

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES, *et al.*,
Plaintiffs,
ex rel. JEROME PALMIERI,
Relator,

v.

ALPHARMA, INC., *et al.*,
Defendants.

Civil Action No. ELH-10-1601

MEMORANDUM OPINION

Jerome Palmieri filed a *qui tam* action on April 20, 2010, on behalf of the United States and various states (collectively, the “*Qui Tam* States”), pursuant to the False Claims Act (“FCA” or the “Act”), 31 U.S.C. §§ 3729 *et seq.*, and analogous state statutes. ECF 2.¹ Initially, Palmieri sued Alharma, Inc. and its subsidiary, Alharma Pharmaceuticals, LLC (collectively, “Alharma”) as well as King Pharmaceuticals, Inc. (“King”). Palmieri added Pfizer, Inc. (“Pfizer”) as a defendant in his First Amended Complaint (sometimes referred to as “FAC”), filed on October 25, 2011. ECF 43.²

¹ Suit was filed in the Eastern District of Pennsylvania (ECF 2) and transferred to the District of Maryland on June 11, 2010, pursuant to the motion of the United States. The case was originally assigned to Judge Catherine Blake and was reassigned to me on January 13, 2011.

The *Qui Tam* States are California; Delaware; Florida; Georgia; Hawaii; Illinois; Indiana; Louisiana; Michigan; Montana; Nevada; New Hampshire; New Jersey; New Mexico; New York; Oklahoma; Rhode Island; Tennessee; Texas; and Wisconsin; the Commonwealths of Massachusetts and Virginia; and the District of Columbia. A district court with jurisdiction under the FCA also has jurisdiction as to state law claims “aris[ing] from the same transaction or occurrence.” 31 U.S.C. § 3732(b).

² Alharma became a wholly owned subsidiary of King in December 2008. In October 2010, King merged with Pfizer. *See* ECF 77, SAC, ¶¶ 25-27.

The Act “imposes liability on individuals and entities who defraud government programs.” *United States ex rel. Bunk and Ammons v. Government Logistics N.V.*, 842 F.3d 261, 2016 WL 6695787, at *2 n. 3 (4th Cir. Nov. 15, 2016). It permits a private party, as relator, to sue on behalf of the United States to recover damages from a defendant who has caused fraudulent claims for payment to be submitted against the public fisc. As an incentive to bring such suits, a successful relator is entitled to share in the government’s recovery from the defendant. *See generally Schindler Elevator Corp. v. United States ex rel. Kirk*, 563 U.S. 401, 404 (2011); *ACLU v. Holder*, 673 F.3d 245, 246-51 (4th Cir. 2011) (describing history and current provisions of FCA).³

On April 26, 2011, about a year after suit was filed, the government and the *Qui Tam* States gave notice of their decision not to intervene. ECF 11. Palmieri elected to pursue the suit on his own, and the case was unsealed on July 5, 2011.⁴ As noted, Palmieri filed his FAC on October 25, 2011. He filed his Second Amended Complaint (sometimes referred to as “SAC”) on April 2, 2013. ECF 77. The SAC includes conduct that allegedly occurred before and after 2010 – the year that the Act was amended. *See Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 283 n.1 (2010).

In an opinion issued on March 21, 2014, I dismissed the suit, concluding that the SAC failed to plead fraud with the particularity required by the heightened pleading standard under Fed. R. Civ. P. 9(b). *See* ECF 88 (Memorandum Opinion); ECF 89 (Order); *see also N. Am.*

³ If the United States declines to intervene in the suit, the relator “litigates alone and recovers proceeds under the FCA” *Holder*, 673 F.3d at 251 (citing 31 U.S.C. § 3730(d)(2)).

⁴ The delay in unsealing was occasioned by the Relator’s request to extend the seal (ECF 12), which Judge Garbis approved. ECF 16.

Catholic Educ. Programming Found., Inc. v. Cardinale, 567 F.3d 8, 13 (1st Cir. 2009); *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 783-84 (4th Cir. 1999).

Thereafter, Palmieri noted an appeal to the United States Court of Appeals for the Fourth Circuit. On April 26, 2016, the Fourth Circuit vacated and remanded. *U.S. ex rel. Palmieri v. AlphaPharma, Inc.*, 647 F. App'x 166 (4th Cir. 2016) (per curiam); *see also* ECF 94; ECF 98 (Mandate). In its ruling, the Fourth Circuit determined that I erred because I “did not address Defendants’ arguments that Palmieri’s claims were precluded by the FCA’s first-to-file bar . . . and public-disclosure bar,” and “[u]nder the pre-2010 version of § 3730 that governs Palmieri’s action...both the first-to-file and public disclosure defenses are jurisdictional in nature...” *Palmieri*, 647 F. App'x at 166 (citations omitted).⁵ Accordingly, the Fourth Circuit remanded to this Court for “consideration in the first instance of whether the FCA’s first-to-file bar *or* public-disclosure bar deprived the district court of subject-matter jurisdiction.” *Id.* at 167 (emphasis added).

I. Factual Background⁶

Defendants manufacture and market Flector Patch, a transdermal patch that delivers, via absorption through the patient’s skin, a topical pain application of 1.3% diclofenac epolamine. *See* SAC, ECF 77, ¶¶ 88–89. The Food and Drug Administration (“FDA”) approved Flector

⁵ I had considered the first-to-file rule in an earlier opinion, issued on March 5, 2013, in the context of the First Amended Complaint. *See* ECF 75; ECF 76; *see also United States ex rel. Palmieri v. AlphaPharma, Inc.*, 928 F. Supp. 2d 840, 846-852 (D. Md. 2013). I also note that Congress amended the public disclosure bar on March 23, 2010. As discussed, *infra*, the original suit and the FAC are limited to conduct that occurred before 2010. But, the SAC includes post-2010 conduct. Although the Fourth Circuit did not indicate why the pre-2010 version of the FCA applies, I assume it is because my jurisdictional analysis must turn on the original Complaint.

