# **United States Court of Appeals**For the First Circuit

No. 13-1948

UNITED STATES ex rel. MICHAEL A. WILSON,

Relator, Appellant,

v.

BRISTOL-MYERS SQUIBB, INC.; SANOFI-AVENTIS U.S. LLC,

Defendants, Appellees.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

[Hon. Mark L. Wolf, <u>U.S. District Judge</u>]

Before

Lynch, <u>Chief Judge</u>, Torruella and Howard, Circuit Judges.

Alastair J.M. Findeis, with whom  $\underline{\text{Milberg LLP}}$  and  $\underline{\text{David Pastor}}$  and  $\underline{\text{Pastor Law Office, LLP}}$  were on brief, for appellant.

<u>Catherine E. Stetson</u>, with whom <u>Jessica L. Ellsworth</u>, <u>Mitchell J. Lazris</u>, <u>Mary Helen Wimberly</u>, <u>Hogan Lovells US LLP</u>, <u>Robert Keefe</u>, and <u>WilmerHale</u> were on brief, for appellee Bristol-Myers Squibb, Co.

Robert J. McCully, with whom <u>Elizabeth C. Burke</u> and <u>Shook, Hardy & Bacon LLP</u> were on brief, for appellee Sanofi-Aventis U.S. LLP.

April 30, 2014

LYNCH, Chief Judge. This appeal primarily involves the scope of the first-to-file rule of the federal False Claims Act ("FCA"), 31 U.S.C. § 3730(b)(5), and the application of the "essential facts" test to determine whether a later-filed complaint is barred by earlier-filed complaints under this provision. See United States ex rel. Duxbury v. Ortho Biotech Prods., L.P., 579 F.3d 13, 32-33 (1st Cir. 2009).

Relator Michael A. Wilson, a former Bristol-Myers Squibb, Co. ("BMS") sales representative, alleged that BMS and Sanofi-Aventis U.S., LLC ("Sanofi") unlawfully promoted Plavix for off-label uses, that BMS also unlawfully promoted Pravachol and Monopril, and that both companies "knowingly" caused the submission of false claims to the government in violation of the FCA. See United States ex rel. Hutcheson v. Blackstone Med., Inc., 647 F.3d 377, 380 (1st Cir. 2011). After the government (and Wilson) benefitted from the settlement of certain claims Wilson brought in his original complaint against BMS, the government declined to intervene in the litigation of the remaining claims. The district court dismissed the remaining FCA claims as expressed in a Second Amended Complaint because they ran afoul of the first-to-file rule.

Wilson now appeals from the dismissal, as well as from the denial of his motion to file a Third Amended Complaint and from denial of his follow-up motion to reconsider. We affirm.

## A. <u>Background and First Amended Complaint</u>

Wilson's employment at BMS was terminated in September 2004. In September 2006, he filed his original FCA complaint in the Central District of California under seal, to allow the United States time to review the complaint and to decide whether to intervene in the action, 31 U.S.C. § 3730(b)(2). He filed an amended complaint ("First Amended Complaint" or "FAC") in October 2006, which alleged, inter alia, that BMS violated the federal criminal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2)(B), and engaged in off-label promotion of Monopril, Plavix, and Pravachol, and that these actions caused false claims to be submitted to the government in violation of the FCA. Physicians may prescribe Plavix, Pravachol, and Monopril for non-FDA-approved indications, but the Food, Drug and Cosmetic Act, 21 U.S.C. § 321 et seq., prohibits companies from marketing medications for such "off-label" uses, 2 and Medicaid generally does not reimburse patients for off-

Wilson's FAC also alleged that BMS retaliated against him and terminated his employment unlawfully. Those employment-related claims have been transferred to California and are not before us in this appeal. <u>United States ex rel. Wilson v. Bristol-Myers Squibb, Inc.</u>, No. 06-12195-MLW, 2013 WL 3327317, \*3-4 (D. Mass. June 27, 2013).

