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First Federal Appellate Court Holds a NonCash Reverse Payment Subject to Antitrust Scrutiny: Is the Third Circuit's Decision in King Drug a Turning Point?

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Recently, the Third Circuit issued the first federal appellate decision interpreting the Supreme Court's landmark decision in *FTC v. Actavis, Inc.*[1], potentially greatly expanding the scope of settling parties in reverse payment cases.The Third Circuit held in *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.* that a pioneer drug manufacturer's agreement not to market an authorized generic product during a generic challenger's 180-day exclusivity period to settle litigation under the Hatch-Waxman Act is subject to rule of reason scrutiny under the Sherman Act.[2] This is significant, because post-*Actavis*, the district courts have reached conflicting determinations as to whether noncash compensation, such as the "no-AG" deal in *King Drug*, constitutes an illegal reverse payment.[3] So-called "reverse payments" occur when a pioneer drug manufacturer pays the alleged generic infringer to drop its patent challenge and delay its market entry. *King Drug* is the first word from the federal appellate judiciary and thus may serve to greatly expand the scope of liability for settling parties if courts outside the Third Circuit follow its lead.

The dispute in *King Drug* centers around Teva Pharmaceutical's ("Teva") challenge to the validity of GlaxoSmithKline's ("GSK") patents covering the active ingredient of its drug Lamictal, a medicine used to treat epilepsy, and Teva's plans to market its own generic version of Lamictal. To increase generic pharmaceutical competition, the Hatch-Waxman Act[4] (the "Act") provides generic manufacturers with unique incentives to challenge the patent protection accorded to pioneer drugs. Instead of requiring detailed studies demonstrating efficacy and safety, the Act permits generic challengers to "piggy-back" on the pioneer drug manufacturer's studies using an abbreviated new drug application (an "ANDA"), so long as the generic challenger demonstrates bioequivalence.[5] And, most importantly, the FDA grants the first successful ANDA filer a 180-day exclusivity period during which time other generic challengers are not permitted to market the drug.[6] The 180-day exclusivity period can be extraordinarily valuable to the generic challenger. However, in order to market a generic drug, a generic challenger must first overcome the pioneer manufacturer's patent monopoly.

The most common form of Hatch-Waxman challenge is known as a Paragraph IV certification. Under Paragraph IV, the generic manufacturer certifies that the pioneer's patents are "invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug."[7] In almost all cases, a Paragraph IV certification provokes patent infringement litigation by the pioneer manufacturer because certification is an act of constructive infringement and the initiation of litigation triggers a 30-month stay of the FDA's consideration of the ANDA application.[8]

In *King Drug*, Teva filed the first ANDA challenging GSK's patent on Lamictal and certified that its generic product did not infringe the patent and/or the patent was invalid under Paragraph IV.[9] In early 2005, the district court adjudicating the claims of noninfringement and invalidity ruled that the patent's primary claim was invalid.[10] Before the court could rule on the patent's remaining claims, GSK and Teva entered a settlement agreement wherein Teva was permitted to market generic Lamictal beginning in July 2008 and GSK agreed not to market an authorized generic Lamictal product during Teva's 180-day exclusivity period.[11] While Teva was entitled to the absence of generic competition by other challengers during its 180-day exclusivity period without the settlement agreement, GSK still would have been permitted to market its own generic product (an "authorized generic") under the Act.