⁶ The facts are gleaned largely from the Relator’s Second Amended Complaint (ECF 77) and my earlier opinions. ECF 75; ECF 88.

Patch for prescription use in December 2007 (*id.* ¶ 93) as a “topical treatment of acute pain due to minor strains, sprains, and contusions.” *Id.* ¶ 95 (citation omitted in original). However, the use was approved only for up to fourteen days. *Id.* ¶¶ 102, 115–16. Flector Patch carries risks of cardiovascular and gastrointestinal side effects that increase with drug usage. *Id.* ¶ 91. Therefore, Flector Patch’s FDA-approved label contains a warning that a patient should use only “the lowest effective dose for the shortest duration consistent with individual treatment goals.” *Id.* (citation omitted in original).

In 2001, Palmieri began working for Alpharma, and later King and Pfizer, as a sales representative to market prescription pain medications, including Flector Patch, to physicians who treat patients with chronic pain. SAC, ECF 77, ¶ 23.

Federal law does not prohibit a physician from prescribing an approved drug for a non-approved, or “off-label,” use. *See* 21 U.S.C. § 396. However, “it is unlawful for a manufacturer to introduce a drug into interstate commerce with an intent that it be used for an off-label purpose, and a manufacturer illegally ‘misbrands’ a drug if the drug’s labeling includes information about its unapproved uses.” *Washington Legal Found. v. Henney*, 202 F.3d 331, 332-33 (D.C. Cir. 2000) (internal citations omitted). “[A] manufacturer’s direct advertising or explicit promotion of a product’s off-label uses is likely to provoke an FDA misbranding or ‘intended use’ enforcement action.” *Id.* at 333; *see also* 21 C.F.R. § 202.1(e)(4)(ii) (stating that an advertisement for an FDA-approved prescription drug generally “may recommend and suggest the drug only for those uses contained in the [FDA-approved] labeling thereof”). Moreover, government-funded health care programs, such as Medicare and Medicaid, generally do not permit reimbursement for off-label uses. *See* 42 U.S.C. § 1396r-8(k)(2)-(3), (6).

Palmieri alleges that defendants engaged in an illegal scheme to promote off-label use of

Flector Patch. According to the Relator, defendants instructed their sales representatives to market Flector Patch aggressively to physicians, such as pain management specialists, rheumatologists, and neurologists, who by the nature of their specialties treated only chronic pain and not the acute, localized pain for which Flector Patch was approved. *See* SAC, ECF 77, ¶¶ 200–07. In addition, defendants allegedly promoted Flector Patch for continuous use, rather than for short-term use. *See id.* ¶¶ 212–28. Defendants also allegedly instructed their sales representatives to discourage shorter prescriptions as “subtherapeutic,” and to cease promotional efforts toward emergency room and urgent care physicians, who routinely treat patients for acute pain and who often resisted prescribing Flector Patch at the 60-patch level. *See id.* In addition, defendants allegedly marketed Flector Patch as an alternative to other prescription medications that are FDA-approved only for the treatment of chronic pain. *See id.* ¶¶ 239–54. According to the Relator, some of these prescriptions were submitted to federal and state government agencies for reimbursement, thereby causing the presentment of false claims. *See generally* SAC, ECF 77. Furthermore, Palmieri alleges that some of defendants’ promotional activities with respect to Flector Patch violated the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). *Id.* ¶¶ 305-14.

In the Second Amended Complaint (ECF 77), the Relator added allegations concerning prescriptions provided by two Pennsylvania doctors to nine patients. Specifically, the Relator alleged that for eight Medicare patients, Dr. Daniel Rubino prescribed Flector Patch off-label and, “upon information and belief,” these eight persons “filled their prescriptions which were submitted to Medicare for payment because they returned to Dr. Rubino for one or more refills.” *Id.* ¶ 274. Similarly, the Relator alleges that a Medicare patient of Dr. Kenan Aksu received an off-label Flector Patch prescription and, based on a subsequent refill request, it would have been

submitted to Medicare for reimbursement. *See id.* ¶ 285.⁷

Additional facts are included in the Discussion.

II. Procedural Background

As indicated, Palmieri filed suit on April 20, 2010. In April 2011, about a year after the suit was filed, the government declined to intervene. Palmieri filed his First Amended Complaint in October 2011, which defendants moved to dismiss. ECF 70 (the “First Motion”). In particular, they argued that the first-to-file rule, 31 U.S.C. § 3730(b)(5), deprived this Court of subject matter jurisdiction. In addition, they contended that, in light of the heightened pleading requirements applicable to fraud claims under Fed. R. Civ. P. 9(b), the FAC failed to state a claim.