The FDA approves drugs to treat particular medical conditions or diseases. Off-label use marketing is for those conditions or diseases not included in the official label approved by the FDA. <u>In re Neurontin Mktg. & Sales Practices Litig.</u>, 712 F.3d 21, 27-28 (1st Cir. 2013). At times the drugs in question may be potentially harmful to patients when put to off-label uses. <u>Id.</u>

label prescriptions. <u>See</u> 42 U.S.C. § 1396r-8(k)(3), (k)(6); <u>United</u> States ex rel. <u>Rost</u> v. <u>Pfizer, Inc.</u>, 507 F.3d 720, 723 (1st Cir. 2007), <u>overruled in part by Allison Engine Co.</u> v. <u>United States ex rel. Sanders</u>, 553 U.S. 662 (2008).

In December 2006, while the government's investigation was ongoing and the FAC was still under seal, the case was transferred to the District of Massachusetts.

On September 28, 2007, Wilson entered into a partial settlement agreement with BMS that concluded part of the case. Under the agreement, Wilson voluntarily dismissed with prejudice all federal FCA claims against BMS "except for claims relating to off-label promotion, retaliation, and wrongful termination to the extent they are alleged in Paragraphs 3-6, 9-60, 161-174, 176-178, 180, and 190-191 of the [FAC]." In the settlement, BMS denied any liability or wrongdoing related to Wilson's allegations, but agreed to execute an agreement with the United States, under which BMS would pay the government \$317,436,081, plus 4.5% per year interest from January 1, 2007 until the settlement amount was paid in full. Wilson received a portion of that sum.

On October 22, 2008, the government declined to intervene in what remained of the case.

at 27.

## B. <u>Second Amended Complaint</u>

On April 9, 2009, Wilson filed his Second Amended Complaint ("SAC"), also under seal. The SAC expanded upon Wilson's earlier (not settled) allegations against BMS, and added Sanofi as a defendant for the first time. The SAC alleged that BMS engaged in schemes to promote Plavix, Pravachol, and Monopril for certain off-label uses, and that Sanofi participated in those schemes that related to the promotion of Plavix only. It is the dismissal of this complaint which is primarily at issue.

More specifically, the SAC alleged that (1) BMS promoted Pravachol, a drug the FDA had approved for lowering cholesterol, for off-label uses related to diabetes or insulin resistance syndrome; (2) BMS and Sanofi promoted Plavix, a drug the FDA had approved for lowering the risk of stroke and heart attack for patients with atherosclerosis or acute coronary syndrome, for off-label use by diabetic patients to prevent peripheral arterial disease ("PAD"); and (3) BMS engaged in the off-label promotion of Monopril, which the FDA approved to treat hypertension.

As to the mechanisms of the off-label promotions, Wilson alleged that BMS used the following schemes to promote Plavix and Pravachol: (1) sponsoring and promoting off-label research for these drugs; (2) training its sales force to promote off-label

prescriptions, including using altered "fax back" requests; and (3) promoting off-label uses in continuing medical education programs. He alleged that Sanofi used the same methods to promote off-label use of Plavix. Finally, Wilson alleged that BMS trained its representatives to promote off-label prescriptions of Monopril.

In August 2009, the court granted a motion to unseal the case. At this point, the parties agreed, with court approval, that because Wilson intended to amend his complaint again, BMS and Sanofi did not need to answer it until the court determined which complaint would govern.

#### C. Denial of Leave to File Third Amended Complaint

On June 24, 2010, Wilson filed a Motion for Leave to Amend and File a Third Amended Complaint, and attached his Proposed Third Amended Complaint ("TAC") to the motion. The TAC sought to add a second relator, Lucius O. Allen, Jr., also a former BMS employee, and to substantially expand the allegations in the SAC.

