

July 19, 2012

Third Circuit Holds that “Reverse Settlement” Payments Are *Prima Facie* Evidence of an Antitrust Violation, Widening Circuit Split

The Federal Trade Commission and class action plaintiffs achieved a significant victory this week in their ongoing effort to invalidate “reverse settlement” payments among manufacturers of branded and generic pharmaceuticals. On July 16, 2012, the U.S. Court of Appeals for the Third Circuit adopted the position, long promoted by the FTC, that reverse settlement payments constitute *prima facie* evidence of an unreasonable restraint of trade, in violation of the federal antitrust laws.¹ In so ruling, the Court rejected the recent decisions of three other federal courts of appeals, widening an existing circuit split and increasing the likelihood that this issue will reach the U.S. Supreme Court.

Background

A reverse settlement involves an agreement to settle patent infringement litigation brought by the manufacturer of a branded pharmaceutical against would-be competitors seeking federal regulatory approval to market a generic version of the same drug. Instead of the defendants (generic drug manufacturers) paying the plaintiff (the branded drug manufacturer) to settle its infringement claims, the plaintiff pays the defendants and defendants agree to delay introduction of a generic version of the drug at issue for some period of time.

The case before the Third Circuit, *In re: K-Dur Antitrust Litigation*, arose out of the settlement of two patent cases concerning K-Dur 20, a drug used to treat potassium deficiencies. In 1989, Schering-Plough received approval of a patent for K-Dur. Six years later, in 1995, Upsher-Smith Laboratories – a competing pharmaceutical manufacturer – applied to the Food & Drug Administration for approval to market a generic version of K-Dur. Schering sued Upsher in federal court in New Jersey for infringing its patent. At around the same time, another drug manufacturer, ESI Lederle, also applied for FDA approval to market generic K-Dur. Schering sued ESI in a separate case, filed in the Eastern District of Pennsylvania. By filing suit against Upsher and ESI, Schering triggered an automatic 30-month stay of the FDA’s approval process for the proposed generics.

The parties proceeded to litigate the patent infringement cases over the next two years. In June 1997, on the eve of trial and with the district court poised to rule on pending cross motions for summary judgment, Schering and Upsher agreed to settle their case. The agreement provided that Upsher would refrain from marketing generic K-Dur until September 1, 2001 – five years before Schering’s patent was set to expire. Additionally, Schering agreed to license several other Upsher products, in exchange for which it would pay Upsher \$60 million over three years, plus additional amounts dependent upon sales of the licensed products.

¹ *In re: K-Dur Antitrust Litig.*, No. 10-2079 (3d Cir. July 16, 2012).

In January 1998, following a court-supervised mediation, Schering and ESI also reached a settlement agreement. Under that agreement, ESI agreed not to market generic K-Dur until January 1, 2004 – almost three years before the expiration of Schering’s patent. Schering agreed to pay ESI \$5 million up front, plus an additional \$10 million contingent on ESI’s generic K-Dur application being approved by the FDA before July 1999 (which it was).

The FTC filed a complaint against Schering, Upsher and ESI in March 2001, and, following an administrative proceeding, concluded that the settlement agreements functioned as unreasonable restraints on trade and were therefore unlawful. Schering appealed the FTC’s ruling to the Eleventh Circuit, which reversed. The Eleventh Circuit’s decision emphasized “the public problems associated with overcrowded court dockets, and the correlative public and private benefits of settlements,” and held that because any restrictions imposed by the agreements “fell well within the protections” of Schering’s patent, they were not illegal.²

Separately, private plaintiffs filed antitrust lawsuits in various jurisdictions challenging the same agreements. Those cases were consolidated in the District of New Jersey. In February 2009, the district court ruled – consistent with the Eleventh Circuit’s decision – that the settlement agreements did not exceed the scope of Schering’s patent, and were therefore not unlawful. Accordingly, the court granted the defendants’ motions for summary judgment and dismissed the case. Plaintiffs appealed.

The Third Circuit’s Decision

The Third Circuit reversed, holding that the district court’s “scope of the patent” test was the wrong legal standard. The Court acknowledged that the Eleventh, Second and Federal Circuits had all adopted that same standard, under which a reverse settlement payment would be upheld unless it exceeded the scope of the patent at issue or had been procured by fraud.³ As the Eleventh Circuit summarized in another case, decided in April of this year: “absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.”⁴ The Third Circuit, however, rejected those courts’ holdings as “improperly restrict[ing] the application of antitrust law” and as “contrary to the policies

² *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1076 (11th Cir. 2005).

³ See *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 604 F.3d 98 (2d Cir. 2010).

⁴ *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298, 1312 (11th Cir. 2012). For a detailed discussion of *Watson*, see Aidan Synnott’s and William Michael’s article, *Federal Trade Commission Suffers Another Setback in Its Campaign to End Pharmaceutical “Reverse Settlement” Agreements*, CPI Antitrust Chronicle (June 2012), available at <https://www.competitionpolicyinternational.com/federal-trade-commission-suffers-another-setback-in-its-campaign-to-end-pharmaceutical-reverse-settlement-agreements/>.

underlying the Hatch-Waxman Act and a long line of Supreme Court precedent on patent litigation and competition.”⁵