With respect to the first-to-file rule, the defense pointed to the case of *United States ex rel. Littlewood*, ELH-10-973 (D. Md.) (“*Littlewood*”), which alleged essentially the same fraudulent scheme set forth by Palmieri. *Littlewood* was filed four days before Palmieri filed his suit.⁸ But, as in this case, the government declined to intervene in *Littlewood*. *Id.*, ECF 16; ECF 18. And, the relator chose not to exercise her right to litigate the suit on her own. Rather, on August 17, 2011, she voluntarily dismissed the case, with the government’s consent, and without prejudice. *Id.*, ECF 19; ECF 21; *see also United States ex rel. Littlewood*, 806 F. Supp. 2d 833

⁷ The Relator identified the second physician as both “Aksu” and “Asku.” *Compare* ECF 77, SAC, ¶¶ 283-85 and ECF 85 at 9 (using “Aksu”) *with* ECF 77, SAC, ¶ 284 and ECF 85 at 10 n.5 (using “Asku”).

⁸ *Littlewood* was an action in this district, and I was the presiding judge. According to the docket in *Littlewood*, the complaint was not entered on the docket until April 20, 2010, the same day that the original Complaint was filed in this case. However, both sides agree that *Littlewood* was actually filed on April 16, 2010. *See United States, ex rel. Littlewood v. King Pharmaceuticals, Inc.*, 806 F. Supp. 2d 833, 834 (D. Md. 2011).

(D. Md. 2011). Palmieri filed his First Amended Complaint in October 2011, *after Littlewood* had been voluntarily dismissed.

In *United States ex rel. Palmieri v. Alparma, Inc.*, 928 F. Supp. 2d 840 (D. Md. 2013) (ECF 75, “*Palmieri I*”), I concluded that the first-to-file rule in § 3730(b)(5) did not bar the Relator’s claim. I relied, *inter alia*, on *United States ex rel. Chovanec v. Apria Healthcare Grp. Inc.*, 606 F.3d 361 (7th Cir. 2010) (Easterbrook, J.). *See Palmieri I*, 928 F. Supp. 2d at 847; 849; 850-51. Because *Littlewood* was no longer pending when Palmieri filed his FAC, I recognized that Palmieri could simply file a new action if I dismissed the case. Given that circumstance, I concluded that it would “elevate form over substance” to require dismissal, only to have Palmieri refile his case. *Id.* at 851–52. Instead, I allowed the case to proceed, as amended, and I then considered the merits of defendants’ First Motion in the context of the FAC. I determined that Palmieri failed to state a claim, because he did not satisfy the Rule 9(b) standard for pleading fraud with particularity. *Id.* at 851–52, 857.⁹

⁹ With regard to the merits of the First Motion, I determined that FAC failed to allege adequately any particular instance in which an off-label or excessive prescription for Flector Patch was submitted to a government health program for reimbursement. I noted that the FAC did not identify any instances in which doctors to whom defendants allegedly gave illegal kickbacks had prescribed Flector Patch to patients covered by government prescription programs. Rather, the FAC recounted the total volume of Flector Patch prescriptions submitted to Medicaid and Medicare since 2008, and the amounts of money paid in reimbursements for those prescriptions, to suggest that at least some of these prescriptions must have been off-label or excessive. *See Palmieri I*, 840 F. Supp. 2d at 846.

I concluded that the FAC was insufficient because, according to Palmieri’s allegations, defendants’ conduct “‘*could* have led, but *need not necessarily* have led, to the submission of false claims.’” *Id.* at 856 (quoting *United States ex rel. Nathan v. Takeda Pharms. N. Am., Inc.*, 707 F.3d 451, 457 (4th Cir. 2013), *cert. denied*, 134 S. Ct. 1759 (2014)). Although Palmieri “allege[d] an illegal scheme that could have resulted in the submission of false claims to the government, he d[id] not provide details of any false claim that actually was submitted.” *Palmieri I*, 840 F. Supp. 2d at 857. Those allegations, I concluded, plainly failed to meet the Rule 9(b) pleading standard under *Nathan*, 707 F.3d 451. *See Palmieri I*, 928 F. Supp. 2d at 856-57.

In light of the pleading deficiencies, I granted the First Motion and dismissed the FAC, without prejudice. ECF 76 (Order). I also directed the Clerk to close the case, with the right to reopen if plaintiff submitted an amended complaint. *Id.* However, I did not require plaintiff to file an entirely new suit. *Palmieri I*, at 857-58.

On April 2, 2013, the Relator filed his Second Amended Complaint, using the original case number. ECF 77. As noted, the SAC included new allegations regarding prescriptions written for nine patients by two Pennsylvania physicians, Dr. Rubino and Dr. Aksu. *See* SAC, ECF 77, ¶¶ 275-85. Although the Complaint, the FAC, and the SAC referred to conduct that occurred prior to 2010, the SAC also referred to conduct that occurred after 2010. *See* SAC, ECF 77, ¶¶ 274-295 (including allegations as early as 2008 and as late as fall 2011).

Defendants moved to dismiss the SAC (ECF 84), supported by a memorandum (ECF 84-1), (collectively, the “Second Motion”). They challenged the SAC on jurisdictional grounds, based on the “first-to-file” bar under 31 U.S.C. § 3730(b)(5), and also based on the public disclosure bar under 31 U.S.C. § 3730(e)(4)(A). In addition, they argued that the SAC did not satisfy the Rule 9(b) heightened pleading standard. *See* ECF 84. The Relator filed an Opposition (ECF 85, “Opposition”), and defendants submitted a Reply. ECF 86.

