



WILL NOVEL CHALLENGE TO “REVERSE-PAYMENT” PATENT SETTLEMENT EXPAND FALSE CLAIMS ACT LIABILITY?

by Peter B. Hutt II and Catherine E. Creely

Brashly testing the frontiers of False Claims Act (FCA) liability, a *qui tam* plaintiff filed a lawsuit asserting that a pharmaceutical manufacturer’s anticompetitive behavior violated not only the antitrust laws, but also the FCA. Although the Department of Justice declined to intervene in the matter, and the plaintiff voluntarily dismissed the lawsuit before the court ruled on its viability, pharmaceutical manufacturers can expect a slew of similar suits in the future.

The plaintiff in *U.S. ex rel. Radice v. Astellas Pharma, Inc.* targeted a category of patent settlements known as “reverse-payment” agreements, which the Federal Trade Commission and private plaintiffs have contested under federal and state antitrust laws for several years. The federal Hatch-Waxman Act encourages generic drug makers to challenge the validity of a brand pharmaceutical company’s patent prior to expiration of that patent. Rather than accept the distractions and costs attendant to years of patent litigation, the parties frequently settle such suits, often on terms where the generic company receives something of value, while the brand company retains its patent rights for an agreed upon period of time (but not beyond the expiration of the patent).

The *Radice* case addressed an agreement affecting name-brand Flomax, which was being sold at prices purportedly inflated by an illegal reverse-payment agreement. The name-brand and generic drug manufacturer defendants allegedly entered into a sham patent-settlement agreement that delayed market entry of generic Flomax. That delayed generic entry then allegedly caused federal and state government payors, including Medicare and Medicaid, to overpay for Flomax because cheaper, generic versions of the drug were not on the market. The complaint further alleged that Medicare and Medicaid also overpaid for generic Flomax because the agreements prevented Astellas from entering the market with its own, competing authorized generic drug. As a result, according to the complaint, the government overpaid on thousands of claims for name-brand *and* generic Flomax.

A firm with extensive experience in *qui tam* suits, Hagens Berman Sobel Shapiro, represented the plaintiff in *Radice*. Such firms are not easily deterred by initial losses when pursuing a novel legal theory, and one can expect the lawyers in *Radice* to refine their approach and continue to file *qui tam* actions targeting reverse-payment agreements. However, this kind of lawsuit will face many challenges.

First, plaintiffs will need to plead their claims with the specificity that is required under Federal Rule of Civil Procedure 9(b), or face dismissal. This requirement can be challenging for many *qui tam* plaintiffs. Indeed, the *Radice* case itself may have been voluntarily dismissed because of the complaint’s lack of a coherent theory of liability and its failure to provide sufficient detail to comply with Rule 9(b).

Peter B. Hutt II is a Partner, and **Catherine E. Creely** is Counsel, with Akin Gump Strauss Hauer & Feld LLP in its Washington, DC office.

Second, in order to establish that claims paid by Medicare and Medicaid were “false” under the FCA, plaintiffs will have to prove that a reverse-payment agreement was illegal. In *FTC v. Actavis*, the Supreme Court held that reverse payments are not *per se* illegal, and it instructed the lower courts to evaluate the anticompetitive effects of reverse-payment agreements on a case-by-case basis. As a result, a plaintiff would need to prove “falsity” by conducting a mini-trial on the anticompetitive effect of a particular reverse-payment agreement. A plaintiff would need to present evidence of multiple factors, including the adverse effects on competition, the market power of the name-brand manufacturer, and the existence of large, unjustified payments. These are technical and complex factors requiring extensive expert testimony.

Third, many claims that might be asserted by *qui tam* plaintiffs would be subject to dismissal under the FCA’s public disclosure bar, which prohibits the filing of lawsuits that are based on publicly disclosed information. There has been extensive prior litigation and reporting in the news media about reverse-payment agreements, which could serve as a bar to subsequent *qui tam* lawsuits over those agreements.

Notwithstanding these obstacles, the *Radice* case serves as a pointed reminder that enterprising plaintiffs’ counsel will continue pursuing *qui tam* suits that stretch the False Claims Act far beyond its original purpose. Rather than using the statute to combat actual fraud in federal programs, plaintiffs’ counsel view the FCA as a “super-enforcement tool” that rewards them richly for purporting to recover funds on behalf of the government. In cases patterned on *Radice*, plaintiffs are not undertaking law enforcement in the absence of government prosecutorial mechanisms. To the contrary, the antitrust laws already provide federal officials with ample authority to pursue allegedly anticompetitive reverse-payment agreements and recover damages if those agreements harm the public.