The court (Gertner, J.) denied Wilson's motion on June 16, 2011, reasoning in a thoughtful opinion that the TAC did not meet the requirements for amendment of Fed. R. Civ. P. 15, and

<sup>&</sup>lt;sup>3</sup> A pharmaceutical company may distribute "third party" publications that describe results of off-label uses of their drugs, but only if the material is distributed in response to requests from physicians. <u>See</u> 21 C.F.R. § 99.101. At BMS, these "requested" materials were referred to as "faxbacks." Wilson alleged that BMS "sales representatives fraudulently altered faxback requests to make the promotion of off-label prescriptions look legitimate."

further, that the substance of the TAC did not, in any event, meet the requirements of the FCA. As to Rule 15, the district court noted that the SAC came almost three years after the original complaint, with the TAC following almost a year after the SAC, and found that Wilson "ha[d] not adequately explained" either set of delays.

The district court relied more heavily on its FCA inadequacy holding. It found that to the extent Allen's allegations replicated claims that Wilson made in the SAC, the TAC violated the "first-to-file" rule, 31 U.S.C. § 3730(b)(5), or the "public disclosure" bar, id. § 3730(e)(4)(B), of the FCA. By contrast, to the extent that the TAC added substantively new allegations not previously disclosed to the government (regardless of which relator provided the information), the district court held that those allegations violated the qui tam filing and service requirements, id. § 3730(b)(2).4

### D. <u>Denial of Motion to Reconsider</u>

In anticipation of Judge Gertner's retirement, the case was reassigned to Judge Wolf on June 21, 2011. Wilson filed a Motion for Reconsideration of the denial of his motion to file the

The FCA requires that a relator filing a new claim must serve "substantially all material evidence and information the person possesses" on the government, and that the complaint must remain under seal for at least 60 days. 31 U.S.C. § 3730(b)(2). The TAC was not filed under seal and was not served on the government before it was filed.

TAC. This motion disputed the Rule 15 ruling, but did not dispute the earlier ruling that new allegations based on Allen's knowledge could not be added to the TAC. Instead, Wilson requested that the court allow the SAC to be amended by "adding certain paragraphs" from the Proposed TAC that were, Wilson represented, based on his own knowledge and investigation. 5

The court denied the motion on March 7, 2012, finding that this was not one of the "limited number of circumstances," United States v. Allen, 573 F.3d 42, 53 (1st Cir. 2009), in which reconsideration was warranted. The district court ordered both BMS and Sanofi to respond to the SAC.

#### E. Motion to Dismiss the FCA Claims in the SAC

BMS and Sanofi moved to dismiss the FCA counts in the SAC. At a hearing on February 7, 2013, the district court granted the motions as to Wilson's federal FCA claims. The court dismissed the FCA claims relating to Plavix and Pravachol for lack of subject matter jurisdiction, Fed. R. Civ. P. 12(b)(1), because they violated the FCA's first-to-file rule, see 31 U.S.C. § 3730(b)(5). It dismissed the Monopril allegations for failure to plead fraud with particularity. Fed. R. Civ. P. 9(b). Wilson does not appeal

<sup>&</sup>lt;sup>5</sup> Along with his motion for reconsideration, Wilson belatedly submitted a declaration from his attorney that purported to address which of the allegations in the Proposed TAC were based on Wilson's (rather than Allen's) knowledge. He offered no such distinction to the district court when he first sought leave to file the TAC.

the district court's dismissal of the FCA claims related to Monopril.

The court's dismissal on first-to-file grounds was based on two complaints that were filed before Wilson filed his original complaint in September 2006. On May 4, 2006, Daniel C. Richardson, a Senior District Business Manager for BMS, had filed a complaint under seal in the District Court for the District of Columbia. The Richardson Complaint alleged that BMS and Sanofi engaged in broad, nationwide schemes to promote and prescribe Plavix and Pravachol for off-label uses. His allegations extended from "1999 through at least 2003, and probably thereafter."