In *United States ex rel. Palmieri v. Alparma, Inc.*, ELH-10-1601, 2014 WL 1168953 (D. Md. Mar. 21, 2014) (ECF 88) (“*Palmieri II*”), I concluded that the SAC failed to satisfy the Rule 9(b) standard. I also said that, “[b]ecause the relator’s allegations fail under Rule 9(b), it is unnecessary to reach defendants’ arguments concerning the first-to-file rule and the public disclosure bar.” ECF 88 at 4 n.8. *Cf. United States ex rel. Brooks v. Lockheed Martin Corp.*, 423 F. Supp. 2d 522, 528 (D. Md. 2006) (stating that because a relator “failed to satisfy the requirements of Rule 9(b), it is not necessary to examine [defendants’] arguments” related to the

first-to-file rule), *dismissed in part, aff'd in part on other grounds*, 237 Fed. App'x 802 (4th Cir. 2007). Thus, by Memorandum Opinion (ECF 88) and Order (ECF 89) of March 21, 2014, I granted the Second Motion and dismissed the case, with prejudice, as to the FCA claims, and without prejudice as to the related state law claims. Palmieri noted an appeal.

As indicated, on April 26, 2016, the Fourth Circuit vacated *Palmieri II*. It concluded that both the first-to-file bar and the public disclosure bar are jurisdictional under the “pre-2010 version” of the FCA, and that the pre-2010 version of the Act “governs” this case. *Palmieri*, 647 F. App'x at 166. Moreover, it concluded that I should have determined whether this Court has jurisdiction before deciding the Rule 9(b) issue. Accordingly, the Fourth Circuit remanded to this Court for a determination as to jurisdiction.

By Order of the same date (April 26, 2016), I directed counsel to inform the Court as to “whether I should review the [jurisdictional claims] based on existing filings or, instead, whether the parties wish to supplement and update their submissions.” ECF 95. In a status report filed on May 16, 2016, the parties advised that “they jointly believe that the Court should evaluate these jurisdictional issues based on the pre-existing briefing and that no evidentiary hearing is necessary to resolve these jurisdictional issues.” ECF 97. The parties referred the Court to the following submissions and case law, *id.* at 1–2:

- Memorandum of Law in Support of Defendants’ Motion to Dismiss Second Amended Complaint, ECF 84-1 at 14-26
- Relator’s Memorandum of Law in Opposition to Defendants’ Motion to Dismiss Second Amended Complaint, ECF 85 at 17-25 (“Opposition”)
- Reply Memorandum of Law in Support of Defendants’ Motion to Dismiss Second Amended Complaint, ECF 86 at 16-25
- *United States ex rel. Carter v. Halliburton Co.*, 710 F.3d 171 (4th Cir. 2013), *rev'd in part, Kellogg Brown & Root Servs., Inc. v. United States ex rel. Carter*, 135 S. Ct. 1970 (2015)

The SAC, which was the subject of the appeal to the Fourth Circuit, included allegations of conduct that occurred before and after 2010. Effective March 23, 2010, the Patient Protection and Affordable Care Act of 2010 (“PPACA”), Pub. L. No. 111-148, 124 Stat. 119, amended the public disclosure bar of the FCA. 31 U.S.C. § 3730(e)(4)(A) (2010) (as amended by § 10104(j)(2) of PPACA); *see Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 283 n.1 (2010). However, the 2010 amendment to the public disclosure bar does not apply to conduct that occurred before March 23, 2010. *Id.* at 283 n.1; *see United States ex el. May v. Purdue Pharma L.P.*, 737 F.3d 908, 915 (4th Cir. 2013) (explaining that the 2010 FCA amendment “retroactivity inquiry looks to when the underlying conduct occurred, not when the complaint was filed”); *accord United States ex rel. Black v. Health & Hosp. Corp. of Marion Cnty.*, 494 Fed. App’x 285, 291 n. 9 (4th Cir. 2012) (per curiam) (pointing out that the “Supreme Court has observed that the new [FCA] lacks the explicit language that would make it retroactive”).

The Fourth Circuit has recognized that the 2010 amendments “significantly changed the scope of the public disclosure bar.” *May*, 737 F.3d at 917. As amended, the public disclosure bar “is no longer jurisdictional.” *Id.* In other words, “[p]ost-amendment, the public-disclosure bar is a grounds for dismissal—effectively, an affirmative defense—rather than a jurisdictional bar.” *Beauchamp v. Academi Training Ctr.*, 816 F.3d 37, 40 (4th Cir. 2016) (citing *United States ex rel. Osheroff v. Humana, Inc.*, 776 F.3d 805, 810 (11th Cir. 2015)).

Because the Fourth Circuit stated that the pre-2010 version of the Act “governs” here, by Order of September 21, 2016 (ECF 99), I asked counsel to submit memoranda addressing whether, in their view, I should consider the Complaint, the First Amended Complaint, and/or the Second Amended Complaint when analyzing the public disclosure bar. I also asked counsel

to address whether the pre-2010 version of the FCA, the post-2010 version, or both apply to any or all of Palmieri's claims. *Id.* at 2. The parties submitted their memoranda on October 6, 2016. *See* ECF 100 (Def. Supp. Mem.); ECF 101 (Relator Supp. Mem.). They also filed replies on October 20, 2016. *See* ECF 102 (Def. Supp. Reply); ECF 103 (Relator Supp. Reply).

III. Discussion

A. The First-to-File Bar

The Act's "first-to-file" rule is codified in 31 U.S.C. § 3730(b)(5).¹⁰ It provides: "When a person brings [a false claims action], no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." The first-to-file rule was one of several amendments to the Act in 1986 that sought to achieve "the golden mean between adequate incentives for whistle-blowing insiders with genuinely valuable information and discouragement of opportunistic plaintiffs who have no significant information to contribute of their own." *United States ex rel. Springfield Terminal Ry. v. Quinn*, 14 F.3d 645, 650 (D.C. Cir. 1994); *see United States ex rel. LaCorte v. Wagner*, 185 F.3d 188, 191 (4th Cir. 1999) (stating that the 1986 amendments "struck a careful balance between encouraging citizens to report fraud and stifling parasitic lawsuits").

