Third Circuit Holds Reverse Payment Settlements Subject to “Quick-Look” Antitrust Scrutiny

Court Rejects “Scope of the Patent” Test Used In Three Other Circuits, Preparing Way for Supreme Court Review

SUMMARY

In In re: K-Dur Antitrust Litig., No. 10-2078 (3d Cir. July 16, 2012), the United States Court of Appeals for the Third Circuit considered patent litigation settlement agreements between patent owner Schering and two generic manufacturers. Those settlements involved substantial payments by Schering to the generics in exchange for, inter alia, delayed entry of generic products that would compete with Schering’s K-Dur® sustained release potassium. Such agreements, which have been associated with Hatch-Waxman patent litigation, are known as “reverse-payment” or “pay-for-delay” settlements. The Second, Eleventh and Federal Circuits have held that reverse-payment settlements are not prohibited by the antitrust laws, so long as competition is restrained only within the scope of the patent’s coverage and there is no evidence that the patent was procured by fraud or that the enforcement suit was objectively baseless. However, reverse-payment settlements continue to be a target of FTC scrutiny and enforcement efforts.

In K-Dur, the Third Circuit rejected the “scope of the patent test” as inconsistent with Supreme Court precedent and the policies underlying the Hatch-Waxman Act. It held that reverse-payment settlements should instead be subject to “quick-look” rule of reason antitrust scrutiny. Specifically, it found that a court must treat any payment from the patent holder to the generic as prima facie evidence of an unreasonable restraint of trade. The presumption that a settlement including a reverse payment is illegal can be rebutted only by showing that the payment (1) was for a purpose other than delayed entry, or (2) offers some pro-competitive benefit. The stark conflict between the Third Circuit and other courts of appeal
means that the appropriate antitrust treatment of reverse-payment settlements in Hatch-Waxman patent litigation may now be considered by the Supreme Court.

**BACKGROUND**

On July 16, 2012, the Third Circuit Court of Appeals issued its decision in *In re: K-Dur Antitrust Litigation*. At issue were Hatch-Waxman patent litigation settlement agreements between a branded pharmaceutical company, Schering-Plough (“Schering”) and two generic manufacturers, Upsher and ESI. The patent litigation involved a Schering patent, which expired in 2006, covering the sustained release formulation of Schering’s K-Dur potassium product. Beginning in 1995, Schering sued for infringement under Hatch-Waxman because Upsher and ESI were seeking FDA approval to market generic versions of K-Dur. In the Upsher settlement, entered in 1997, Schering agreed to pay Upsher $60 million in exchange for Upsher’s agreement to delay marketing its generic K-Dur product until 2001. In the ESI settlement, entered in 1996, Schering agreed to pay ESI approximately $10 million in exchange for ESI’s agreement to delay marketing of its generic version of K-Dur until 2004.

Various private parties filed antitrust suits attacking the Upsher and ESI settlements, claiming they were overcharged for purchases of K-Dur because of the delay in generic entry as a result of the settlements. The district court certified a direct-purchaser class but granted summary judgment to the defendants, holding that the settlements could not violate the antitrust laws because they did not restrain competition beyond the scope of Schering’s patent. On appeal, the Third Circuit affirmed certification of the class, but reversed the grant of summary judgment to defendants.

**THE THIRD CIRCUIT’S DECISION**

Prior to *K-Dur*, the Second, Eleventh and Federal Circuits had applied a “scope of the patent” test to reject antitrust challenges to reverse-payment settlement agreements. These courts concluded that the Hatch-Waxman Act encourages such settlements because, unlike traditional infringement suits where the patent holder can negotiate by agreeing to forego the infringement damages, under Hatch-Waxman the litigation generally takes place before any damages accrue. Under the scope of the patent test, “there is no injury cognizable under existing antitrust law” from a reverse payment settlement, “as long as

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1 In March 2001, the FTC filed a complaint alleging that the settlements constituted an unreasonable restraint of trade. The administrative law judge held that neither agreement violated the antitrust laws. The FTC reversed, finding, *inter alia*, a “direct nexus” between Schering’s payment and Upsher’s agreement to delay generic entry that “unreasonably restrained commerce.” The Eleventh Circuit reversed in *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005). The FTC has made reverse-payment settlements “a top enforcement priority in recent years.” *K-Dur*, slip. op. at 16.