More specifically, the Richardson Complaint alleged that BMS and Sanofi promoted Plavix for off-label treatment of acute coronary syndrome, 6 and promoted Pravachol, which was approved for reducing cholesterol and cardiac events, for uses "such as decreasing CD-40 ligand, decreasing matrix metalloproteinases, decreasing hsCRP levels and other mechanisms for 'plaque stabilization' not included in the FDA-approved label." The Richardson Complaint alleged that BMS and Sanofi used several mechanisms to promote these off-label uses, 7 including the schemes

<sup>&</sup>lt;sup>6</sup> The FDA approved Plavix for the treatment of acute coronary syndrome in February 2002; however, the Richardson Complaint's allegations of BMS and Sanofi's promotion of this off-label use covered the period before the FDA approved it.

<sup>&</sup>lt;sup>7</sup> The Richardson Complaint also alleged that BMS and Sanofi paid "tens of thousands of dollars in kickbacks to Medicare and

of "target[ing] hospitals and . . . follow[ing] up on medical education and [Continuing Medical Education] programs," using "fax back[s]" to send off-label information, sponsoring research of off-label uses, and training its sales forces to promote those uses.

A second relevant complaint was filed by Joseph Piacentile in the District of New Jersey on June 7, 2005 against Sanofi. That complaint alleged that Sanofi paid illegal kickbacks to physicians in order to push them to prescribe Plavix for certain off-label uses. Because Wilson had earlier sought to withdraw his allegations as to illegal kickbacks, the Piacentile Complaint, the court concluded, was ultimately "not material to the outcome."

The court noted that the off-label promotions and schemes alleged in the SAC were substantially similar to those alleged in the Richardson Complaint. Both complaints referred to promotion of off-label uses as to the same drugs, and both alleged the use of certain mechanisms -- among them, faxbacks and off-label marketing through continuing medical education -- to further these schemes. The difference was the off-label uses -- the treatment of

Medicaid providers, causing the providers to falsely certify that they ha[d] complied with the anti-kickback provisions when in fact they had not." We do not dwell on this portion of the Richardson complaint.

<sup>&</sup>lt;sup>8</sup> Wilson's allegations regarding illegal kickbacks were barred by the settlement agreement and accompanying release of claims that Wilson signed in September 2007.

particular diseases and symptoms -- for which Plavix and Pravachol were promoted.

The district court applied the "essential facts" test to determine whether the SAC violated the FCA's first-to-file rule, as set forth in <u>United States ex rel. Duxbury v. Ortho Biotech Products, L.P.</u>, 579 F.3d 13, 32 (1st Cir. 2009). It concluded that the only new information contained in Wilson's SAC was the particular off-label <u>uses</u> for treatment of different diseases that BMS and Sanofi were promoting. Because "Wilson's complaint d[id] not alert the government to a new type of fraudulent scheme or even new aspects of an existing scheme allegedly being perpetrated by the defendants," the court reasoned, it was barred by the FCA's first-to-file rule. Accordingly, the district court dismissed the FCA claims in the SAC as to Plavix and Pravachol. This appeal followed.

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The FCA first-to-file rule is jurisdictional, and we review a dismissal on those grounds de novo. <u>United States ex rel.</u>

<u>Heineman-Guta v. Guidant Corp.</u>, 718 F.3d 28, 34 (1st Cir. 2013).

The rule comes from the statutory prohibition that bars any "person other than the Government" from "bring[ing] a <u>related action</u> based on <u>the facts</u> underlying the pending action" in the FCA context. 31

U.S.C. § 3730(b)(5) (emphasis added). This prohibition is "exception-free." <u>Duxbury</u>, 579 F.3d at 33 (quoting <u>United States</u>

ex rel. Lujan v. Hughes Aircraft Co., 243 F.3d 1181, 1187 (9th Cir.
2001)) (internal quotation marks omitted).

