; MERCK & CO., *Defendants.*	No. 15-17055 D.C. No. 2:09-cv-03010-MCE-EFB

UNITED STATES EX REL. FRANK SOLIS, *Plaintiff-Appellee*, v. SCHERING-PLOUGH CORPORATION; MERCK & CO., *Defendants-Appellants*, and MILLENNIUM PHARMACEUTICALS, INC., *Defendant.*	No. 15-17057 D.C. No. 2:09-cv-03010-MCE-EFB

Appeal from the United States District Court
for the Eastern District of California
Morrison C. England, Jr., District Judge, Presiding

Argued and Submitted October 17, 2017
San Francisco, California

Filed March 15, 2018

Before: J. Clifford Wallace, Consuelo M. Callahan, and Jacqueline H. Nguyen, Circuit Judges.

Opinion by Judge Wallace

SUMMARY*

False Claims Act

The panel affirmed in part, and vacated and remanded in part, the district court's Fed. R. Civ. P. 12(b)(1) dismissal of a False Claims Act ("FCA") action brought against three pharmaceutical companies.

Frank Solis alleged that his former employers violated state law and the federal FCA by promoting dangerous off-label uses of a cardiovascular drug, Integrilin, and by paying physicians kickbacks to prescribe Integrilin and an antibiotic drug, Avelox. The district court found that Solis's FCA claims were foreclosed by the public disclosure bar, which deprives federal courts of subject matter jurisdiction over FCA suits when the alleged fraud has already been publicly disclosed, unless the relator is deemed an original source, and declined to exercise supplemental jurisdiction over the state law claims.

The panel held that Solis's Integrilin claims were substantially similar to those in prior public disclosures, and were close enough in kind and degree to have put the government on notice to investigate the alleged fraud before Solis filed his complaint. The panel vacated the dismissal of Solis's Integrilin claims and remanded for the district court to determine whether Solis qualified for the "original source" exception under *United States ex rel. Hartpence v. Kinetic Concepts, Inc.*, 792 F.3d 1121, 1123, 1129–30 (9th Cir. 2015)

* This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

(en banc). The panel did not reach the sufficiency of Solis's Integrilin claims.

Concerning Solis's Avelox claims, the panel held that the district court clearly erred in finding that the Avelox claims were publicly disclosed based on court complaints that never mentioned Avelox. The panel affirmed dismissal of Solis's Avelox claims on the alternative ground that they failed to satisfy Fed. R. Civ. P. 9(b). The panel remanded with instructions to the district court to determine whether to grant Solis leave to amend his Avelox claims.

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OPINION

WALLACE, Circuit Judge:

Frank Solis appeals from the dismissal of his False Claims Act action against three pharmaceutical companies. We have jurisdiction under 28 U.S.C. § 1291, and we affirm in part and vacate and remand in part.

I.

Millennium Pharmaceuticals, Inc. hired Solis to promote sales of a cardiovascular drug, Integrilin. He moved to Schering-Plough Corp. after Schering acquired the right to market Integrilin. There, he also promoted an antibiotic drug, Avelox. Schering later merged with Merck & Co., and Merck fired Solis a year later.

Solis filed this action in 2009. He alleged that his former employers violated state laws and the False Claims Act (FCA) by promoting dangerous off-label uses of Integrilin and by paying physicians kickbacks to prescribe Integrilin and, in the case of Schering and Merck (collectively, Schering), Avelox. Following a three-year investigation, the United States and all twenty-four states named in Solis's initial complaint chose not to intervene.

The district court dismissed Solis's FCA claims under Federal Rule of Civil Procedure 12(b)(1), finding them foreclosed by the FCA's so-called public disclosure bar. After dismissing Solis's federal claims, the district court declined to exercise supplemental jurisdiction over his state law claims. Solis appealed.

II.

