Circuit Splits Surrounding FCA Endure Post-Takeda

Law360, New York (May 02, 2014, 3:54 PM ET) -- When the U.S. Supreme Court denied the petition of a relator seeking review of the Fourth Circuit decision United States ex rel. Nathan v. Takeda Pharmaceuticals North America, 707 F.3d 451 (4th Cir. 2013), which had affirmed the dismissal of his complaint based primarily on Federal Rule of Civil Procedure 9(b), the high court maintained the viability of False Claims Act defenses at the motion to dismiss stage, as well as a circuit split on their application.

While the Supreme Court did not disturb the circuit split on Rule 9(b) and federal pleading standards, there are multiple key FCA issues also subject to circuit splits, which means that defendants are facing a slightly different FCA minefield in every circuit.

Rule 9(b) and the Federal Pleading Standards

The Supreme Court’s decision in Takeda means that the challenged authority of existing case law in the Fourth Circuit and certain other circuits will remain in place, providing important defenses to companies sued under the FCA based on both Rule 9(b) and the related plausibility standard applicable to Rule 8(a). However, a circuit split will also remain in place on the scope of these defenses, which means their effectiveness will vary for defendants according to the evolving circuit case law, as well as the location of the trial courts chosen by plaintiffs.

The Supreme Court’s decision is consistent with the recommendation of the Solicitor General, who on Feb. 25, 2014, filed an amicus curiae brief on behalf of the United States. The brief agreed that the lower courts have reached “inconsistent conclusions about the precise manner in which a qui tam relator may satisfy the requirements of Rule 9(b).”

Several courts of appeals have held that a qui tam complaint satisfies Rule 9(b) if it contains detailed allegations supporting a plausible inference that false claims were submitted to the government, even if the complaint does not identify specific requests for payment, as permitted by the First, Fifth, Seventh and Ninth Circuits. Other circuit court decisions have required the relator to plead the details of particular false claims, as required by the Fourth, Sixth, Eighth and Eleventh Circuits.
The Solicitor General's brief disagreed with the latter rule, and disagreed that the Fourth Circuit had endorsed the latter rule in Takeda; however, the Solicitor General stated that the Takeda case was “not a suitable vehicle for resolving the question presented.”

Nathan, the relator, petitioned the Supreme Court in May 2013 to hear his case, involving allegations of “off-label” promotion of certain stomach acid drugs, after the Eastern District of Virginia dismissed the case for failure to identify a false claim, and the dismissal was affirmed by the Fourth Circuit in January 2013. The district court rejected the relaxed pleading standard due to Fourth Circuit case law, which “adheres to a strict application of Rule 9(b) to FCA claims.”

The Fourth Circuit, affirming the district court decision, ruled primarily on Rule 9(b), but also recognized that to survive a Rule 12(b)(6) motion to dismiss, a complaint must “state a claim to relief that is plausible on its face,” as required by Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). Facts that are “merely consistent with” liability do not establish a plausible claim to relief. In addition, according to the Fourth Circuit, although “we must view the facts alleged in the light most favorable to the plaintiff, we will not accept ‘legal conclusions couched as facts or unwarranted inferences, unreasonable conclusions or arguments.’”

Nathan’s allegations were based in part on statistical inference, and the Fourth Circuit decision was based in part on the pleading standards under Iqbal, in conjunction with the requirements of Rules 8(a) and 9(b). The question then presented to the Supreme Court by relator Nathan focused on Rule 9(b) and the circuit split on its application.

According to Takeda Pharmaceuticals’ opposition, the circuit split was not implicated because “the shortcomings in the [complaint] would have resulted in its dismissal under any circuit’s pleading standard,” since “the assorted statistics and generalized allegations” did not provide “sufficient ‘indicia of reliability’ to demonstrate that a false claim was presented to the government for payment.”

According to the Solicitor General's brief, the Fourth Circuit correctly held that the relator’s complaint failed to satisfy the requirements of both Rule 9(b) and Iqbal, “because it did not plausibly allege that false claims were presented to the government. Because the complaint failed not merely for lack of specificity, but also for lack of plausibility, this suit could not go forward even under the pleading standard most favorable to relators.” In addition, because the issue “continues to percolate in the lower courts,” the Supreme Court’s “consideration of the question presented should await a case in which it would be outcome-determinative.”