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competition is restrained only within the scope of the patent.” Tamoxifen, 466 F.3d at 213. A settlement generally passes the test so long as, on its face, the patent could exclude the products covered by the settlement, and the settlement does not create a bottleneck excluding other generics. Id. The test does not apply where the patent was procured by fraud or the enforcement suit was objectively baseless. Id.

In K-Dur, the Third Circuit found “unpersuasive” the decisions applying the scope of the patent test. K-Dur, slip. op. at 22 n.8. “As a practical matter,” it noted, “the scope of the patent test does not subject reverse payment agreements to any antitrust scrutiny.” Id. at 26. Thus, it held, the test “improperly restricts the application of antitrust law and is contrary to the policies underlying the Hatch-Waxman Act and a long line of Supreme Court precedent on patent litigation and competition.” Id. at 27.

The Third Circuit found that the test improperly relied on a presumption that the patent is both valid and infringed. Because “many patents issued by the PTO are later found to be invalid or not infringed,” the court concluded that “reverse payments enable the holder of a patent that the holder knows is weak to buy its way out of both competition with the [generic] and possible invalidation of its patent.” Id. at 27-28.

The court also found that decisions applying the scope of the patent test had “overlooked” Supreme Court cases such as Edward Katzinger Co. v. Chicago Metallic Mfg. Co., 329 U.S. 324 (1947), which held that a patent licensor could not be estopped from challenging the validity of a patent under a licensing agreement that also contained a price-fixing term. This decision was applicable to the K-Dur settlements, the Third Circuit held, because “reverse payments permit the sharing of monopoly rents between would-be competitors without any assurance that the underlying patent is valid.” K-Dur, slip. op. at 29-30.

Finally, the Third Circuit found the scope of the patent test inconsistent with policies underlying the Hatch-Waxman Act because “in passing the Hatch-Waxman Act, Congress drew a careful line between patent protection and the need to provide incentives for competition in the pharmaceutical industry.” Id. at 31. This line, the court held, “strongly supports the application of rule of reason scrutiny of reverse-payment settlements” so that a patent holder cannot “pay its potential generic competitors not to compete.” Id.

Reversing the district court’s grant of summary judgment to defendants, the Third Circuit held that, instead of the scope of the patent test, reverse-payment settlements should be subject to “quick-look” antitrust scrutiny under the rule of reason. The court set forth the nature of that scrutiny as follows:

[T]he finder of fact must treat any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as prima facie evidence of an unreasonable restraint of trade, which could be rebutted by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit.

3 The Sixth Circuit and D.C. Circuit have rejected reverse-payment settlement agreements that created bottlenecks to entry by other generics. See In re Cardizem CD Antitrust Litig., 332 F.3d 896 (6th Cir. 2003); Andrx Pharms., Inc. v. Bioval Corp. Int’l, 256 F.3d 799 (D.C. Cir. 2001).
The court noted that a patent holder may rebut the plaintiff’s prima facie case by “arguing that there is in fact no reverse payment because any money that changed hands was for something other than a delay in market entry” or because the “reverse payment increases competition.” *Id.* However, the patentee cannot avoid liability by claiming that it would have prevailed in the patent litigation. The Third Circuit held that, where a settlement includes a reverse payment, “there is no need to consider the merits of the underlying patent suit,” because in these circumstances “it is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise.” *Id.* at 33.

**IMPLICATIONS**

The *K-Dur* decision has broad implications for the settlement of Hatch-Waxman patent litigation, particularly in light of the large number of branded pharmaceutical companies located in New Jersey, a Third Circuit jurisdiction. Careful analysis and consideration of the specific provisions of any settlement will be required going forward to avoid subjecting the settling parties to attack by the FTC or class action plaintiffs. However, given the disagreement between the Third Circuit and the other circuits that have addressed reverse-payment settlements, the Supreme Court may soon consider the issue, either in *K-Dur* or another case that presents it.

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