We review *de novo* the district court's dismissal for lack of subject matter jurisdiction. *United States ex rel. Hartpence v. Kinetic Concepts, Inc.*, 792 F.3d 1121, 1126 (9th Cir. 2015) (en banc). Plaintiff bears the burden to establish subject matter jurisdiction by a preponderance of the evidence. *United States ex rel. Mateski v. Raytheon Co.*, 816 F.3d 565, 569 (9th Cir. 2016). We review for clear error the findings of fact underlying the subject matter jurisdiction determination. *Hartpence*, 792 F.3d at 1126–27.

III.

The FCA allows whistleblowers, known as relators, to bring an action on the government's behalf against companies that "knowingly present[], or cause[] to be presented . . . a false or fraudulent claim for payment or approval" to the federal government. 31 U.S.C. § 3729(a)(1) (2006)[1]; *see Mateski*, 816 F.3d at 569. The statute, however, deprives federal courts of subject matter jurisdiction over FCA suits when the alleged fraud has already been publicly disclosed, unless the relator is deemed an original source. *See* 31 U.S.C.

[1] The district court determined that the version of the FCA in effect when Solis filed his initial complaint governs this action. Solis does not challenge this determination on appeal.

§ 3730(e)(4) (2006) (amended 2010). This public disclosure bar is triggered if three conditions are met: "(1) the disclosure at issue occurred through one of the channels specified in the statute; (2) the disclosure was 'public'; and (3) the relator's action is 'based upon' the allegations or transactions publicly disclosed." *Mateski*, 816 F.3d at 570, quoting *Malhotra v. Steinberg*, 770 F.3d 853, 858 (9th Cir. 2014). Solis challenges only the third condition, as he contends his allegations are not based upon a prior public disclosure.

"Under our case law, for a relator's allegations to be based upon a prior public disclosure, the publicly disclosed facts need not be identical with, but only substantially similar to, the relator's allegations." *Id.* at 573 (internal quotation marks and citation omitted). A prior disclosure and an allegation may be substantially similar when the prior public disclosure put the government "on notice to investigate the fraud before the relator filed his complaint." *Id.* at 574.

IV.

We first consider Solis's Integrilin claims. These claims, brought in 2009, fall into three categories: combination use claims, other off-label claims, and kickback claims. The district court held the combination use claims were substantially similar to those in a complaint filed in state court by an unrelated plaintiff in 2006. It further held the other off-label use and kickback claims were substantially similar to those in five complaints filed in federal court by unrelated plaintiffs in 2007.

We compare Solis's combination use claims to those in the 2006 complaint to determine whether they are substantially similar. Solis alleged that Millennium and

Schering fraudulently promoted the use of Integrilin in combination with the drugs tenecteplase and heparin, which was "extremely dangerous" and "increased bleeding risk." He also alleged that publicly available studies identified this increased bleeding risk and that Schering managers gave those studies to its sales representatives. By comparison, the 2006 complaint alleged that Schering and Millennium were negligent in (1) failing to warn adequately physicians who would prescribe Integrilin about the "danger of causing intracranial bleeds," (2) failing to warn physicians about the "dangers of using [Integrilin] in combination with tenecteplase and heparin," and (3) "marketing [Integrilin] for use in combination with tenecteplase and heparin."

The publicly disclosed allegations from the 2006 complaint are substantially similar to Solis's 2009 combination use claims. Both sets of allegations point to the same actors (Schering and Millennium), the same conduct (marketing Integrilin for use in combination with tenecteplase and heparin), and the same risk (increased bleeding). While there may be some differences in the focus and framing of the 2006 complaint compared with Solis's 2009 combination use claims, the degree of overlap is sufficient to show substantial similarity.

Solis argues that his combination use claims are not substantially similar to those in the 2006 complaint because he provided "139 more pages of detail." But much of his complaint amounts to legal boilerplate, reciting the elements of dozens of federal and state law counts. As to the few unique details about the studies, he fails to explain how they would be material to a government investigation. *See Mateski*, 816 F.3d at 579 (explaining that a relator must provide "genuinely new and material information"). Solis's

reliance on *Mateski* is also unpersuasive. There, we held that the public disclosure bar did not apply because the relator's complaint "allege[d] fraud that is different in kind and in degree" from the prior public disclosure, a point we emphasized twice in our decision. *Id.* at 567, 578. But here, Solis's complaint and the 2006 complaint are similar in kind, even if slightly less so in degree. The prior disclosure "need not be identical with" Solis's allegations to bar his claims. *Id.* at 573.

