Not for Publication

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, et al., ex rel. LAURIE SIMPSON, *Plaintiff-Relator*, v. BAYER A.G., et al., *Defendants*.	Civil Action No. 05-3895 **OPINION & ORDER**

John Michael Vazquez, U.S.D.J.

Before the Court is Defendants Bayer A.G.; Bayer Healthcare, LLC; Bayer Corporation; and Bayer Heathcare Pharmaceuticals, Inc.'s (collectively "Bayer") motion to certify for interlocutory appeal, D.E. 353, this Court's April 23, 2019 Opinion and Order (the "April 23 Decision") denying their motion for partial summary judgment, D.E. 351, 352. Plaintiff-Relator Laurie Simpson ("Relator") filed an opposition brief, D.E. 355, to which Bayer replied, D.E. 357.[1] After opposition was filed, this matter was transferred from Chief Judge Linares to the undersigned. D.E. 356. The Court has considered the parties' submissions and decided the motion without oral argument pursuant to Fed. R. Civ. P. 78(b) and L. Civ. R. 78.1(b). For the following reasons, Bayer's motion is **DENIED**.

[1] The Court will refer to Bayer's moving brief (D.E. 353-1) as "Def. Br.", Relator's opposition brief as "Pl. Opp.", and Bayer's reply brief as "Def. Reply".

I. FACTUAL AND PROCEDURAL HISTORY

The Court's previous decisions have detailed this matter's facts and procedural history. *See, e.g.*, D.E. 208 at 1-5,[2] D.E. 351 at 2-8. Accordingly, the Court provides only an abbreviated background.

Relator, a former Bayer employee, filed this *qui tam* action under the whistleblower provisions of the False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.*, on August 5, 2005. D.E. 1. The Government declined to intervene. D.E. 16. In her Tenth Amended Complaint ("10AC"), D.E. 213, Relator alleges that "Bayer engaged in unlawful marketing, including off-label marketing and payment of kickbacks, in order to increase the market shares of its prescription drugs Trasylol and Avelox." 10AC ¶ 9.

1. Trasylol

Bayer's drug product Trasylol reduces surgical and post-surgical bleeding. *Id.* ¶ 109. The Food and Drug Administration ("FDA") had approved Trasylol "for patients undergoing repeat coronary artery bypass graft ("CABG") surgery using a cardiopulmonary bypass pump . . . and for patients undergoing such surgery for the first time . . . who were at high risk of bleeding." *Id.* ¶ 110. The FDA later had expanded approval to "low-risk primary on-pump CABG patients." *Id.* ¶ 113. Despite this narrow indication, off-label Trasylol use was ubiquitous. *Id.* ¶ 114. Relator alleges that Bayer promoted off-label Trasylol use by deliberately concealing and downplaying the drug's risks while falsely touting the its benefits. *Id.* ¶¶ 120-86. Relator alleges that Bayer misbranded Trasylol and, consequently, that Trasylol's introduction into interstate commerce was illegal. *Id.* ¶ 215. Relator also alleges that Bayer illegally paid kickbacks to healthcare professionals to motivate them to prescribe Trasylol. *Id.* ¶¶ 187-214.

[2] The Court references CM/ECF-generated page numbers for this previous decision.

Bayer's illegal kickbacks and off-label marketing schemes, Relator avers, caused the submission of false claims for Trasylol to Medicare, Medicaid, and other federally and state-funded healthcare programs. *Id.* ¶¶ 13, 16, 19. Based on Bayer's conduct related to Trasylol, Relator asserts ten FCA claims (Counts I to X) and various, related state and local law claims (Counts XIII to XXXIII). *Id.* ¶¶ 329-418, 433-568.

2. Avelox

Bayer's drug product Avelox is a broad-spectrum bactericide approved to treat and prevent infections caused or strongly suspected to be caused by certain bacterial strains. *Id.* ¶¶ 242-43. Relator alleges that Bayer engaged in several illegal kickback schemes to increase Avelox prescriptions. *Id.* ¶¶ 249-50. Among these alleged schemes were (i) cash honoraria to key opinion leaders for promoting Avelox; (ii) cash and gift honoraria to sham "consultants;" (iii) honoraria to physicians in the form of "medically related items" for viewing electronic presentations, participating in internet-based interactive learning programs, or listening to telesymposia; (iv) gifts to physicians for attending continuing medical education programs that promoted Avelox; and (v) a cash honorarium to at least one Kaiser Permanente-affiliated physician to present Avelox information at an in-house meeting. *Id.* ¶¶ 251-82.