In February 2012, a group of direct Lamictal purchasers sued GSK and Teva in the District of New Jersey, claiming that the agreement constituted an illegal reverse payment that violated Sections 1 and 2 of the Sherman Act.[12] While the case was pending, the Supreme Court issued its decision in *Actavis*. Rejecting the prevailing "scope of the patent test," which held that reverse payment settlements were immune from antitrust scrutiny so long as generic market entry occurred prior to the expiration of the challenged patent, *Actavis* held that reverse payment settlements are subject to rule of reason analysis. Notwithstanding, because *Actavis* only analyzed a cash reverse payment, the district court in *Lamictal* refused to extend its reasoning to the no-AG deal and dismissed the direct purchasers' complaint.[13]

On appeal, the Third Circuit held that noncash reverse payments are subject to antitrust scrutiny.[14] Reviewing the five factors the Supreme Court identified in *Actavis* that favor subjecting cash reverse payments to antitrust scrutiny, the court found that each applied equally to noncash reverse payments: (1) the potential for genuine adverse effects on competition; (2) the likelihood that anticompetitive consequences will at least sometimes prove unjustified; (3) the fact that the patentee likely possesses the power to cause anticompetitive harm; (4) that the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness; and (5) the fact that the parties may be able to find other ways to settle the infringement litigation.[15]

The Third Circuit explained that "no-AG agreements are likely to present the same types of [anticompetitive] problems as reverse payments of cash."[16] "[A] brand's commitment not to produce an authorized generic means that it must give up the valuable right to capture profits in the new two-tiered market. The no-AG agreement transfers the profits the patentee would have made from its authorized generic to the settling generic – plus potentially more, in the form of higher prices, because there will now be a generic monopoly instead of a generic duopoly."[17] According to the court, if the drug pioneer induces the generic to abandon the patent fight using such valuable noncash consideration, "the chance of dissolving a questionable patent vanishes (and along with it, the prospects of a more competitive market)."[18] Because the key inquiry under *Actavis* is whether the "'the payment's objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market,'"[19] the court reasoned that the form of reverse payment consideration is not determinative.

While the number of courts that follow *King Drug* outside of the Third Circuit remains to be seen, it is clear that the decision exposes pharmaceutical manufacturers to significant liability from private antitrust plaintiffs claiming that the parties entered into a noncash reverse payment settlement. Private litigants often have the ability to forum-shop and numerous pharmaceutical manufacturers have facilities in the Third Circuit. We expect an uptick in antitrust case filings in the Third Circuit challenging reverse payment settlements. Even the FTC, which has objected consistently to noncash reverse payment settlements well prior to the decision in *King Drug*, may opt for the Third Circuit as a friendly venue for its own enforcement proceedings.

[1] 133 S. Ct. 2223 (2013).

[2] *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 2015 U.S. App. LEXIS 10859 (3d Cir. Jun. 26, 2015).

[3] *See, e.g.*, *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735 (E.D. Pa. 2014); *In re Effexor XR Antitrust Litig.*, 2014 U.S. Dist. LEXIS 142206 (D.N.J. Oct. 6, 2014); *In re Loestrin 24 FE Antitrust Litig.*, 2014 U.S. Dist. LEXIS 123322 (D.R.I. Sep. 4, 2014); *In re Nexium (Esomeprazole) Antitrust Litig.*, 986 F. Supp. 2d 367 (D. Mass. 2013).

[4] 21 U.S.C. § 355, *et seq*.

[5] 21 U.S.C. § 355(j).

[6] 21 U.S.C. § 355(j)(5)(B)(iii), (iv).

[7] 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

[8] 35 U.S.C. § 271(e)(2)(A); 21 U.S.C. § 355(j)(5)(B)(iii).

[9] *King Drug*, 2015 U.S. App. LEXIS 10859, at *14.

[10] *Id.*

[11] *Id.*at *14-15.

[12] *Id.*at *17.

[13] *In re Lamictal Direct Purchaser Antitrust Litig.*, 2014 U.S. Dist. LEXIS 9257, at *24-25 (D.N.J. Jan. 24, 2014).

[14] *King Drug*, 2015 U.S. App. LEXIS 10859, at *32 ("We do not believe *Actavis's* holding can be limited to reverse payments of cash.").

[15] *Id.*at *29-32.

[16] *Id.*at *34.

[17] *Id.*at *36.

[18] *Id.*

[19] *Id.*at *21 (*quoting Actavis*,133 S. Ct. at 2236).

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- **John R. Ingrassia**
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