One underlying purpose of § 3730(b)(5) is "to provide incentives to relators to 'promptly alert[] the government to the essential facts of a fraudulent scheme, '" <a href="id.">id.</a> at 24 (alteration in original) (quoting <u>Lujan</u>, 243 F.3d at 1188). It is also part of the larger balancing act of the FCA's qui tam provision, which "attempts to reconcile two conflicting goals, specifically, preventing opportunistic suits, on the one hand, while encouraging citizens to act as whistleblowers, on the other." United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc., 149 F.3d 227, 233 (3d Cir. 1998); see also United States ex rel. Ge v. Takeda Pharm. Co., 737 F.3d 116, 123 (1st Cir. 2013) (while the FCA's financial incentives encourage would-be whistleblowers to expose fraud, they also attract "parasitic relators who bring FCA damages claims based on information within the public domain or that the relator did not otherwise discover" (quoting <u>United States</u> ex rel. Duxbury v. Ortho Biotech Prods., L.P. ("Duxbury II"), 719 F.3d 31, 33 (1st Cir. 2013)); <u>United States ex rel. Chovanec v.</u> Apria Healthcare Grp., Inc., 606 F.3d 361, 363-64 (7th Cir. 2010);9

<sup>&</sup>lt;sup>9</sup> As to such parasitic suits, as the Seventh Circuit (Easterbrook, J.) has observed:

Me-too suits designed to divert some of the reward to latecomers do not serve any useful purpose, and they weaken the incentive to dig out the facts and launch the initial action. What's more, secondary suits that do no more than remind the United States of what it has learned

<u>Lujan</u>, 243 F.3d at 1187. The application of the first-to-file rule advances both functions of § 3730(b)(5). <u>See LaCorte</u>, 149 F.3d at 233.

"have interpreted § 3730(b)(5) to bar 'a later allegation [if it] states all the essential facts of a previouslyfiled claim' or 'the same elements of a fraud described in an earlier suit.'" <u>Duxbury</u>, 579 F.3d at 32 (alteration in original) (quoting <u>LaCorte</u>, 149 F.3d at 232-33). In using this judicially created "essential facts" or "material elements" test, which we adopted for the first time in Duxbury, 579 F.3d at 32-33, we are in line with all of the circuit courts which have considered this section. See LaCorte, 149 F.3d at 232-33; United States ex rel. Carter v. Halliburton Co., 710 F.3d 171, 181-82 (4th Cir. 2013); United States ex rel. Branch Consultants v. Allstate Ins. Co., 560 F.3d 371, 378 (5th Cir. 2009); Walburn v. Lockheed Martin Corp., 431 F.3d 966, 971 (6th Cir. 2005); Chovanec, 606 F.3d at 363-64; Lujan, 243 F.3d at 1187-88; United States ex rel. Grynberg v. Koch Gateway Pipeline Co., 390 F.3d 1276, 1279-80 (10th Cir. 2004); United States ex rel. Hampton v. Columbia/HCA Healthcare Corp., 318 F.3d 214, 217-18 (D.C. Cir. 2003).

Under the essential facts standard (with exceptions not relevant here), the first-to-file rule "still bar[s] a later claim

from the initial suit deflect recoveries from the Treasury to rewards under [31 U.S.C.] § 3730(d). Chovanec, 606 F.3d at 364.

'even if that claim incorporates somewhat different details,'"

<u>Duxbury</u>, 579 F.3d at 32 (quoting <u>LaCorte</u>, 149 F.3d at 233). That is because "once the government knows the essential facts of a fraudulent scheme, it has enough information to discover related frauds." <u>Branch Consultants</u>, 560 F.3d at 378 (quoting <u>LaCorte</u>, 149 F.3d at 234) (internal quotation marks omitted).

The plain statutory text is the basis for the judicially crafted essential facts rule and is the reason we do not use an "identical facts" rule. "[E]arlier-filed complaints must provide only the essential facts to give the government sufficient notice to initiate an investigation into allegedly fraudulent practices." Heineman-Guta, 718 F.3d at 36-37. Section 3730(b)(5) bars later "related action[s]" based on the same underlying facts; it does not require that the actions be identical for the rule to come into play. It "would be contrary to the plain language and legislative intent" of the first-to-file rule to impose an "identical facts" test. Lujan, 243 F.3d at 1189.

