Third Circuit Rules Reverse Payment Agreements Are Potentially Anticompetitive

On July 16, 2012, the United States Court of Appeals for the Third Circuit held that a "reverse payment" settlement agreement resolving an infringement claim brought by a pioneer drug manufacturer against a potential generic competitor could be anticompetitive and should be scrutinized under the "quick look" approach to rule of reason analysis.[1] In "reverse payment" settlements, a patent holder pays the allegedly infringing generic drug company and the generic rival delays entering the market until a specified date. This avoids determination of whether the patent is invalid or would be infringed by the generic competitor. The Third Circuit's approach to "reverse payment" agreements is in stark contrast to the one taken by the Second, Eleventh and Federal Circuits that find such agreements 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 underlying suit was a sham. The Third Circuit's opinion creates a clear circuit split and makes it more likely that this issue will be taken up by the Supreme Court.

I. Background

Schering-Plough Corporation ("Schering") developed K-Dur 20, a drug used to treat potassium deficiencies, including those that arise as a side effect of the use of diuretic products to treat high blood pressure.[2] Schering's patent concerned the controlled released coating for the drug. The patent was due to expire in September 2006. Schering obtained approval from the Food and Drug Administration ("FDA") to market the prescription drug. In 1995, Upsher-Smith Laboratories ("Upsher") developed a generic version and sought to obtain fast track approval from the FDA to market the drug.

The procedures for obtaining such fast track approval from the FDA were established by Congress in 1984 through the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act.[3] The Hatch-Waxman Act creates incentives for generic manufacturers to compete with drug pioneers. It creates an abbreviated drug approval process for generic drugs and, in turn, requires the generic manufacturer to certify that its proposed drug will not infringe the patent or that the patent is invalid. The Hatch-Waxman Act gives the first generic manufacturer to file an Abbreviated New Drug Application ("ANDA") a valuable 180 day window of exclusivity on the day it begins commercial marketing of its drug. The pioneer has the option of initiating an infringement suit based on the generic manufacturer's certification under paragraph IV that the patent is invalid or not infringed.[4] This infringement suit automatically stays the entry of the generic drug for 30 months, or a lesser period if the court finds that the patent is invalid or not infringed.

In August 1995, Upsher filed the first ANDA with respect to the drug, which led Schering to commence an infringement action. In June 1997, shortly before the summary judgment decision was due, the parties settled.[5] The settlement agreement provided that Upsher would refrain from marketing its generic drug until September 1,

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[1] *In re K-Dur Antitrust Litigation*, Nos. 10–2077, 10–2078, 10–2079, 10–4571 (3d Cir. July 16, 2012) *available at* http://www.ca3.uscourts.gov/opinarch/102077p.pdf.

[2] Slip. Op. at 7.

[3] *Id.* at 7-10 (discussing the Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984)).

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

[5] Slip. Op. at 11-12.

2001, after which it would receive a non-royalty, non-exclusive license to sell the generic drug. Upsher also granted Schering licenses for several other drugs. In exchange, Schering promised to pay Upsher $60 million dollars over three years, plus additional smaller sums depending on its sale of certain licensed drugs.

Meanwhile, in December 1995, another generic manufacturer, ESI Lederle ("ESI") filed an ANDA and paragraph IV certification leading Schering again to bring suit.[6] That action was settled following a court ordered mediation in the fall of 1996. Schering gave ESI a royalty-free license beginning in January 1, 2004. Schering also agreed to pay ESI $5 million upfront and an additional amount if the drug was approved by the FDA within a specified time period.

In March 2001, The Federal Trade Commission ("FTC") filed suit claiming both of the settlements were anticompetitive and in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45.[7] Specifically, the FTC alleged that these were "pay for delay" agreements that were intended to improperly preserve Schering's monopoly. Following a lengthy trial and appeal, the FTC ruled that the agreements were anticompetitive. Schering appealed the FTC's ruling to the Eleventh Circuit, which reversed in *Schering-Plough Corp.* v. *FTC*, 402 F.3d 1056 (11th Cir. 2005). The Eleventh Circuit ruled that the settlement agreements fell within the scope of the patent's coverage, which created a lawful monopoly and for that reason did not raise antitrust concerns. The Supreme Court denied certiorari.

Separate from the FTC's challenge, various wholesalers and retailers brought private antitrust suits challenging the settlements.[8] Those suits were consolidated in the District of New Jersey by the Judicial Panel on Multidistrict Litigation. In 2006, by consent of the parties, a Special Master was appointed to handle all motions, including motions for summary judgment. In 2009, the Special Master issued a Report and Recommendation granting defendants' motions for summary judgment. The Report followed the Eleventh Circuit's framework, which begins with the presumption that, having been issued the Patent Office, the patent was valid and that it gave Schering the right to exclude infringing products until the end of its term, including through reverse payment settlements. Under the Special Master's analysis, which tracks the analysis of the majority of the other circuits, the settlement agreements would be subject to antitrust scrutiny only if (1) the agreements exceeded the scope of the patent, or (2) the underlying patent suit was objectively baseless. The Special Master found none of the exceptions applied. The District Court adopted the Special Master's Report in its entirety.