The statutory "command is simple: as long as a first-filed complaint remains pending, no related complaint may be filed." *United States ex rel. Batiste v. SLM Corp.*, 659 F.3d 1204, 1210 (D.C. Cir. 2011). In other words, "if one person 'brings an action' then no one other than the Government may 'bring a related action' while the first is 'pending.'" *United States ex rel. Chovanec v. Apria Healthcare Gp. Inc.*, 606 F.3d 361, 362 (7th Cir. 2010) (quoting statute).

¹⁰ The current version of § 3730(b)(5) is identical to the version in effect at the time the Relator's claims arose.

The first-to-file rule creates “an incentive for relators with valuable information to file—and file quickly.” *In re Nat. Gas Royalties Qui Tam Litigation (CO₂ Appeals)*, 566 F.3d 956, 961 (10th Cir. 2009). In effect, it sets off “a race to the courthouse among those with knowledge of fraud.” *Campbell v. Redding Med. Ctr.*, 421 F.3d 817, 821 (9th Cir. 2005). And, as the Fourth Circuit recently explained in *United States ex rel. Carter v. Halliburton Co.*, 710 F.3d 171, 181 (4th Cir. 2013), *rev’d in part on other grounds, Kellogg Brown & Root Services, Inc. v. U.S. ex rel. Carter*, ___ U.S. ___, 135 S. Ct. 1970 (2016), “whoever wins the race to the courthouse prevails and the other case *must be dismissed*.” (Emphasis added).

Under the first-to-file rule, the *qui tam* relator who wins the race to the courthouse need not “share in . . . recovery with third parties who do no more than tack on additional factual allegations to the same essential claim.” *Grynberg v. Koch Gateway Pipeline Co.*, 390 F.3d 1276, 1279 (10th Cir. 2004). Thus, the first-to-file rule “functions both to eliminate parasitic plaintiffs who piggyback off the claims of a prior relator, and to encourage legitimate relators to file quickly by protecting the spoils of the first to bring a claim.” *In re Nat. Gas Royalties*, 566 F.3d at 961. The rule also precludes “a double recovery” against the defendant. *United States ex rel. Precision Co. v. Koch Indus., Inc.*, 31 F.3d 1015, 1018 (10th Cir. 1994) (quoting *Erickson ex rel. United States v. Am. Inst. of Bio. Sci.*, 716 F. Supp. 908, 918 (E.D. Va. 1989)).¹¹

¹¹ Each of the false claims acts of the *Qui Tam* States also contains a first-to-file rule. See Cal. Gov’t Code § 12652(c)(10); Del. Code Ann. tit. 6, § 1203(b)(5); Fla. Stat. Ann. § 68.083(7); Ga. Code Ann. § 49-4-168.2(c)(6); Haw. Rev. Stat. § 661-25(e); 740 Ill. Comp. Stat. § 175/4(b)(5); Ind. Code Ann. § 5-11-5.5-4(g); La. Rev. Stat. Ann. § 46:439.2(A)(3); Mich. Comp. Laws Ann. § 400.610a(4); Mont. Code Ann. § 17-8-406(7); Nev. Rev. Stat. Ann. § 357.080(2); N.H. Rev. Stat. Ann. § 167:61-c(II)(b); N.J. Stat. Ann. § 2A:32C-5(i); N.M. Stat. Ann. § 44-9-5(E); N.Y. State Fin. Law § 190(4); Okla. Stat. Ann. tit. 63, § 5053.2(B)(5); R.I. Gen. Laws Ann. § 9-1.1-4(b)(5); Tenn. Code Ann. § 4-18-104(c)(10); Tex. Hum. Res. Code Ann. § 36.106; Wis. Stat. Ann. § 20.931(5)(e), now repealed by 2015 Wis. Act 55, § 945n; Mass. Gen. Laws Ann. ch. 12, § 5C(6); Va. Code Ann. § 8.01-216.5(E); D.C. Code § 2-381.03(b)(6).

The federal courts consistently view the first-to-file rule as a jurisdictional bar. *See, e.g., Carter*, 710 F.3d at 181; *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 16 (1st Cir. 2009) (describing first-to-file rule as a “jurisdictional bar[] that limit[s] a district court’s subject matter jurisdiction over qui tam actions”); *United States ex rel. Branch Consultants v. Allstate Ins. Co.*, 560 F.3d 371, 376-77 (5th Cir. 2009) (“Congress has placed a number of jurisdictional limits on the FCA’s *qui tam* provisions, including § 3730(b)(5)’s first-to-file bar.^[1] Under this provision, if [the relator’s] claim had already been filed by another, the district court lacked subject matter jurisdiction and was required to dismiss the action.”); *Walburn v. Lockheed Martin Corp.*, 432 F.3d 966, 970 (6th Cir. 2005) (describing first-to-file rule as a “jurisdictional limitation[] on *qui tam* actions”); *Grynberg, supra*, 390 F.3d at 1278 (stating that § 3730(b)(5) “is a jurisdictional limit on the courts’ power to hear certain duplicative qui tam suits”).