Relator avers that these illegal kickbacks caused the submission of false claims for Avelox to Medicare, Medicaid, and other federally and state-funded healthcare programs. *Id.* ¶¶ 16, 19, 283. Based on Bayer's conduct related to Avelox, Relator brings two FCA claims (Counts XI and XII) and various, similar state and local law claims (Counts XIII to XXXIII). *Id.* ¶¶ 419-568.

3. Retaliation

Finally, Relator alleges that Bayer retaliated against her for reporting to her supervisors what she believed to be fraudulent conduct. *Id.* ¶¶ 569-72. Bayer's retaliation, Relator alleges, violates 31 U.S.C. § 3730(h) (Count XXXIV) and N.Y. Fin. Law § 191 (Count XXXV). *Id.*

Specifically, Relator avers that she complained to her supervisor Carol D'Eugenio, Trasylol's Product Manager Bill Allen, Randy Santiago in Scientific Affairs, and others that certain meetings described as market research or advisory meetings were promotional in nature. *Id.* ¶¶ 309-11. Afterward, Relator avers that she was passed over for a promotional opportunity and excluded from meetings of Bayer's New Products Evaluation Team. *Id.* ¶¶ 312-13. Relator alleges that in March 2004 she complained again to Dean Slack, Director of the Strategic Analysis Department, who relayed her concerns to in-house counsel David Reed and Director of Marketing Stanley Horton. *Id.* ¶ 317. The next month, Relator alleges that Bayer excluded her from the business planning process for Trasylol. *Id.* ¶ 318. And in July 2014, Bayer allegedly promoted Relator's less qualified colleague into an unadvertised position that would have been a promotion for Relator. *Id.* ¶ 324. D'Eugenio was allegedly told by a human resources employee that the department would have found a way to disqualify Relator had she applied. *Id.* In September 2004, Bayer terminated Relator, citing a workforce reduction initiative. *Id.* ¶ 326. Relator avers that this reason was a pretext and that she was replaced by a less qualified individual. *Id.* ¶ 327.

4. The Court's April 23 Decision

Trasylol is administered in *inpatient* settings. D.E. 323-2 ¶ 18; D.E. 330-1 at 9-10. Medicare (under Part A) and many state Medicaid programs reimburse hospitals for inpatient procedures primarily through a fixed-fee system—i.e., a system based on pre-determined rates rather than reasonable costs. D.E. 323-2 ¶¶ 4-5; D.E. 330-1 at 3-4. Bayer contends that this fixed-

fee payment system is fatal to Relator's Trasylol-related FCA claims.[3] *See, e.g.*, D.E. 323-1 at 18-25. Bayer argues that because the Government pays the same price for a given procedure regardless of whether Trasylol is used, any alleged misrepresentation regarding Trasylol is not capable of influencing the Government's decision to pay a claim. *See id.* Thus, Bayer contends that the fixed fee payment system renders any alleged misrepresentation regarding Trasylol immaterial as a matter of law. *See id.*

Despite discovery being substantially incomplete, the Court ordered the parties to cross move for partial summary judgment on this narrow issue to facilitate a potential settlement. D.E. 322 at 5:1-22; D.E. 321 at 1-2. After considering the parties' submissions, the parties' oral arguments, and the United States' statement of interest, the Court rejected Bayer's legal theory. D.E. 351, 352. The Supreme Court's decision in *Escobar* clarified that the materiality inquiry focuses on "the 'Government's payment *decision*.'" D.E. 351 at 24 (citing *Escobar*, 136 S. Ct. at 2002). The focus "is not [on] the *amount* of payment." *Id.* Indeed, "[t]he Government considers factors other than the bald dollar amount of a reimbursement request when deciding whether to pay a claim, including the claimant's compliance with applicable regulatory requirements." *Id.* In denying Bayer's motion for partial summary judgment, the Court ruled as follows:

> Bayer may be held liable under the [FCA] for claims for Medicare and Medicaid reimbursement for surgical procedures in which Trasylol was administered, regardless of whether the relevant requests for reimbursement were bundled rather than itemized[, and]

[3] Liability under the FCA attaches to any person who "(A) knowingly presents, or causes to be presented [to the United States Government], a false or fraudulent claim for payment or approval; [or] (B) knowingly makes uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A)-(B). Relevant here, a claim can be "false or fraudulent" based on "lies about [a claimant's] compliance with a statutory, regulatory, or contractual requirement." *United States ex rel. Greenfield v. Medco Health Solutions, Inc.*, 880 F.3d 89, 94 (3d Cir. 2018). But those lies "must be material to the Government's payment decision in order to be actionable under the [FCA]." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1996 (2016).