The Solicitor General's brief illustrates the importance to defendants of the plausibility standard under Iqbal and its predecessor decision Bell Atlantic v. Twombly, 550 U.S. 544 (2007). As described in Iqbal, the pleading standard under Rule 8 demands “more than an unadorned, the-defendant-unlawfully-harmed-me accusation.” A pleading that offers “labels and conclusions” or “a formulaic recitation of the elements of a cause of action will not do.”

To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to “state a claim to relief that is plausible on its face.” A claim has facial plausibility “when the plaintiff pleads factual
content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” See Iqbal, 556 U.S. at 678-79.

According to the Solicitor General's brief in the Takeda case, the “lack of plausible allegations that respondent’s conduct led to the presentation of false claims would have doomed petitioner’s complaint before every court of appeals, even those that apply the most relator-friendly pleading standards.”

Thus, defendants facing FCA complaints must be prepared to defend themselves at the motion to dismiss stage, embracing the defenses of both Rule 9(b) and the pleading standards for Rule 8 under the Supreme Court precedent Iqbal and Twombly.

Now that the Court has denied the petition in the Takeda case, the Fourth and other circuits can preserve the significant gatekeeping mechanism of Rule 9(b) at the pleading stage, but defendants must be wary of the evolving case law and the circuit split that still exists, and tailor their defenses to the unique precedent of the respective circuit courts.

**Other FCA Circuit Splits and Minefields Still Looming for Defendants**

Shortly following the Supreme Court decision in the case against Takeda brought by Nathan, a new and related issue was petitioned to the high court in a separate case against Takeda, concerning reporting of adverse events, brought by a different relator in the First Circuit. On April 10, 2014, this relator petitioned the Supreme Court to hear a case on the issue of a qui tam plaintiff’s ability to amend a complaint, arguing that there is a circuit split on when such permission should be granted by the trial court following the entry of judgment.

The district court had ruled in United States ex rel. Ge v. Takeda Pharmaceutical Co. that Ge’s allegations failed under the First Circuit’s precedent on Rule 9(b), and also failed under Rule 12(b)(6) for failure to state a claim, based on the First Circuit precedent on legal falsity, United States ex rel. Hutcheson v. Blackstone Medical, Inc., 647 F.3d 377 (1st Cir. 2011). The First Circuit affirmed, finding that Ge’s arguments based on Rule 9(b) were waived and affirming the district court’s denial of a motion to amend the complaint. Now this decision has been petitioned to the Supreme Court, highlighting another problematic issue looming for defendants.

Prior to denying Nathan’s petition on Rule 9(b), the Supreme Court had in the past few years also denied petitions originating in the First and Sixth Circuits, illuminating circuit splits on FCA liability issues involving implied certification and the 2009 FCA amendments. In addition, petitions still pending address a circuit split on the first-to-file rule and the unique ruling of the Fourth Circuit concerning the statute of limitations. There are splits or differences among the circuits on each of these five inter-related issues, which are discussed below.

**Legal Falsity and Implied Certification**

More than two years ago, in December 2011, the Supreme Court passed on the opportunity to take on
controversial issues surrounding the liability theory of legal falsity or implied certification, when it denied the petition for certiorari in the First Circuit case noted above, United States ex rel. Hutcheson v. Blackstone Medical Inc. According to Blackstone’s petition two years ago, “every circuit has staked out at least some ground on the issue of ‘legally false’ FCA claims and their parameters, and the circuits are not so much split as they are splintered.”

Because the Supreme Court denied that petition, the circuit courts have continued to establish diverging tests for legal falsity under the FCA. The Fourth and Fifth circuits have rejected, questioned and declined allegations of implied certification at the motion to dismiss stage. The D.C. and First Circuits have adopted the most flexible and expansive standards for implied certification and legal falsity, narrowing the few limitations on the common law theories. Other circuits are somewhere in between.

The Fourth Circuit rulings declining to recognize implied certification are consistent with its holdings on Rule 9(b). At the other end of the spectrum, the First Circuit rulings permitting allegations of legal falsity at the motion to dismiss stage are consistent with its more liberal holdings on Rule 9(b). However, Rule 9(b) remains a defense in implied certification cases. The Ninth Circuit, when adopting the implied certification theory in 2010, accepted a relaxed standard on Rule 9(b), but also affirmed the dismissal of the complaint based on Rule 9(b). And even if plaintiffs prevail at the motion to dismiss stage, defendants may prevail at summary judgment; for example, the Seventh Circuit also falls into the more liberal category on Rule 9(b), but has precedent on legal falsity favorable to defendants at the summary judgment stage.