With respect to § 3730(b)(5), “every court of appeals to consider” the meaning of the statutory phrase “a related action based on the facts underlying [a] pending action” has construed it to mean an action based on the same “*material* facts” or the same “*essential* facts” as the pending action, rather than “*identical* facts.” *Chovanec*, 606 F.3d at 363 (quoting statute) (collecting cases) (emphasis in original); *see Carter*, 710 F.3d at 182. Moreover, the “circuits that have addressed this subject understand the ‘material’ or ‘essential’ facts to be those on which the original Relator is entitled to compensation if the suit prevails.” *Chovanec*, 606 F.3d at 363. This, in turn, depends on a comparison of the date and content of the pleadings in the pending case with the date and content of the other pleadings. *See, e.g., In re Nat. Gas Royalties*, 566 F.3d at 964 (“The first-to-file bar is designed to be quickly and easily determinable, simply requiring a side-by-side comparison of the complaints.”).

Here, the Relator filed his FCA Complaint (ECF 2) on April 20, 2010. On April 26, 2011, the government and the states notified the Court of their decision not to intervene (ECF 11) and the suit was unsealed on July 5, 2011. See ECF 20. On October 25, 2011, the Relator filed the First Amended Complaint (ECF 43), which was the operative pleading at the time of my decision in *Palmieri I*, 928 F. Supp. 2d 840. In their First Motion (ECF 70), defendants argued that the case was barred by the first-to-file rule, because *Littlewood*, another *qui tam* suit alleging essentially the same fraudulent scheme, was filed on April 16, 2010, four days before Palmieri filed his Complaint in this case. See *United States ex rel. Littlewood v. King Pharmaceuticals, Inc., et al.*, ELH-10-973 (D. Md.).

Without question, *Littlewood* alleged the same material facts. See *Anderson v. Fed. Deposit Ins. Corp.*, 918 F.2d 1139, 1141 n.1 (4th Cir. 1990) (stating, in the context of a Rule 12(b)(1) motion to dismiss, that “a district court should properly take judicial notice of its own records”). Like Palmieri, the relator in *Littlewood* was a sales representative with Alharma. *Littlewood*, 806 F. Supp. 2d at 834. Like Palmieri, she alleged that Alharma and its parent companies engaged in a scheme to market Flector Patch for off-label uses with the intent and effect of causing false claims to be submitted to governmental health care programs. *Id.* In addition, *Littlewood* and this case included the same *Qui Tam* States. *Id.* at 835 n. 2. And, as noted, the United States declined to intervene in *Littlewood*. Thereafter, the relator dismissed the case. Although *Littlewood* was no longer “pending” when Palmieri filed his First Amended Complaint on October 25, 2011, it was certainly pending when Palmieri first filed his suit.

As mentioned, in *Palmieri I*, I recognized the jurisdictional nature of the first-to-file bar. *Palmieri I*, 928 F. Supp. 2d at 848-52. I also recognized that “*Littlewood* was already ‘pending’ when this case began.^[1]” *Id.* at 849. However, it had since been dismissed, before Palmieri filed

his FAC. I concluded that if I were to dismiss the suit, it would be without prejudice to Palmieri's right to refile suit, based on my analysis of *Chovanec*, 606 F.3d at 365 (holding that the district court's dismissal of a *qui tam* suit on the basis of the first-to-file bar should have been without prejudice because the first-filed *qui tam* action was "no longer pending . . .") and *In re Natural Gas Royalties*, *supra*, 566 F.3d at 964 ("[I]f that prior claim is no longer pending, the first-to-file bar no longer applies . . . when he drops his action another relator who qualifies as an original source may pursue his own"). Therefore, I reasoned, *id.* at 851–52 (citing 31 U.S.C. § 3730(b)(5)):

If the Court were to dismiss the Amended Complaint, it would do so without prejudice, and the first-to-file rule would not preclude Mr. Palmieri from filing an identical pleading under a new case number tomorrow It would elevate form over substance to dismiss the Amended Complaint on first-to-file grounds at this juncture. Accordingly, I conclude that the first-to-file rule does not bar Mr. Palmieri's [First] Amended Complaint.

Accordingly, I proceeded to consider other contentions in the First Motion. And, as discussed, I dismissed the FAC, without prejudice, and with leave to amend, because, in my view, it failed to comply with the pleading standards of Rule 9(b). *Id.* at 857.

On March 18, 2013, just a few weeks after I issued *Palmieri I*, the Fourth Circuit decided *United States ex rel. Carter v. Halliburton Co.*, *supra*, 710 F.3d 171. In *Carter*, the Fourth Circuit characterized the first-to-file bar "as an absolute, unambiguous exception-free rule." *Id.* at 181. Soon after, on April 2, 2013, Palmieri filed his SAC. ECF 77.¹² Again, defendants moved to dismiss. ECF 84.

In the Second Motion, defendants renewed their argument that this Court lacks jurisdiction based on the first-to-file rule. *See* ECF 84-1 at 18–20. In particular, defendants relied on the Fourth Circuit's ruling in *Carter*, claiming that the first-to-file rule mandated

¹² In light of *Carter*, it is puzzling that the Relator persisted in amending his suit, in lieu of filing a new case.

dismissal of the suit because a similar action was pending when Palmieri filed suit. ECF 84-1 at 18. They asserted: “That Palmieri has since filed an amended complaint does not cure the original jurisdictional defect.” *Id.* at 19. Moreover, defendants argued that dismissal of the Second Amended Complaint would not elevate form over substance. *Id.* According to defendants, “whether the case proceeds under the same caption or as a newly filed case has substantive consequences.” *Id.*

In his Opposition (ECF 85), the Relator characterized *Carter* differently. *Id.* at 22–23. According to Palmieri, the Fourth Circuit “concluded” that the “district court erred in dismissing Carter’s complaint with prejudice.” *Id.* at 22. He argued that, “as the Fourth Circuit explained, and contrary to Defendants’ suggestions, ‘the first-to-file bar allows a plaintiff to bring a claim later’” and that “‘this is precisely what a dismissal without prejudice allows a plaintiff to do as well.’” *Id.* at 22–23 (quoting *Carter*). The Relator maintained that “nothing in the holding of the Fourth Circuit’s decision in *Carter* suggests that this Court should revise its earlier decision on this issue.” ECF 85 at 23.