> regardless of whether the administration of Trasylol in these procedures affected the total amount of corresponding reimbursement.

Id. at 33-34.[4]

II. LEGAL STANDARD

The statute governing interlocutory appeals, 28 U.S.C. § 1292(b), provides in relevant part:

> When a district judge, in making in a civil action an order not otherwise appealable under this section, shall be of the opinion that such order involves a controlling question of law as to which there is substantial ground for difference of opinion and that an immediate appeal from the order may materially advance the ultimate termination of the litigation, he shall so state in writing in such order. The Court of Appeals which would have jurisdiction of an appeal of such action may thereupon, in its discretion, permit an appeal to be taken from such order[.]

Thus, a district court may certify a non-final order for interlocutory appeal where the order "(1) involve[s] a controlling question of law, (2) offer[s] substantial ground for difference of opinion as to its correctness, and (3) if appealed immediately [would] materially advance the ultimate termination of the litigation." *Katz v. Carte Blanche Corp.*, 496 F.2d 747, 754 (3d Cir. 1974) (internal quotation marks omitted). A controlling question of law is one in which, either (1) "if erroneous, would be reversible error on final appeal;" or (2) is "serious to the conduct of litigation, either practically or legally." *Id.* at 755. "[Q]uestions about a district court's application of facts of the case to established legal standards are not controlling questions of law for the purposes of section 1292(b)." *Morgan v. Ford Motor Co.*, No. 06-1080, 2007 WL 269806, at *2 (D.N.J. Jan. 25, 2007).

[4] As "[b]oth parties acknowledge[d] ongoing disputes of fact that are material to a determination of liability on any element" of Relator's Trasylol-related FCA claims, the Court also denied Relator's motion for partial summary judgment. *Id.* at 34.

A substantial ground for difference of opinion must arise "out of genuine doubt as to the correct legal standard." *Kapossy v. McGraw-Hill, Inc.*, 942 F. Supp. 996, 1001 (D.N.J. 1996). Mere disagreement with the district court's ruling is not enough. *Id.* Rather, "[a] substantial ground for difference of opinion exists where reasonable jurists might disagree on an issue's resolution, not merely where they have already disagreed." *Reese v. BP Exploration (Ala.) Inc.*, 643 F.3d 681, 688 (9th Cir. 2011). Therefore, "when novel legal issues are presented, on which fair-minded jurists might reach contradictory conclusions, a novel issue may be certified for interlocutory appeal without first awaiting development of contradictory precedent." *Id.*

Lastly, certification would materially advance the ultimate termination of the litigation "where the interlocutory appeal eliminates: (1) the need for trial; (2) complex issues that would complicate trial; or (3) issues that would make discovery more costly or burdensome." *F.T.C. v. Wyndham Worldwide Corp.*, 10 F. Supp. 3d 602, 635 (D.N.J. 2014). This element does not require a movant to establish that an appeal would guarantee termination of the litigation, but rather "requires the court to analyze whether an immediate appeal *may materially* advance the termination of the litigation." *A.S. ex rel. Miller v. SmithKline Beecham Corp.*, No. 13-2382, 2013 WL 6506570, at *3 (M.D. Pa. Dec. 12, 2013).

"The burden is on the movant to demonstrate that all three requirements are met." *Piacentile v. Thorpe*, No. 12–7156, 2016 WL 3360961, at *2 (D.N.J. June 8, 2016) (quoting *Litgo N.J., Inc. v. Martin*, No. 06-2891, 2011 WL 1134676, at *2 (D.N.J. Mar. 25, 2011)). However, "even if all three criteria . . . are met, the district court may still deny certification, as the decision is entirely within the district court's discretion." *Id.* (quoting *Morgan*, 2007 WL 269806, at *2 (D.N.J. Jan. 25, 2007)). Further, Section 1292(b) "is to be used sparingly and only in exceptional circumstances that justify a departure from the basic policy of postponing review until the entry of

the final order." *Acosta v. Pace Local I-300 Health Fund*, No. 04-3885, 2007 WL 1074093, at *1 (D.N.J. Apr. 9, 2007) (quoting *Morgan*, 2007 WL 269806, at *2 (internal quotation marks omitted)); *see also Kapossy*, 942 F. Supp. at 1001 (stating that interlocutory appeal is "used sparingly" since it is "a deviation from the ordinary policy of avoiding piecemeal appellate review of trial court decisions which do not terminate the litigation") (quoting *United States v. Hollywood Motor Car Co.*, 458 U.S. 263, 265 (1982) (internal quotation marks omitted)).