This reading is consistent with the purpose of the quitam provision, which allows private parties to bring actions in order "to reduce fraud against the government." Heineman-Guta, 718 F.3d 36. In light of that purpose, a "later-filed complaint that mirrors the essential facts as the pending earlier-filed complaint does nothing to help reduce fraud of which the government is already aware." Id.

The Richardson Complaint put the government on notice of allegations that BMS (and Sanofi with respect to Plavix) was engaged in a systematic, nationwide scheme (not rogue actors)<sup>10</sup> to promote Plavix and Pravachol for named off-label uses. Those named particular uses were identified with an introductory "such as." The complaint, which covered several of the same years as Wilson's SAC, identified particular mechanisms used for promotion, and alleged that the scheme caused the submission of "tens of thousands" of false claims to the government. Those mechanisms of promotion, alleged first in the Richardson Complaint, included the use of faxbacks, targeting of continuing medical education programs, and training sales representatives in off-label promotion.

The overlaps among the two complaints were considerable: the same defendants, the same drugs, the assertion of nationwide schemes, and the allegations of specific mechanisms of promotion common to both and leading to common patterns of submission of false claims under the federal Medicaid program.

The differences between the first-filed Richardson Complaint and the SAC were that the Richardson Complaint referred to promotion of off-label uses of the two same drugs, but tied to

We are not faced with the pure question of whether differences in location alone are enough to make schemes so dissimilar as not to invoke the first-to-file rule. Obviously, the materiality of such distinctions must be determined on a case-by-case basis.

certain diseases and symptoms for Plavix (treatment of acute coronary syndrome) and for Pravachol (decreasing CD-40 ligand and hsCRP levels), while the SAC referred to promotion of off-label uses for different diseases and symptoms (for Plavix, for use by diabetic patients to treat symptoms associated with PAD, and for Pravachol, for uses related to diabetes or insulin resistance syndrome). While the results of the essential facts test must vary with the facts of each case, those differences are not enough to reasonably conclude the earlier Richardson Complaint was not a related claim to the government based on the facts. Whether the first complaint results in there being an actual government investigation and whether any such investigation extends to off-label uses to treat different diseases is not the point.

Wilson argues that our opinion in <u>Duxbury</u> counsels the opposite result. Not so, for several reasons, including that <u>Duxbury</u> supports our conclusion. Duxbury's original complaint was the first one filed that alleged particular FCA violations relating to Procrit, but it did not allege an off-label promotion and marketing scheme. We rejected his argument that the off-label promotion and marketing schemes that he added in his first amended complaint were not barred even though another relator (Blair) had filed a complaint in the period between Duxbury's original and first amended complaints. <u>Duxbury</u>, 579 F.3d at 32-33. Duxbury's original complaint relied on a single drug study "and nowhere

refer[red] to an 'off-label' promotion scheme." <u>Id.</u> at 33 (emphasis added). By contrast, Blair's complaint alleged a complex off-label promotion and direct marketing scheme. We concluded that Duxbury's original complaint "[could] not trump the Blair Complaint for purposes of the 'first-to-file' rule." <u>Id.</u>

By contrast here, the Richardson Complaint and the SAC allege a set of the same off-label promotion mechanisms or channels, and so <u>Duxbury</u>'s holding was dealing with a different problem. Once the government is equipped with allegations that detail the drugs and mechanisms of wrongdoing as to those particular medications, it is able to "initiate an investigation," <u>Heineman-Guta</u>, 718 F.3d at 37, into those channels.

Wilson's reading of § 3730(b)(5) would transform our "essential facts" test into an already rejected "identical facts" test. That interpretation of the first-to-file rule is contrary to our precedent, see <u>Duxbury</u>, 579 F.3d at 32, and to the views of at least four other circuits. <u>See LaCorte</u>, 149 F.3d at 233 (rejecting an "identical facts" test that would "bar only suits alleging facts identical to those in previous actions"); <u>see also United States ex rel. Poteet</u> v. <u>Medtronic</u>, Inc., 552 F.3d 503, 516 (6th Cir. 2009) (adopting <u>LaCorte</u> approach); <u>Hampton</u>, 318 F.3d at 217-18 (same); <u>Lujan</u>, 243 F.3d at 1188-89 (same).