The Third Circuit specifically took issue with what it described as “the scope of the patent test’s almost un rebuttable presumption of patent validity.”⁶ The Court emphasized that Supreme Court precedent, and the public interest, “supports judicial testing and elimination of weak patents.”⁷ But reverse settlement payments, the Court reasoned, enable the holders of weak patents to buy their way out of challenges to the validity of their patents and to avoid the threat of competition. The Court rejected the assumption (made by the Second Circuit and other courts) that “subsequent challenges by other generic manufacturers will suffice to eliminate weak patents preserved through a reverse payment to the initial challenger.”⁸ In this regard, the Court noted that “the high profit margins of a monopolist drug manufacturer may enable it to pay off a whole series of challengers rather than suffer the possible loss of its patent through litigation.”⁹

In addition, the Court observed that the central policy goal of the Hatch-Waxman Act, which established the process for manufacturers of generic pharmaceuticals to seek FDA approval, is to increase availability of low-cost generic drugs. “That goal is undermined by application of the scope of the patent test which entitles the patent holder to pay its potential generic competitors not to compete.”¹⁰

In light of these considerations, the Court rejected the scope of the patent test that the Second, Eleventh and Federal Circuits have adopted. In its place, the Third Circuit directed the district court to apply a “quick look” rule of reason analysis to determine whether reverse settlement payments run afoul of the antitrust laws. Such analysis – which the Supreme Court has applied in cases involving naked restraints on price and output but which stops short of *per se* illegality – presumes that the challenged practice has at least some anticompetitive effect and places the burden on the defendant to demonstrate a procompetitive justification.¹¹ Specifically, the Third Circuit held that district courts must treat any reverse settlement payment “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.”¹²

⁵ *K-Dur*, slip op. at 26.

⁶ *Id.* at 27.

⁷ *Id.* at 29.

⁸ *Id.* at 28.

⁹ *Id.* at 28-29.

¹⁰ *Id.* at 31.

¹¹ See, e.g., *NCAA v. Bd. of Regents of Univ. of Okla.*, 468 U.S. 85, 109-10 (1984).

¹² *K-Dur*, slip op. at 33.

Victory for the FTC, and an Increased Likelihood of Supreme Court Review

The Third Circuit's decision represents a major victory for the FTC, even though it was not a party to the case. For over a decade, the FTC has targeted reverse settlement agreements as a top enforcement priority – taking the position that such agreements, which it terms “pay for delay,” unreasonably restrain competition in violation of the antitrust laws. In an amicus brief to the Third Circuit in *K-Dur*, as elsewhere, the FTC argued that reverse settlement agreements should be treated as presumptively unlawful under the Sherman Act.¹³ To date, however, the FTC has found little support for its efforts in the federal courts or in Congress, where it has pushed for legislation banning reverse settlements.

Early on, the FTC gained support for its position in the D.C. Circuit and Sixth Circuit Courts of Appeals, which (in 2001 and 2003, respectively) condemned reverse payment agreements involving the prescription drug Cardizem CD, used to treat hypertension.¹⁴ Since then, however, the federal courts have become increasingly hostile toward the government's and private plaintiffs' claims in this area. As noted above, the Second, Eleventh and Federal Circuits have, since 2003, roundly rejected challenges to pharmaceutical reverse settlements. Likely as a result of this trend toward acceptance in the courts, the number of reverse settlement agreements has risen steadily over the past several years – a development that the FTC has described as “extremely troubling.”¹⁵

To date, the Supreme Court has refused numerous requests, by the FTC and others, to address this issue. That may change in light of the Third Circuit's decision, which both widens and brings into sharp relief an existing split among the courts of appeals. The split in authority is plainly outcome-determinative, as demonstrated by the fact that the same agreements have now been deemed legal in the Eleventh Circuit and illegal in the Third Circuit. If the Supreme

¹³ In 2009, the Department of Justice aligned itself closely with the FTC on this issue, and argued (unsuccessfully) in a brief to the Second Circuit Court of Appeals that reverse settlement agreements should be presumed to violate Section 1 of the Sherman Act. Brief for the United States in Response to the Court's Invitation, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, No. 05-2851-cv (2d Cir. July 6, 2009), available at <http://www.usdoj.gov/atr/cases/f247700/247708.pdf>. The DOJ's brief is discussed in our July 20, 2009 publication, “DOJ Antitrust Division Declares Reverse Settlements ‘Presumptively Unlawful,’” available at <http://www.paulweiss.com/files/upload/20Jul09DOJ.pdf>.

¹⁴ *In re Andrx Pharms. Inc. v. Biovail Corp. Int'l*, 256 F.3d 799 (D.C. Cir. 2001); *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003).

¹⁵ Prepared Statement of the Federal Trade Commission, Before the United States House of Representatives Committee on the Judiciary, Subcommittee on Courts and Competition Policy (July 27, 2010), available at <http://www.ftc.gov/os/testimony/100727antitrustoversight.pdf>. See also “Agreements Filed With the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2011, A Report by the Bureau of Competition,” available at <http://www.ftc.gov/os/2011/10/1110mmaagree.pdf> (finding that in 2010 and 2011, there were 59 agreements to settle patent disputes between brand and generic manufacturers that potentially involved reverse payments – a number almost equal to the total number of reverse settlement payments identified in the preceding six years (2004-2009) combined).

Court does not step in to resolve this conflict, there will be an obvious opportunity for forum-shopping by plaintiffs and persistent uncertainty for pharmaceutical companies engaged in patent litigation against generic rivals.

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This memorandum is not intended to provide legal advice, and no legal or business decision should be based on its content. Questions concerning issues addressed in this memorandum should be directed to:

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