II. Decision

The Third Circuit reversed the district court's grant of summary judgment to defendants. The appellate panel began its analysis by surveying the treatment of such reverse payment settlements by its sister circuits. It noted the D.C. Circuit and the Sixth Circuit had found such agreements were presumptively anticompetitive agreements to allocate markets, while the Second, Eleventh and Federal Circuits had applied the presumption that the patent was valid and any agreements that fell within the scope of the monopoly granted by the patent were not unlawful.[9] The Third Circuit rejected the "scope of the patent" analysis adopted by the majority of the circuits.

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[6] *Id.* at 12-13.

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

[8] *Id.* at 15-16.

[9] *Id.* at 18- 26.

In rejecting the scope of the patent analysis, the Court first focused on the test's presumption of the patent's validity. The Court concluded that this presumption "assumes away the question being litigated in the underlying patent suit," which is whether or not the patent holder would have prevailed in court. The Third Circuit expressed concern that settlements could be used to protect invalid or weak patents. The Court found that the scope of the patent test was too deferential to patent holders simply because they held a patent and did not subject settlement agreements to sufficient antitrust scrutiny. The Court observed that many patents are later found to be invalid and that the presumption of patent validity is simply a "procedural device" and not a substantive right.[10]

The Court also rejected the assumption of other circuits that other generic manufacturers would still have incentives to challenge weak patents. The Court noted that the other challengers would not benefit from the 180 day exclusivity period and that as a practical matter the pioneer could settle with multiple challengers and still prevent its margins from being eroded.[11] The Third Circuit observed that other courts had overlooked the general public policy in challenging weak or invalid patents. Relying on a 1947 Supreme Court case, *Edward Katzinger Co.* v. *Chicago Mettalic Manufacturing Co.*, 329 U.S. 394 (1947), the Court said that "the public interest supports judicial testing and elimination of weak patents".[12] Thus, the Court concluded, the scope of the patent analysis undermines the primary goal of the Hatch-Waxman Act to increase the availability of low cost prescription drugs.

Finally, the Court dismissed one of the key factors identified in the Eleventh Circuit's very recent decision in *FTC* v. *Watson Pharmaceuticals, Inc.*[13] (and reflected in earlier decisions for the Second and Federal Circuits as well) – that the scope of the patent analysis comports best with the judiciary's institutional concern about not second-guessing settlements. The "judicial preference for settlement," the Third Circuit explained, "while generally laudable, should not displace countervailing public policy objectives or, in this case, Congress's determination . . . that litigated patent challenges are necessary to protect consumers from unjustified monopolies by name brand drug manufacturers."[14]

The Third Circuit requires lower courts to adopt an abbreviated "quick look rule of reason" analysis, which would be "based on the economic realities of the reverse payment settlement rather than the labels applied by the settling parties."[15] This analysis requires the finder of fact to "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."[16] This presumption could be rebutted by showing that the payment was "(1) for a purpose other than delayed entry or (2) offers some pro-competitive benefit."[17]

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[10] *Id.* at 27.

[11] *Id.* at 28-29.

[12] *Id.*

[13] 677 F.3d 1298 (11th Cir. 2012) *available at* http://www.ca11.uscourts.gov/opinions/ops/201012729.pdf.

[14] Slip. Op. at 32.

[15] *Id.* at 32-33.

[16] *Id.* at 33.

[17] *Id.*

III. Significance of decision

After an initial decision by the Sixth Circuit finding that reverse payment settlements were illegal *per se*,[18] the trend in the Circuit Courts for almost a decade has been to uphold such settlements if they did not extend beyond the scope of the patent (and were not based on a fraud on the Patent Office or the product of sham litigation). That trend had been maintained just months ago by the Eleventh Circuit in its *Watson* decision. The decision from the Court of Appeals for the Third Circuit departs from this trend. In fashioning its test, the Third Circuit declined to require the antitrust court to make a retrospective assessment of the likely outcome of the underlying patent litigation at the time of the settlement, a proposal advanced by the FTC in *Watson* that was criticized by the Eleventh Circuit. Instead, the Third Circuit adopted a standard of presumptive illegality for reverse payment settlements, subject to limited and defined rebuttal possibilities. With the almost simultaneous decision by the Eleventh Circuit declining to review its *Watson* decision *en banc*,[19] the odds have increased substantially that one (or both) of these decisions dealing with reverse payment settlements will be addressed by the Supreme Court.

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If you have any questions about the issues addressed in this memorandum or if you would like a copy of any of the materials mentioned, please do not hesitate to call or email Elai Katz at 212.701.3039 or ekatz@cahill.com; Dean Ringel at 212.701.3521 or dringel@cahill.com; or Mihir Kshirsagar at 212.701.3316 or mkshirsagar@cahill.com.

[18] *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003).

[19] No. 10-12729 (11th Cir. July 28, 2012).