III. ANALYSIS

In requesting certification, Bayer argues that the April 23 Decision involves the question of whether the Government's fixed-fee payment system renders any alleged fraud regarding Trasylol immaterial as a matter of law, as the Government pays the same price for a surgical procedure regardless of whether Trasylol is used. Def. Br. at 8. Bayer argues that this question is a "controlling question of law" for which there is a "substantial ground for difference of opinion." *Id.* at 8-10. In support, Bayer cites to the lack of mandatory authority and the split in district courts on the issue. *Id.* at 9-10; Def. Reply at 2-4. Bayer also argues that "certification could very well eliminate the need for trial . . . but at the very least, [certification] would drastically reduce the scope and complexity of any discovery and trial that might occur thereafter." Def. Br. at 10. Namely, Bayer contends that an appellate decision in their favor would significantly trim down this litigation because "Relator has not identified any exceptions to the . . . fixed-fee payment system" and has identified only one false claim for the other drug product at issue, Avelox. *Id.* Bayer further contends that this Court's April 23 Decision requires the parties "to propound additional significant discovery on multiple government agencies." *Id.* at 11. Bayer provides a non-exclusive list of questions that need to be addressed, and Bayer argues that a reversal of this

the April 23 Decision would obviate the need for this burdensome, additional discovery. *Id.* at 11-13.

Relator does not contest that the question Bayer seeks to certify is a controlling question of law. *See* Pl. Opp. Rather, Relator contends that Bayer has not satisfied the burden of demonstrating the applicable test's second and third prongs—i.e., there is a substantial ground for difference of opinion and immediate appeal would materially advance the litigation's ultimate termination. *Id.* at 7-13.[5] Relator argues that the second prong requires the "substantial ground for difference of opinion . . . [to] arise 'out of genuine doubt as to the correct legal standard.'" *Id.* at 7 (quoting *Kapossy*, 942 F. Supp. at 1001). *Escobar* clarified the legal standard for materiality under the FCA: whether the Government's knowledge of a false claim would affect the Government's payment decision. Pl. Opp. at 8. Because Bayer cites only pre-*Escobar* cases to support their contention of a district court split, Relator argues that Bayer has not shown a substantial ground for difference of opinion. *Id.* at 7-9. Regarding the third prong, Relator contends that the advanced stage of this litigation weighs against certifying the question for interlocutory appeal. *Id.* at 10-11. The significant discovery burden, Relator argues, "is of Bayer's creation and cannot justify the excessive delay caused by an interlocutory appeal. . . ." *Id.* at 11. Relator contends that much of Bayer's proposed discovery runs afoul of Federal Rules of Civil Procedure 26(c) and 45. *Id.* at 11-12. Further, Relator highlights that the Court has appointed a Special Master to resolve any discovery disputes. *Id.* at 10-11. Finally, Relator contends that regardless of an interlocutory appeal, she would still be able to proceed on other claims not implicated by the April 23 Decision. *Id.* at 13.

[5] Page numbers in cites to Relator's opposition brief reference CM/ECF-generated page numbers.

The Court will not certify its April 23 Decision for interlocutory appeal. Bayer has not convinced the Court that this case involves "exceptional circumstances that justify a departure from the basic policy of postponing review until the entry of the final order," and the Court finds that Bayer has not met their burden of showing that an interlocutory appeal would materially advance the ultimate termination of this litigation. *See Acosta*, 2007 WL 1074093, at *1; *accord Piacentile*, 2016 WL 3360961, at *2.

First, Relator's Trasylol-related FCA claims form only one set of claims within a larger lawsuit. *See* 10AC. Even if the Third Circuit were to rule in Bayer's favor, Relator's Avelox-related FCA claims and FCA retaliation claim would remain. Those claims "are still being actively litigated, and their merits would not be resolved or clarified in any way on an immediate appeal concerning" the April 23 Decision. *See Ferreras v. Am. Airlines, Inc.*, No. 16-2427, 2017 WL 1709597, at *2 (D.N.J. May 1, 2017) (finding that an interlocutory appeal would not materially advance the ultimate termination of the litigation where two claims would remain regardless of an appeal's outcome); *accord Shevlin v. Phoenix Life Ins. Co.*, No. 09-6323, 2015 WL 348552, at *7 (D.N.J. Jan. 23, 2015) (finding that an interlocutory appeal would not materially advance the ultimate termination of the litigation where any appellate decision "would not render the breach-of-contract claim terminated or moot).

