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Assessing Reverse Payment Settlements Under The Antitrust Laws: A Split Among Circuit Court of Appeals

The U.S. Third Circuit Court of Appeals' *K-Dur* decision,[1] addressing what standard should be applied by the courts in evaluating whether certain settlements of patent lawsuits between generic and patent-holding manufacturers are legal under the antitrust laws, may open the door for U.S. Supreme Court review of the issue.

Background

K-Dur is a sustained-release potassium chloride supplement manufactured by Schering-Plough Corporation ("Schering"). Schering holds a patent for the controlled release coating that it applies to potassium chloride crystals. Schering sued certain generic manufacturers alleging that their product infringed its patent. Schering and the generic manufacturers settled the case ("K-Dur Patent Settlement") on terms that included certain cross-licensing agreements, an agreement by the generic manufacturers not to enter the market for a fixed period of time, and a cash transfer from Schering (deemed a "reverse payment settlement").

The Circuit Split

More than a decade ago, the U.S. Federal Trade Commission ("FTC" or "Commission") filed a complaint against Schering and the generic manufacturers alleging that the K-Dur Patent Settlement violated the antitrust laws.[2] Specifically, the FTC alleged that the companies "enter[ed] into anticompetitive agreements aimed at keeping low-cost generic drugs off the market."[3]

After trial, an administrative law judge dismissed the FTC's complaint.[4] The Commissioners reversed and held the settlement to be unlawful.[5] Schering appealed

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[1] *In re: K-Dur Antitrust Litigation*, Nos. 10-2077, 10-2078, 10-2079, and 10-4571 (July 16, 2012) *available at* http://www.ca3.uscourts.gov/opinarch/102077p.pdf.
[2] Complaint, *available at* http://www.ftc.gov/os/2001/04/scheringpart3cmp.pdf.
[3] Press Release, *FTC Charges Schering-Plough over Allegedly Anticompetitive Agreements with Two Other Drug Manufacturers* (Apr. 2, 2001) *available at* http://www.ftc.gov/opa/2001/04/schering.shtm.
[4] *In the Matter of Schering-Plough Corp.*, Docket No. 9297, Initial Decision (June 27, 2002), *available at* http://www.ftc.gov/os/2002/07/scheringinitialdecisionp1.pdf.
[5] *In the Matter of Schering-Plough Corp.*, Docket No. 9297, Final Order (Dec. 8, 2003), *available at* http://www.ftc.gov/os/adjpro/d9297/031218finalorder.pdf.

the Commission's decision to the Eleventh Circuit, which set aside the decision and held that the agreements between Schering and generic manufacturers were "well within the protections of the [Schering] patent, and were therefore not illegal" — what has been referred to as the scope-of-the-patent test.[6] The Supreme Court declined to hear the case.

The Eleventh Circuit has since affirmed its ruling that the scope-of-the-patent test is the appropriate standard by which to adjudge whether such patent-generic settlements are legal under the antitrust laws.[7] The Second and Federal Circuits have also adopted the test.[8]

In a decision issued on July 16, 2012, the Third Circuit held otherwise. A class of 44 wholesalers and retailers, who purchased K-Dur directly from Schering, and nine individual plaintiffs, had sued Schering in federal district court in New Jersey alleging antitrust damages stemming from the K-Dur Patent Settlement. On a motion for summary judgment, the district court dismissed the private plaintiff lawsuit and held that the relevant patent was valid and that it gave Schering the right to exclude infringing products until the end of its term. In short, the district court applied the scope-of-the-patent test.

A panel of the Third Circuit reversed on appeal. The court took issue with the scope-of-the-patent test's "almost unrebuttable presumption of patent validity" and noted that "[m]any patents issued by the PTO are later found to be invalid or not infringed." According to the Third Circuit, "the public interest supports judicial testing and elimination of weak patents," and the judicial preference for settlement should not displace that public interest. The court required rule of reason scrutiny of "reverse payment settlements in the pharmaceutical industry" in lieu of the scope-of-the-patent test. Specifically, the court directed that "a quick look rule of reason analysis based on the economic realities of the reverse payment settlement" be undertaken, treating any payment from a patent holder to a generic patent challenger who agreed to delay entry into the market as *prima facie* evidence of an unreasonable restraint of trade.

Conclusion

We expect that a motion for a hearing before the Third Circuit *en banc* will be filed.[9] Absent a change in the Third Circuit's opinion on the issue, the split among the circuit courts of appeal will be self-evident with the Eleventh and Third Circuits applying different legal standards to the same of facts and three circuits adopting the scope-of-the-patent test and one rejecting it. The issue may be ripe for Supreme Court review.

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6 *Schering-Plough Corp. v. F.T.C.,* 402 F.3d 1056, 1076 (11th Cir. 2005).
7 *See, e.g., Federal Trade Commission v. Watson Pharmaceuticals, Inc.,* No. 10-12729 (11th Cir. April 25, 2012).
8 *See In re Tamoxifen Citrate Antitrust Litig.,* 466 F.3d 187 (2d Cir. 2006) and *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008) .
9 "A majority of the circuit judges who are in regular active service and who are not disqualified may order that an appeal or other proceeding be heard or reheard by the court of appeals en banc. An en banc hearing or rehearing is not favored and ordinarily will not be ordered unless: (1) en banc consideration is necessary to secure or maintain uniformity of the court's decisions; or (2) the proceeding involves a question of exceptional importance." Fed. R. App. P. 35.