In analyzing the jurisdictional issue here, it is helpful to review the factual and procedural background of *Carter*, as recounted by the Supreme Court, 135 S. Ct. at 1974-75:

From January to April 2005, [the Relator] worked in Iraq for one of the petitioners as a water purification operator. He subsequently filed a *qui tam* complaint against petitioners (*Carter I*), alleging that they had fraudulently billed the Government for water purification services that were not performed or not performed properly. The Government declined to intervene.

In 2010, shortly before trial, the Government informed the parties about an earlier filed *qui tam* lawsuit, *United States ex rel. Thorpe v. Halliburton Co.*, No. 05–cv–08924 (C.D. Cal., filed Dec. 23, 2005), that arguably contained similar claims. This initiated a remarkable sequence of dismissals and filings.

The District Court held that respondent’s suit was related to *Thorpe* and thus dismissed his case without prejudice under the first-to-file bar. Respondent appealed, and while his appeal was pending, *Thorpe* was dismissed for failure to

prosecute. Respondent quickly filed a new complaint (*Carter II*), but the District Court dismissed this second complaint under the first-to-file rule because respondent's own earlier case was still pending on appeal. Respondent then voluntarily dismissed this appeal, and in June 2011, more than six years after the alleged fraud, he filed yet another complaint (*Carter III*). . . .

Petitioners sought dismissal of this third complaint under the first-to-file rule, pointing to two allegedly related cases, one in Maryland and one in Texas, that had been filed in the interim between the filing of *Carter I* and *Carter III*. This time, the court dismissed respondent's complaint with prejudice. The court held that the latest complaint was barred under the first-to-file rule because the Maryland suit was already pending when that complaint was filed. The court also ruled that the WSLA applies only to criminal charges and thus did not suspend the time for filing respondent's civil claims. As a result, the court concluded, all but one of those claims were untimely because they were filed more than six years after the alleged wrongdoing.

The Fourth Circuit reversed, rejecting the District Court's analysis of both the WSLA and first-to-file issues. *United States ex rel. Carter v. Halliburton Co.*, 710 F.3d 171 (2013). Concluding that the WSLA applies to civil claims based on fraud committed during the conflict in Iraq,¹ the Court of Appeals held that respondent's claims had been filed on time. The Court of Appeals also held that the first-to-file bar ceases to apply once a related action is dismissed. Since the Maryland and Texas cases had been dismissed by the time of the Fourth Circuit's decision, the court held that respondent had the right to refile his case. The Court of Appeals thus remanded *Carter III* with instructions to dismiss without prejudice.

After this was done, respondent filed *Carter IV*, but the District Court dismissed *Carter IV* on the ground that the petition for a writ of certiorari in *Carter III* (the case now before us) was still pending.

Notably, the relator in *Carter* had argued that the subsequent dismissals of the earlier related cases meant they were no longer "pending" and that they could not "continue to have a preclusive effect on his action." 710 F.3d at 182. The Fourth Circuit rejected that view, stating: "Following the plain language of the first-to-file bar, Carter's action *will be barred* by [the earlier actions] if either case was pending *when Carter filed suit*." *Id.* at 183 (emphasis added). Observing that "both actions were pending when Carter filed his complaint," and that courts must "look at the facts as they existed when the claim was brought to determine whether an

action is barred by the first-to-file bar,” the Court concluded that Carter’s claims were barred. *Id.*

The Fourth Circuit also stated that “a later suit is barred if it is based upon the ‘same material elements of fraud’ as the earlier suit, even though the subsequent suit may ‘incorporate somewhat different details.’” *Carter*, 710 F.3d at 182 (quoting *United States ex rel. Lujan v. Hughes Aircraft Co.*, 243 F.3d 1181, 1183 (9th Cir. 2001)). Adopting the “material elements test,” the Fourth Circuit explained that the first-to-file rule “prevents the less vigilant whistleblower from using insignificant factual variations to allege what is essentially the same fraudulent scheme already made known to the government.” *Carter*, 710 F.3d at 182 (citations and quotations omitted). Applying the “material elements test,” the Court determined that the actions pending when Carter suit initially filed suit were “substantially similar,” and therefore the first-to-file bar was triggered. *Id.* And, of particular significance here, the Fourth Circuit highlighted that, “if a case is brought while the original case is pending it must be dismissed ‘rather than left on ice.’” *Id.* at 183 (quoting *Chovanec*, 606 F.3d at 365).

“However,” the Fourth Circuit continued, “this [did] not end [the] inquiry.” *Carter*, 710 F.3d at 183 (alteration added). Although the Fourth Circuit was clear that dismissal was required, it proceeded to analyze whether the first-to-file bar required dismissal of the suit with or without prejudice. *Id.* Relying on *Chovanec*, 606 F.3d at 365, and *In re Natural Gas Royalties*, 566 F.3d at 963–64, the Fourth Circuit concluded that “the district court erred in dismissing Carter’s complaint with prejudice.” *Carter*, 710 F.3d at 183.