Each circuit has its own unique precedent on legal falsity at either the motion to dismiss stage or the summary judgment stage. A defendant facing claims of legal falsity must look first to the applicable circuit precedent on Rule 9(b) and the federal pleading standards, as well as legal falsity and implied certification. If a complaint succeeds at the motion to dismiss stage, other defenses may be successful at summary judgment, although they may vary in the circuits. These include two key defenses or limitations recognized by the D.C. and First Circuit precedent, based on lack of scienter and materiality. However, these defenses may be impacted by the 2009 FCA amendments discussed below.

**Retroactivity of FERA Amendment to Pending Cases**

In June 2013, the Supreme Court denied the petition for review of the Sixth Circuit decision in United States ex rel. Sanders v. Allison Engine Co., 703 F.3d 930 (6th Cir. 2012), which held that a key liability provision in the 2009 FCA amendments applies retroactively to pending cases. Because of this provision, concerning the use of a false record or statement, implicates scienter and materiality, it could also implicate defenses to the implied certification theory.

In the 2008 Supreme Court decision in Allison Engine, the high court held that liability under the statutory text of the FCA, 31 U.S.C. Section 3729(a)(2) (prior to its amendment in 2009), required that the defendant made or used a false record or statement with the purpose of getting a false or fraudulent claim paid or approved by the government.

In the Fraud Enforcement and Recovery Act, Congress expanded the scope of the FCA and amended it to
legislatively overrule the Supreme Court’s 2008 decision. FERA removed the language (“to get”) interpreted by the Supreme Court, added a materiality provision and stated that the amended FCA liability provision (Section 3729(a)(1)(B)) “shall take effect as if enacted on June 7, 2008, and apply to all claims under the [FCA] ... that are pending on or after that date.”

Thus, the FERA amendments stated that this new provision applies to all “claims” pending on or after June 7, 2008, which was two days before the Supreme Court’s Allison Engine decision on June 9, 2008. But the Sixth Circuit held that the new provision applies retroactively to all cases that were pending on or after June 7, 2008.

As set forth in the Allison Engine petition, the Ninth and Eleventh Circuits had held that “claims,” as used in the applicable retroactivity provision of the 2009 amendments, refers to a request for payment or approval as defined by the FCA; but the Second and Seventh Circuits had held, like the Sixth, that “claims” means cases or civil actions.

The question presented was whether the new provision applies retroactively to cases pending on or after June 7, 2008, where no allegedly false claim for payment was pending on or after that date. Because the new provision implicates the defenses of scienter and materiality, its retroactive application could impact defenses to implied certification or legal falsity. Defendants facing such allegations must therefore be sensitive to the applicable circuit court’s holdings on the FERA amendments and their retroactive application.

**The Statute of Limitations and First-To-File Rule**

On June 24, 2013, the same day the Supreme Court denied the petition in Allison Engine, it was petitioned by the defendants in United States ex rel. Carter v. Halliburton Co., 710 F.3d 171 (4th Cir. 2013), following the Fourth Circuit decision in March in which the panel’s majority ruled that the Wartime Suspension of Limitations Act (“WSLA”) applied to the FCA in the civil as well as criminal context.

Located in the federal criminal code, the WSLA, as amended in 2008, suspends or “tolls” the running of any statute of limitations applicable to (as relevant here) any “offense” involving fraud against the United States when the country is at war or Congress has authorized the use of the armed forces. 18 U.S.C. Section 3287.

In three short paragraphs, the majority opinion in Carter decided that the WSLA applies in the civil context, even if the United States was not a party, based on the majority’s interpretation of an ambiguous 1944 amendment to the statute. In a lengthy dissent, the minority argued that the WSLA does not apply to relators.

The Fourth Circuit decision also held that “once a case is no longer pending the first-to-file bar does not stop a relator from filing a related case.” The FCA’s first-to-file bar, 31 U.S.C. Section 3730(b)(5), provides that “[w]hen a person brings an action under [the FCA], no person other than the [g]overnment may intervene or bring a related action based on the facts underlying the pending action.” Carter had previously filed related actions that were pending when he filed his current case, but which were later dismissed. The district court here dismissed the complaint with prejudice, and the circuit reversed.
Thus, the questions presented by the petition to the Supreme Court are: (1) whether the WSLA applies to civil FCA claims brought by private relators, in a manner that leads to indefinite tolling, and (2) whether the FCA’s first-to-file bar, which “creates a race to the courthouse to reward relators who promptly disclose fraud against the government, while prohibiting repetitive, parasitic claims — functions as a ‘one-case-at-a-time’ rule allowing an infinite series of duplicative claims so long as no prior claim is pending at the time of filing.”