Second, a favorable appellate decision for Bayer would not completely dispose of Relator's Trasylol-related FCA claims. For example, Relator would still be able to proceed on Trasylol-related FCA claims for physician and hospital claims billed under Medicare Part B. Pl. Opp. at 13. Relator would be able to proceed on "outlier" claims billed under Medicare Part A.[6] *See* 42

[6] "Outlier" claims are ones where the hospital's actual costs exceed Medicare's fixed payment by a certain amount. 42 C.F.R. § 412.80. The Government must make additional payments for these unusually costly cases of patient treatment. 42 U.S.C. § 1395ww(d)(5)(A).

U.S.C. § 1395ww(d)(5)(A). And Relator would be able to proceed on claims at "critical access hospitals" in rural areas. D.E. 338 at 4 n.1.

Bayer does not argue that an interlocutory appeal would resolve Relator's Avelox-related FCA claims or completely resolve Relator's Trasylol-related FCA claims. *See* Def. Br.; Def. Reply. Indeed, Bayer seems to admit that an appeal might not resolve these claims. *See, e.g.*, Def. Br. at 8 n.3; Def. Reply at 5 n.3. Instead, Bayer contends that despite years of litigation, Relator has not been able to identify any exceptions to the fixed-payment system and has identified only an insignificant amount in allegedly false Avelox claims. Def. Br. at 10. Therefore, Bayer contends certification "would drastically reduce the scope and complexity of any discovery and trial that might occur thereafter." *Id.*

The Court affords little weight to this argument. The Court in its April 23 Decision noted that discovery remained substantially incomplete. D.E. 351 at 14. Bayer has acknowledged as much, and has further stated that the Government to date has refused to participate in discovery. Def. Br. at 13; Def. Reply 5-6. If Bayer's statement regarding Government participation is true, the Court, at least for the purpose of this motion, will not fault Relator for not identifying any "outlier" claims or exceptions to the fixed payment system. Similarly, the Court will not consider the number or value of Relator's Avelox-related claims based on limited discovery. Ongoing discovery may uncover more evidence to support Relator's claims. Consequently, an interlocutory appeal very well may not meaningfully reduce the cost or burden of discovery. *See Wyndham Worldwide*, 10 F. Supp. 3d at 635. The Court notes that it has appointed a Special Master to oversee discovery and that the Special Master is more than capable of limiting the scope and complexity of discovery to an appropriate level. *See* D.E. 328. To the extent Bayer is suggesting an interlocutory appeal would facilitate settlement (Def. Br. at 8 n.3), the Court notes that it has

conducted three settlement conferences without success, the parties have litigated three motions to dismiss, the Complaint is in its tenth iteration, and the parties have struggled to resolve any discovery issue without Court intervention. *See* D.E. 310, 316, 319, 328 at 2-3, Pl. Opp. at 10. For these reasons, the Court finds that Bayer has not met their burden of showing that an interlocutory appeal would materially advance the ultimate termination of this litigation.[7] *See Piacentile*, 2016 WL 3360961, at *2.

Finally, even if the Bayer had satisfied the three-part test, the Court would exercise its discretion to deny certification. *See Piacentile*, 2016 WL 3360961, at *2. The Court stands by its previous holding, which is well supported by case law. Therefore, although an interlocutory appeal might provide clarity on one issue in this large dispute, the Court finds it more likely that an appeal would simply defer resolution of a case that is 14-years old. *See U.S. ex rel. Galmines v. Novartis Pharm. Corp.*, No. 06-3213, 2013 WL 4511626, at *2 (E.D. Pa. Aug. 26, 2013) (denying certification in a seven-year-old case where the court's prior holding was well supported by case law); *Singh v. Daimler-Benz, AG*, 800 F. Supp. 260, 263 (E.D. Pa. 1992) (denying certification where clear statutory language supported its previous holding); *Shevlin*, 2015 WL 348552, at *6 ("A critical factor is whether the interlocutory appeal will cause excessive delay."). The Court cannot justify the delay of an interlocutory appeal under these circumstances.

[7] Because Bayer has not satisfied the third-prong of the test, the Court will not address the parties' arguments regarding "substantial ground for difference of opinion." *See Liberty Salad, Inc. v. Groundhog Enters., Inc.*, No. 17-0226, 2019 WL 1303829, at *3 (E.D. Pa. Mar. 20, 2019) ("All three criteria must be satisfied [for a court to grant certification].").

IV. CONCLUSION

For these reasons, and for good cause shown,

IT IS on this 16th day of July 2019,

ORDERED that Defendants' motion to certify this Court's April 23, 2018 Opinion and Order for interlocutory appeal (D.E. 353) is **DENIED.**

s/ John Michael Vazquez
John Michael Vazquez, U.S.D.J.