The *Carter* Court said: “Although the doctrine of claim preclusion may prevent the filing of subsequent cases, § 3730(b)(5) does not.” *Id.* In addition, it stated, *id.* (emphasis added):

We agree that once a case is no longer pending the first-to-file bar does not stop a relator *from filing a related case*. In this case, both of the original

actions have been dismissed. Because of this, the first-to-file bar does not preclude Carter *from filing an action*. *The first-to-file bar allows a plaintiff to bring a claim later; this is precisely what a dismissal without prejudice allows a plaintiff to do as well*. Therefore, Carter’s only impediment at the moment is the district court’s dismissal *with prejudice*. And, as we have already concluded the district court erred in dismissing Carter’s complaint *with prejudice*.

The Fourth Circuit unequivocally announced in *Carter*, 710 F.3d at 181: “Under the first-to-file bar, if Carter’s claims had been previously filed by another relator, then the district court lacked subject matter jurisdiction.” And, it opined that “whoever wins the race to the courthouse prevails and the other case *must be dismissed*.” *Id.* (alteration and emphasis added). It reasoned: “Section 3730(b)(5) is *jurisdictional* and if an action is later filed that is based on the facts underlying the pending case, *the court must dismiss the later case for lack of jurisdiction*.” *Id.* (emphasis added).¹³

Because *Littlewood* was pending when this case began in 2010, and because *Littlewood* and the case *sub judice* allege essentially the same fraudulent scheme to promote Flector Patch, this case was barred at its inception by the first-to-file rule, and the first-to-file bar deprived this Court of subject matter jurisdiction. *See Carter*, 710 F.3d at 181–183; *see also Walburn, supra*, 431 F.3d at 972 n.5 (“[T]he ultimate fate of an earlier-filed action does not determine whether it bars a later action under § 3730(b)(5); rather, the question is only whether the earlier action was ‘pending’ at the time the later action was filed.”); *Lujan*, 243 F.3d at 1188 (“To hold that a later dismissed action was not a then-pending action would be contrary to the plain language of the

¹³ On appeal to the Supreme Court, *Carter* was reversed in part on grounds unrelated to the first-to-file rule. *See Kellogg Brown & Root Services, Inc. v. United States, ex rel Carter*, ___ U.S. ___, 135 S. Ct. 1970 (2016). Much of the Supreme Court’s opinion focused on the application of the Wartime Suspension of Limitations Act. *See id.* at 1975–78. With respect to the first-to-file rule, the Court clarified the meaning of “pending” under the FCA, abiding by its “ordinary meaning” (*id.* at 1978), and noting that “a *qui tam* suit under the FCA ceases to be ‘pending’ once it is dismissed.” *Id.* Notably, the Supreme Court did not disturb the Fourth Circuit’s analysis as to the first-to-file rule.

statute and the legislative intent.”); *see also United States ex rel. Branch Consultants, LLC v. Allstate Ins. Co.*, 782 F. Supp. 2d 248, 259–260 (E.D. La. 2011) (stating that, “if [the relator’s] action was barred under [jurisdictional limits in the FCA] at the time the original complaint was filed, the Court must dismiss the case, notwithstanding any amendments” to the complaint); *see, e.g., United States ex rel. Sandager v. Dell Marketing, L.P.*, 872 F. Supp. 801, 811 (D. Minn. 2012) (dismissing claims based on the first-to-file bar); *United States ex rel. Folliard v. Synnex Corp.*, 789 F. Supp. 2d 66, 77 (D.D.C. 2011) (same); *United States ex rel. Ortega v. Columbia Healthcare, Inc.*, 240 F. Supp. 2d 8, 20–21 (D.D.C. 2003) (same, among other grounds).

Carter makes clear that because *Littlewood*, a substantially similar FCA action, was pending when Palmieri first filed his suit, Palmieri’s case should have been dismissed, without prejudice to Palmieri’s right to file a new suit. I erred in *Palmieri I* when I determined that it would elevate form over substance to dismiss without prejudice, merely because Palmieri could refile his suit. That is what the first-to-file rule required. I also erred in *Palmieri II* by proceeding to the Rule 9(b) issue without revisiting my earlier jurisdictional ruling in light of the *Carter* decision.

B. The Public Disclosure Bar

The public disclosure bar will often bar second-filed *qui tam* suits even when the first-to-file bar does not. *See Chovanec*, 606 F.3d at 365.

The public disclosure bar, 31 U.S.C. § 3730(e)(4), “disqualifies private suits based on fraud already disclosed in particular settings—such as hearings, government reports, or news reports—unless the relator meets the definition of an ‘original source.’” *United States ex rel. Beauchamp, supra*, 816 F.3d at 39. It “aims ‘to strike a balance between encouraging private persons to root out fraud and stifling parasitic lawsuits’ in which a relator, instead of plowing

new ground, attempts to free-ride by merely reiterating previously disclosed fraudulent acts.” *Id.* at 43 (quoting *Graham Cnty. Soil & Water Conservation Dist.*, 559 U.S. at 295).

Because I conclude that the the first-to-file rule deprives the Court of jurisdiction, I need not decide whether the public disclosure bar would also deprive the Court of jurisdiction.

IV. Conclusion

For the foregoing reasons, I conclude that this Court lacks subject matter jurisdiction under the FCA’s first-to-file rule.

An Order follows.

Date: December 16, 2016

/s/
Ellen Lipton Hollander
United States District Judge