Solis also contends that his combination use claims are not substantially similar because he alleged fraud, while the 2006 complaint alleged only negligence. We disagree. The absence of any explicit allegation of wrongdoing in the prior public disclosure "is simply of no moment" so long as "the material transactions giving rise to the [defendant's] allegedly unlawful . . . schemes were publicly disclosed." *A-1 Ambulance Serv., Inc. v. California*, 202 F.3d 1238, 1245 (9th Cir. 2000); *see also United States v. Alcan Elec. & Eng'g, Inc.*, 197 F.3d 1014, 1019–20 (9th Cir. 1999). Here, the 2006 complaint revealed the material transactions or allegations giving rise to Solis's later claims: that Schering and Millennium "market[ed] the drug [Integrilin] for use in combination with tenecteplase and heparin" and that this combination increased the risk of bleeding.

Solis does not argue that his other off-label use and kickback claims allege more detail than those in the 2007 federal court complaints, and for good reason. These claims closely mirror those in the 2007 complaints. Rather, Solis argues that the 2007 complaints are not substantially similar because they "discuss[] many 'subject drugs' as a group, of which Integrilin was only one." We reject this argument. Solis cites no legal authority suggesting the public disclosure

bar is inapplicable where a prior public disclosure uses a defined term. As the district court observed, the use of a defined term "to avoid repeating the names of seven drugs–one of which was Integrilin–hundreds of times" does not make the similarity any less substantial. *United States ex rel. Solis v. Millennium Pharm., Inc.*, 95 F. Supp. 3d 1208, 1218 (E.D. Cal. 2015).

Finally, we disagree with Solis that his claims contain "more current allegations, including facts which transpired after the 2007 cases." Each 2007 complaint alleged that the "acts and omissions as alleged herein . . . continue[] to be undertaken."

We are satisfied that Solis's Integrilin claims are substantially similar to those in the prior public disclosures. They are close enough in kind and degree to have put the government on notice to investigate the alleged fraud before Solis filed his complaint. *See Mateski*, 816 F.3d at 574.

V.

Solis can still establish subject matter jurisdiction, however, if he can show that he qualifies as an "original source." 31 U.S.C. § 3730(e)(4). Under our precedent in effect at the time the district court considered Solis's allegations, we applied a three-part test to determine whether a relator qualifies as an original source: (1) he must have "direct and independent knowledge" of the information on which his allegations are based; (2) he must have "voluntarily provided the information to the Government before filing" his FCA action; and (3) he "must have had a hand in the public disclosure of allegations that are a part of [his] suit." *Wang ex rel. United States v. FMC Corp.*, 975 F.2d 1412, 1417–18

(9th Cir. 1992), *overruled by Hartpence*, 792 F.3d at 1123. The first two parts of the test derive directly from the text of the FCA; the third part—the hand-in-the-public-disclosure requirement—we had inferred from the statute's legislative history. *Id.* Invoking this test, the district court concluded that Solis did not qualify as an original source because he did not satisfy the hand-in-the-public-disclosure requirement. *Solis*, 95 F. Supp. 3d at 1220.

Intervening circuit law, however, has undercut the basis for the district court's conclusion. In our recent en banc decision in *Hartpence*, we repudiated the third part of our original source test, holding that it had no basis in the statutory text. 792 F.3d at 1128. After *Hartpence*, only the first two parts—those explicitly provided in the statute—are relevant to the original source inquiry. *Id.*

Without the benefit of *Hartpence*, the district court determined Solis could not qualify as an original source on the sole ground that he failed to show he had a hand in the prior public disclosure. *Solis*, 95 F. Supp. 3d at 1220. Because that requirement is inapplicable after *Hartpence*, we remand so that the district court can determine, in the first instance, whether Solis meets the other two parts of the original source test. *Hartpence*, 792 F.3d at 1129–30.

