

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA ex rel. : CIVIL ACTION
MATTHEW CESTRA, et al. : NO. 14-01842
: :
v. : :
: :
CEPHALON, INC., et al. : :
: :
O'NEILL, J. : October 9, 2014

MEMORANDUM

This matter comes before me on defendant Cephalon's motion to dismiss plaintiff Matthew Cestra's Fentora claims contained in his second amended complaint for lack of subject matter jurisdiction pursuant to Fed. R. Civ. P. 12(b)(1) (Dkt. Nos. 1-41) and plaintiff's response (Dkt. No. 1-49). Also before me are the parties' supplemental briefing. In its motion, Cephalon moves to dismiss plaintiff's False Claims Act (FCA) claims with regard to the medication Fentora. Cephalon contends that § 3730(b)(5) of the FCA, or the "first-to-file" rule, bars plaintiff's action due to the existence of previously filed Fentora claims pending before me in Boise v. Cephalon, Inc., No. 08-287 (E.D. Pa.). For the reasons that follow, I will grant Cephalon's motion.

BACKGROUND

Fentora is a powerful pain medication approved by the FDA for treatment of breakthrough pain in opioid-tolerant cancer patients. See Dkt. No. 1-2 at ¶ 4, No. 08-287, Dkt. No. 14 at ¶ 77. On August 30, 2010, plaintiff filed his original complaint in the Southern District of New York alleging that Cephalon's off-label marketing of Fentora caused prescribing physicians to submit false claims for reimbursement from government programs in violation of the FCA. See Dkt. No. 1-2. On March 11, 2011 Cestra filed his first amended complaint (Dkt. No. 1-25)

and on June 24, 2013 Cestra filed his second amended complaint (Dkt. No. 1-39), which both include Fentora allegations. All of Cestra's complaints have been unsealed and the government declined to intervene in his action. See Dkt. No. 1. On March 19, 2014, this case was transferred to me by Judge Stein of the Southern District of New York. See id.

However, on February 1, 2008 relator Boise filed his original complaint in a separate action, Boise v. Cephalon, Inc., No. 08-287 (E.D. Pa.) also alleging that Cephalon's off-label marketing of Fentora caused prescribing physicians to submit claims for reimbursement from government programs in violation of the FCA. See No. 08-287, Dkt. No. 1. On January 14, 2010 Boise filed a first amended complaint and on March 4, 2014 he filed a second amended complaint, which both include Fentora allegations but which also add allegations related to other medications and additional relators. See id., Dkt. Nos. 14, 69. All of Boise's complaints have been unsealed and the government declined to intervene in his action.

STANDARD OF REVIEW

Federal Rule of Civil Procedure 12(b)(1) authorizes dismissal of a complaint for lack of subject matter jurisdiction. A motion under Rule 12(b)(1) may be treated as either a facial attack on the complaint or a factual challenge to the court's subject matter jurisdiction. Gould Elecs., Inc. v. United States, 220 F.3d 169, 176 (3d Cir. 2000). A court reviewing a facial attack may consider only the allegations of the complaint and any documents referenced therein or attached thereto in the light most favorable to the plaintiff. Id. In reviewing a factual attack, a court may consider evidence outside the pleadings. Id.

A plaintiff bears the burden of persuasion when subject matter jurisdiction is challenged, but the legal standard for surviving a Rule 12(b)(1) motion is a low one. Kehr Packages v. Fidelcor, Inc., 926 F.2d 1406, 1409 (3d Cir. 1991). "A claim may be dismissed under Rule

12(b)(1) only if it ‘clearly appears to be immaterial and made solely for the purpose of obtaining jurisdiction’ or is ‘wholly insubstantial and frivolous.’” Gould, 220 F.3d at 178. Nevertheless, “dismissal for lack of jurisdiction is not appropriate merely because the legal theory alleged is probably false, but only because the right claimed is ‘so insubstantial, implausible, foreclosed by prior decisions of this Court, or otherwise completely devoid of merit as not to involve a federal controversy.’” Kulick v. Pocono Downs Racing Ass’n, 816 F.2d 895, 899 (3d Cir. 1987), quoting Oneida Indian Nation v. Cnty. of Oneida, 414 U.S. 661, 666 (1974).

DISCUSSION

The FCA’s first-to-file rule provides that: “[w]hen a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action.” 31 U.S.C. § 3730(b)(5). Cephalon contends that plaintiff’s Fentora claims are barred by § 3730(b)(5) because complaints containing substantially similar Fentora allegations were filed in the Boise action before Cestra filed his original complaint on August 30, 2010 in this action. See Dkt. No. 1-41.