The Fourth Circuit decision on the first-to-file bar adds to a circuit split, consistent with decisions of the Seventh and Tenth circuits, but departing from others including the First, Fifth, Ninth and Eleventh. Most recently, since the petition was filed, the D.C. Circuit has issued a decision on April 11, 2014, in United States ex rel. Shea v. Cellco Partnership, which disagrees with the decisions of the Fourth, Seventh and Tenth, including Carter.

The Fourth Circuit decision on the WSLA is unique so far among the circuits, and it is unclear how the WSLA and FCA statute of limitations will be interpreted by the other circuits as well as the trial courts. At least two significant decisions by district courts outside the Fourth Circuit have followed the minority in Carter, while at least two have followed the majority, including a major case against Wells Fargo Home Mortgage involving mortgage loans insured by the Federal Housing Administration.

The same two questions presented by the Carter petition have been the subject of a second petition to the Supreme Court following another Fourth Circuit decision issued in December, United States ex rel. May v. Purdue Pharma LP, 737 F.3d 908 (4th Cir. 2013). That petition also presents a third issue, the circuit split on the application of the FCA’s pre-2010 public-disclosure bar.

**Implications of the Carter Decision and Pending Petition**

Although the Supreme Court did not disturb the First Circuit decision on legal falsity in Blackstone or the Sixth Circuit ruling on FERA retroactivity in Allison Engine or the Fourth Circuit decision on Rule 9(b) in Takeda, the high court still has the opportunity to address the equally consequential decision by the Fourth Circuit in Carter.

With this petition, the Supreme Court can address two critical issues of statutory interpretation that, if left unresolved, will become increasingly problematic to the FCA litigation that has risen to historic proportions nationwide over the last several years. According to the petition and amicus briefs, the Fourth Circuit decision will have “dire effects” for “a host of industries,” including defense, health care and financial services.

The decisions by the Fourth and Sixth circuits in Carter and Allison Engine both expand the reach of the FCA on a temporal basis. Under these decisions plaintiffs could attempt to not only evade the FCA statute of limitations entirely, but to apply the new FCA liability provision retroactively to events that would previously have been excluded by the statute of limitations. Defendants, therefore, will be forced to oppose the application of these holdings outside those respective circuits. The FCA’s 10-year statute of repose in Section 3731(b)(2) could operate to prevent indefinite tolling, but has not been tested under the Fourth Circuit
decision.

The problematic holdings in Carter and Allison Engine would be compounded if asserted in conjunction with legal falsity or implied certification theories, or if unconstrained by Rule 9(b) and federal pleading standards. In good news for defendants, while the Fourth Circuit has suspended the statute of limitations in the Carter case, the same Fourth Circuit has consistently maintained significantly prodefendant rulings on both Rule 9(b) and implied certification.

It remains concerning, however, that a plaintiff who is barred by the holding of a particular circuit on Rule 9(b), legal falsity or another issue might attempt to use the Fourth Circuit reasoning on the first-to-file bar to file suit again on the same facts in a different venue. This type of forum shopping would be an opportunistic tactic by plaintiffs that the statute correctly discourages, but which has been permitted by the Fourth and other circuits.

The prospect of forum shopping based on limited application of the first-to-file rule is compounded by circuit splits that exist on other FCA issues, presenting additional minefields for defendants. For example, when the Fifth Circuit ruled in the 2012 decision Little v. Shell Exploration & Production Co. that federal employees could serve as relators, it stated there was “something of a split already” on the issue, acknowledging that at least the First Circuit had taken a contrary position.

The Supreme Court, after permitting circuit splits on various other FCA liability issues to flourish, should step in to address the first-to-file bar and statute of limitations issues left in controversy by the Carter case. The Supreme Court’s decisions to deny the petitions in Blackstone, Allison Engine, and Takeda provide good reason why it should grant the petition in Carter.

But given that the Supreme Court may deny the Carter petition as well, FCA defendants must brace themselves for a continuing minefield of diverging precedent on FCA liability issues, not only between the respective circuits, but within certain circuits on the various inter-related FCA interpretation issues that may be decided in favor of defendants or plaintiffs. Defendants must adapt their defense strategies accordingly and harmonize their arguments with the evolving case law of the controlling courts of appeals.

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