Solis argues the district court "already found" he met the remaining two parts of the original source test. This is incorrect. The district court simply observed in dicta that Solis "may well have direct and independent knowledge of the subject matter of the allegedly fraudulent claims" and that Solis "claims he did provide the information to the government before filing his suit." *Solis*, 95 F. Supp. 3d at 1220; *United States ex rel. Solis v. Millennium Pharm., Inc.*,

No. 2:09-CV-03010-MCE-EFB, 2014 WL 1270581, at *9 (E.D. Cal. Mar. 26, 2014). These observations are neither legal conclusions nor findings of fact. At most, they are assumptions made by the district court for the sake of argument en route to finding that Solis did not satisfy the hand-in-the-public-disclosure requirement. A straightforward reading of the district court's orders demonstrates the district court did not consider whether Solis satisfied the other two requirements of the original source test.

VI.

We now turn to Solis's Avelox claims, which relate only to the payment of kickbacks. Defendants do not argue that the public disclosure bar applies to Solis's Avelox claims. This is because none of the disclosures deemed to bar the Integrilin claims even mentions Avelox. The district court clearly erred in finding that the Avelox claims were publicly disclosed based on court complaints that never mention Avelox.

We may affirm, however, on any ground supported by the record. *See United States ex rel. Kelly v. Serco, Inc.*, 846 F.3d 325, 330 (9th Cir. 2017). FCA claims are subject to Federal Rule of Civil Procedure 9(b). *United States v. United Healthcare Ins. Co.*, 848 F.3d 1161, 1180 (9th Cir. 2016). This means a relator must state with particularity "the who, what, when, where, and how of the misconduct charged." *Id.*, quoting *Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 998 (9th Cir. 2010). We have held that Rule 9(b) does not require a relator to allege the details of every false claim submitted to the federal government for reimbursement, so long as he alleges "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *United*

Healthcare Ins., 848 F.3d at 1180, quoting *Ebeid*, 616 F.3d at 998–99.

Solis's only particularized allegations show efforts by Schering to get Avelox placed "on formulary" at two hospitals. Even assuming these efforts established a scheme to submit false claims, Solis has failed to identify a single claim submitted pursuant to the scheme. Nor has he provided reliable indicia supporting a strong inference that such claims were submitted. For example, Solis does not allege that being "on formulary" meant such claims would be submitted, or even that being on formulary meant Avelox would be prescribed. Being "on formulary" merely means the drug is *available* to be used or prescribed. *See* Consolidated Second Cross-Appeal Brief of Defendants-Appellees/Cross-Appellants at 75; *accord J.B.D.L. Corp. v. Wyeth-Ayerst Labs., Inc.*, 485 F.3d 880, 884 (6th Cir. 2007) ("Formularies are, generally, a listing of medications for which [a managed care organization] provides coverage"). Solis's complaint provides no other details linking the alleged scheme to any claim submitted to a federal healthcare program. It was Solis's burden to supply these missing links and he has failed to do so. Solis has not pleaded with the particularity required by Rule 9(b).

Solis argues that we should direct the district court to grant him leave to amend his complaint for the third time if deemed deficient. The district court had no occasion to consider this question, having denied Schering's Rule 12(b)(6) and 9(b) motion before granting its Rule 12(b)(1) motion. *United States ex rel. Solis v. Millennium Pharm., Inc.*, No. 2:09-CV-03010-MCE-EFB, 2015 WL 1469166, at *7 (E.D. Cal. Mar. 30, 2015). On remand, we instruct the district court to decide this question in the first instance.

VII.

In conclusion, we vacate the dismissal of Solis's Integrilin claims and remand for the district court to determine whether Solis qualifies for the original source exception under *Hartpence*. We do not reach the sufficiency of Solis's Integrilin claims. We affirm dismissal of Solis's Avelox claims on the alternative ground that they fail to satisfy Rule 9(b). Finally, we remand with instructions to the district court to determine whether to grant Solis leave to amend his Avelox claims.

Each party shall bear its own costs.

AFFIRMED in part; **VACATED** in part; **REMANDED**.