# CLIENT ALERT

## Third Circuit Rules That FTC v. Actavis Covers More Than Cash

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On June, 26, 2015, the U.S. Court of Appeals for the Third Circuit held that non-cash "payments" made by a patentee drug manufacturer to a prospective generic drug manufacturer in exchange for delayed entry of a generic drug is an actionable "reverse payment" and may be subject to antitrust scrutiny under the Supreme Court's decision in *FTC v. Actavis*, 133 S. Ct. 2223 (2013). *King Drug Company of Florence, Inc. v. Smithkline Beecham Corp., et al.*, Case No. 14-1243 (*Smithkline*).

The Third Circuit's ruling overturned the district court's dismissal of a class action lawsuit against Smithkline Beecham d/b/a GlaxoSmithKline (GSK), Teva Pharmaceutical Industries Ltd., and Teva Pharmaceuticals USA, Inc. (collectively, "Teva"), alleging antitrust violations based on a pharmaceutical settlement agreement in which no cash payments changed hands. The ruling seems to open the door for the possibility that agreements that include other forms of non-cash consideration may be subject to antitrust scrutiny under *Actavis*, if the agreements include "an unexplained large transfer of value from the patent holder to the alleged infringer."

Parties to pharmaceutical settlement agreements should be aware that cash payments under so-called "reverse payment" agreements are not the only payments subject to antitrust scrutiny under *Actavis*. The Third Circuit's opinion represents yet another attempt by a court to interpret and apply the framework set forth by the Supreme Court in *Actavis*.

Direct purchasers of Lamictal, a brand-named drug used to treat epilepsy and bipolar disorder, brought a suit alleging that an agreement between GSK and Teva to delay entry of generic lamotrigine (the active ingredient in Lamictal) violated Sections 1 and 2 of the Sherman Act (15 U.S.C. §§ 1 & 2). In the agreement, Teva agreed to drop litigation challenging GSK's patent on lamotrigine (U.S. Patent No. 4,602,017), and to delay launch of its generic version of Lamictal tablets until the day before the expiration of the patent,[1] on the condition that GSK delay the launch of its own authorized generic (AG) version of Lamictal until after Teva's statutorily granted 180-day market exclusivity period under the Hatch-Waxman Act,[2] the "no-AG" component of the settlement agreement.

The district court initially dismissed the plaintiffs' claims, ruling that the GSK-Teva agreement was outside of the reach of *Actavis*—and antitrust scrutiny—because it did not involve an exchange of money. The Third Circuit, however, vacated and remanded the district court's decision.

The Third Circuit held that *Actavis* applied to a no-AG agreement "when [the agreement] represents an unexplained large transfer of value from the patent holder to the alleged infringer." For example, the court explained that the 180-day exclusivity period could be worth "several hundred million dollars" and "may be where the bulk of the first-filer's profits lie." The court also noted that the "brand's commitment not to produce an authorized generic" during the 180-day market exclusivity period would result in a generic monopoly, with higher generic prices. And such a transfer of value gives rise to an inference that the agreement was made in order to eliminate the risk of competition.

The Third Circuit held that ultimately, the no-AG agreement led to the same problems as those at issue in *Actavis*: a patentee unlawfully leverages its patent power to eliminate competition. Accordingly, the *Smithkline* Court found that "[t]he anticompetitive consequences of this pay-for-delay may be as harmful as those resulting from reverse payments of cash." In so holding, the Third Circuit rejected the defendants' arguments that the no-AG agreement operated as an "'exclusive license' exempt from antitrust scrutiny."[3] The fact that GSK's patent had been invalidated at trial may well have influenced the decision here. The goal of the Hatch-Waxman Act was to provide incentives for generic companies to bring suit to invalidate brand patents, thereby bringing competition to the marketplace and reducing the costs to consumers. The fact that Teva had successfully invalidated the patent, but the parties nevertheless made an agreement that reduced competition, may have been viewed as frustrating the purpose of the Hatch-Waxman Act. It also made it difficult to argue that the settlement was about something other than eliminating the risk of competition.

The Third Circuit's decision is notable for several reasons. First, it expands the reach of *Actavis* and makes clear that non-cash consideration may result in antitrust scrutiny. Second, it marks the first time a federal appeals court has analyzed the *Actavis* decision, likely providing persuasive authority in currently pending lawsuits. Finally, the Third Circuit's decision is in line with the California Supreme Court's recent ruling in *In re Cipro Cases I & II*, Case No. S198616, 2015 WL 2125291 (Cal. May 7, 2015), which made clear that non-cash payments could give rise to the same antitrust scrutiny under California law that applies to reverse settlement agreements involving cash payments. *Id.* at Slip Op. 32-33 n.11 ("[C]ourts ... should not let creative variations in the form of consideration result in the purchase of freedom from competition escaping detection."). See our previous Client Alert: "CA Supreme Court Fashions 'Structural' Rule of Reason Analysis for Pay-For Delay Settlement Agreements." Other courts may take notice and rule in a similar fashion.

The ultimate effect of the *Smithkline* decision on reverse payment litigation remains to be seen, but in the short term, in order to minimize antitrust exposure, parties should be aware that any unexplainable transfers of value, whether cash or non-cash, coupled with delays to entry into the relevant market may be subject to antitrust scrutiny.

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[1] The entry date, which was for generic lamotrigine tablets, was predicated on GSK receiving a "pediatric exclusivity" extension. The entry date for the less popular generic lamotrigine chewables was June 1, 2005.

[2] Teva was the first filer to submit an "Abbreviated New Drug Application" under the Hatch-Waxman Act. As a result, GSK filed an infringement suit against Teva, but Teva prevailed in a bench trial in which the judge held that the invention of lamotrigine was invalid. As a result, Teva was granted a 180-day exclusivity period during which time no other generic manufacturer could enter the market. Importantly, the 180-day market exclusivity period does not prevent the brand-patentee from marketing its own "authorized generic" version of the drug, so absent the agreement, GSK would have been free to market its own generic version of Lamictal.

[3] The *Smithkline* court also separately found that it was error for the district court to itself engage (in the alternative) in the rule of reason analysis, which is properly a determination for the trier of fact.

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