We also affirm the rejections of Wilson's efforts to cure the ills of his SAC through formal motions to amend and less formal requests that portions of his Proposed TAC survive. We affirm the initial denial of his motion for leave to file the TAC, along with the later rejection of his motion to reconsider.

Review of the denial of a motion to amend is for abuse of discretion. <u>Ge</u>, 737 F.3d at 127. We "defer to the district court's hands-on judgment so long as the record evinces an adequate reason for the denial." <u>Aponte-Torres</u> v. <u>Univ. of P.R.</u>, 445 F.3d 50, 58 (1st Cir. 2006).

As to the denial of his motion for leave to file the TAC, we affirm on both grounds asserted by the district court. Undue delay is a permissible ground for denying leave to amend, Foman v. Davis, 371 U.S. 178, 182 (1962), and when "a considerable period of time has passed between the filing of the complaint and the motion to amend, courts have placed the burden upon the movant to show some valid reason for his neglect and delay," Nikitine v. Wilmington Trust Co., 715 F.3d 388, 390-91 (1st Cir. 2013) (quoting Hayes v. New Eng. Millwork Distribs., Inc., 602 F.2d 15, 19-20 (1st Cir. 1979)) (internal quotation marks omitted). Wilson did not meet his burden of explaining the delay before the district court.

The Proposed TAC was filed over a year after the SAC and nearly four years after the start of the case. And even before the

SAC was filed, portions of the case had been settled and the government had investigated and declined to intervene on the remaining claims. Motions to amend "require[] the court to examine the totality of the circumstances and to exercise its informed discretion in constructing a balance of pertinent considerations."

Palmer v. Champion Mortg., 465 F.3d 24, 30-31 (1st Cir. 2006). The district court's undue delay determination was eminently reasonable. 11

As to the ruling the TAC failed under FCA requirements, Wilson disputes only the district court's attribution of some portion of the new allegations in the TAC to Allen, the new relator. The argument is gone. It was Wilson who made no attempt to differentiate the allegations that came from him from the ones that came from Allen. There was no reason for the court to conclude otherwise than that the new paragraphs in the Proposed TAC were attributable to the new relator and so conclude that they

of the length of the government's investigation and the accompanying length of the seal period. Whether or not that could ever justify delay, the argument is undermined by the timeline in the case. The government declined to intervene in October 2008, but the Proposed TAC was not filed until June 2010. Cf. Nikitine, 715 F.3d at 391 (affirming dismissal on undue delay grounds where "the plaintiff allowed nearly a year to elapse before seeking to amend his complaint and proffered no good reason for the delay").

We also reject Wilson's claim that the district court should have allowed the Proposed TAC "with the caveat that Allen not be included." He sought the wholesale filing of the TAC, and it was not an abuse of discretion for the district court to decline to fashion sua sponte a limited grant of his motion to amend.

violated the FCA's filing and service requirements. <u>See</u> 31 U.S.C. § 3730(b)(2).

Finally, as to his appeal from the denial of his motion for reconsideration, Wilson's arguments fail. Not only is his appeal reviewed for abuse of discretion, <u>Ge</u>, 737 F.3d at 127, but "[f]or such a motion to succeed, 'the movant must demonstrate either that newly discovered evidence (not previously available) has come to light or that the rendering court committed a manifest error of law.'" <u>Mulero-Abreu v. P.R. Police Dep't</u>, 675 F.3d 88, 94 (1st Cir. 2012) (quoting <u>Palmer</u>, 465 F.3d at 30). There is no assertion these grounds are met, only that there was a manifest error of law. As we have reasoned, the district court was correct in rejecting the TAC.

IV.

The judgment of the district court is <u>affirmed</u>. Costs are awarded to appellees. <u>So ordered</u>.