“[T]he phrase ‘related action based on the facts underlying the pending action,’ clearly bars claims arising from events that are already the subject of existing suits.” U.S. ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc., 149 F.3d 227, 232 (3d Cir. 1998). As long as “a later allegation states all the essential facts of a previously-filed claim, the two are related and section 3730(b)(5) bars the later claim, even if that claim incorporates somewhat different details.” Id. at 232-33. Stated differently, the first-to-file rule applies when an earlier complaint “subsumes all the material elements” of a later claim or where a later claim merely “echo[e]s . . . the broader allegation” of the earlier complaint. Id. at 238, 236.

In Lacorte, the Court of Appeals applied § 3730(b)(5) by conducting a claim-by-claim analysis of the original and later-filed complaints and determining whether each discrete claim was barred. Id. at 235-36. Thus, some claims contained in a later complaint might be barred by the earlier complaint while others might survive. See, e.g., U.S. ex rel. Galmines v. Novartis Pharm. Corp., No. 06-3213, 2013 WL 2649704, at *10 (E.D. Pa. June 13, 2013) (barring complaint’s kickback claims under § 3730(b)(5) but declining to bar later complaint’s off-label marketing claims because they involved different medical conditions) certificate of appealability denied, 2013 WL 4511626 (E.D. Pa. Aug. 26, 2013) and on reconsideration in part, 2013 WL 5924962 (E.D. Pa. Nov. 5, 2013). “The first-to-file bar is designed to be quickly and easily determinable, simply requiring a side-by-side comparison of the complaints.” In re Natural Gas Royalties Qui Tam Litig. (CO2 Appeals), 566 F.3d 956, 964 (10th Cir. 2009).

I. Which Complaints Are Compared

As a threshold issue, the parties disagree over which versions of the Cestra and Boise complaints are relevant to my analysis under § 3730(b)(5). Cephalon contends that I should compare the complaints as they existed at the time Cestra brought his later action, which would mean comparing the Boise first amended complaint and Cestra’s original complaint. See Dkt. Nos. 1-41 at 5, 1-51 at 1-2, 8 at 5 n.6. Cestra contends that the relevant comparison is between the Boise first amended complaint and his complaint as it exists today, which would mean his second amended complaint. See Dkt. Nos. 1-49 at 2 n.2, 10 at 3 n.2.

The courts that have expressly considered this issue in the context of the first-to-file bar agree with Cephalon. See Grynberg v. Koch Gateway Pipeline Co., 390 F.3d 1276, 1279 (10th Cir. 2004) (noting that in determining which complaints to compare “we judge whether § 3730(b)(5) barred Grynberg’s qui tam action by looking at the facts as they existed at the time

that action was brought”); U.S. ex rel. Branch Consultants, L.L.C. v. Allstate Ins. Co., 782 F. Supp. 2d 248, 259 (E.D. La. 2011) (agreeing with the Tenth Circuit and conducting a searching inquiry into the basis of that interpretation); U.S. ex rel. Shea v. Verizon Bus. Network Servs. Inc., 904 F. Supp. 2d 28, 35 (D.D.C. 2012) (agreeing with Branch), aff’d sub nom. U.S., ex rel. Shea v. Cellco P’ship, 748 F.3d 338 (D.C. Cir. 2014). I find the reasoning of those courts persuasive.

Under the first-to-file rule, a plaintiff cannot “bring a related action based on the facts underlying the pending action.” 31 U.S.C. § 3730(b)(5). “One ‘brings’ an action by commencing suit.” U.S. ex rel. Chovanec v. Apria Healthcare Grp. Inc., 606 F.3d 361, 362 (7th Cir. 2010). “This interpretation of the statute is consistent with the fundamental rule that the jurisdiction of the court depends upon the state of things at the time of the action brought.” Shea, 904 F. Supp. 2d at 35 (citations omitted). Thus, for the purposes of determining whether Boise’s action bars Cestra’s Fentora claims under § 3730(b)(5) I will compare the Boise first amended complaint (No. 08-287, Dkt. No. 14) and Cestra’s original complaint (Dkt. No. 1-2).

II. Application of the First-To-File Bar

The parties do not dispute that both complaints contain similar factual allegations regarding Cephalon’s general off-label promotion of Fentora. See Dkt. Nos. 1-41 at 2, 1-49 at 8. Both complaints allege that Cephalon engaged in a fraudulent scheme to promote Fentora off-label for non-cancer pain, targeted non-oncologists and attempted to convert prescriptions of a previous drug Actiq to off-label Fentora prescriptions. Compare Dkt. No. 1-2 at ¶¶ 23-26 and No. 08-287, Dkt. No. 14 at ¶¶ 76-85. Instead, Cestra asserts that he has made three specific Fentora claims that are sufficiently distinct from Boise’s earlier claims to avoid the first-to-file bar.

First, Cestra contends that Boise only pled a cause of action under § 3729(a)(1)(A) of the FCA, which requires that defendants caused a false claim to be presented to the government. In contrast, Cestra argues that only he has pled that defendants made actually false statements about Fentora thus giving rise to an additional cause of action under § 3729(a)(1)(B), which contains a double falsity requirement of making a false statement in order to obtain the false claim. See Dkt. No. 1-49 at 6-7.

Cestra is mistaken. Boise pled a violation of § 3729(a)(1)(B) as part of Count I of his first amended complaint.¹ See No. 08-287, Dkt. No. 14 at ¶¶ 100-108. Boise pled specifically that “defendants knowingly . . . used false records and statements . . . to induce the Government to approve and pay such false and fraudulent claims.” Id. at ¶ 103. Furthermore, despite Cestra’s contention that “the gravamen of [Cestra’s] Fentora claims is . . . the off-label promotion was accomplished by intentionally supplying health care professionals with false, fraudulent, and misleading information” Cephalon is correct that I did “not find any alleged false statement regarding Fentora” in plaintiff’s original complaint. Dkt. Nos. 1-49 at 9, 1-51 at 3. Cestra’s § 3729(a)(1)(B) cause of action is a mere repetition of the Boise complaint and his claim is based on the same essential elements contained in the Boise complaint. Thus, Cestra’s Fentora allegations underlying his § 3729(a)(1)(B) claim are not distinct allegations under the first-to-file rule.

Second, Cestra contends that only his complaint includes “specific kickback allegations . . . regarding [Cephalon’s] use of financial inducements to affect physicians’ prescribing behavior.” Dkt. No. 1-29 at 12. Cestra’s original complaint, however, did not include kickback

¹ I must analyze each reasonably discrete claim of fraud for jurisdiction regardless of how the complaint is formally structured. See U.S. ex rel. Galmines v. Novartis Pharm. Corp., No. 06-3213, 2013 WL 2649704, at *10 n.7 (E.D. Pa. June 13, 2013), citing United States ex rel. Boothe v. Sun Healthcare Grp., Inc., 496 F.3d 1169, 1177 (10th Cir. 2007).

allegations. Furthermore, the Boise first amended complaint does generally allege kickbacks, though it lacks specifics with regard to Fentora. See No. 08-287, Dkt. Nos. 14 at ¶¶ 3, 35-39. Thus, Cestra's complaint does not allege a different fraudulent scheme distinguishing it from the earlier filed Boise complaint.

Lastly, Cestra correctly asserts that only he has pled that Cephalon violated its Corporate Integrity Agreement. But Cestra does not allege any unique facts or a different illegal promotion scheme that would give rise to this allegation. Rather, that violation is merely an inference based upon facts already alleged and “echo[e]s . . . the broader allegation” of the earlier Boise complaint. LaCorte, 149 F.3d at 236. Thus, even though Cestra makes this new allegation, his original complaint still states all of the same essential facts as the earlier Boise first amended complaint.

This case is not analogous to Galmines, where the Court did not bar a later-filed claim alleging that the same drug at issue in an earlier filed action was promoted off-label for a separate set of conditions. 2013 WL 2649704, at *10. Here there is nothing in Cestra's complaint that “pertains to a different off-label promotion scheme” that would “government notice of the need to investigate” that separate scheme. Id. Both Cestra and Boise's complaints allege that Cephalon sought to convert Actiq prescriptions to Fentora after Actiq lost its patent protection. Compare No. 08-2987, Dkt. No. 14 at ¶¶ 76-79 with Dkt. No. 1-2 at ¶¶ 165-69, 177-80. Both complaints allege that the significant majority of Cephalon's Fentora sales force and marketing is directed at the off-label use of Fentora and alleges the same methods of off-label promotion such as the targeting of non-oncology physicians. Compare No. 08-2987, Dkt. No. 14 at ¶¶ 83-4 with Dkt. No. 1-2 at ¶¶ 192-96. The additional details in Cestra's original complaint primarily refer to Fentora's FDA history and Cephalon's market research studies detailing

statistics about Fentora prescriptions. See Dkt. No. 1-2 at ¶¶ 183-91, 193. Cestra has not demonstrated how any of the allegations in his original complaint differ substantially from the Boise first amended complaint much less how they differ so substantially as to constitute an unrelated action evading the § 3730(b)(5) bar.

CONCLUSION

For the reasons set forth above, I will grant Cephalon's motion to dismiss Cestra's Fentora claims.

An appropriate Order follows.

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v.	:	
	:	
CEPHALON, INC., et al.	:	

ORDER

AND NOW, this 9th day of October, 2014, upon consideration of the motion to dismiss by defendant Cephalon, Inc. (Dkt. Nos. 1-41) and plaintiff's response (Dkt. No. 1-49), and consistent with the accompanying memorandum of law, it is ordered that Cephalon's motion is GRANTED and plaintiff's Fentora claims are DISMISSED.

s/Thomas N. O'Neill, Jr. _____
THOMAS N. O'NEILL, JR., J.