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Third Circuit Sides with FTC Position on So-Called Pay-for-Delay Settlements, Virtually Guaranteeing Supreme Court Review on The Issue

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Case: In Re: K-Dur Antitrust Litigation, No. 10-2077, 10-2078, 10-2079, 10-4571 (3d Cir. July 16, 2012).

In an important decision for the pharmaceutical sector and intellectual property law generally, the Third Circuit on July 16 adopted the long-held position of the Federal Trade Commission that so-called "pay-for-delay," or "reverse payment," settlements between brand-name and generic pharmaceutical manufacturers are presumptively unlawful under antitrust law. The holding gives the FTC its first win on this issue in almost a decade and creates a 3 to 3 split among the U.S. Court of Appeals, virtually ensuring Supreme Court review of this controversial issue.

This case is the latest in a long line of cases to address the antitrust implications of settlements of patent infringement cases brought under the Hatch-Waxman Act. The FTC has been waging a decade-long campaign against reverse settlements, but for the last seven years, the agency has lost in court, with the Eleventh, Second, and Federal Circuits all applying a permissive "scope of the patent" test under which settlements are lawful provided the entry date falls within the life of the patent at issue.

The Third Circuit decision is the first time in almost a decade that an appellate court has sided with the FTC for which these cases have been a centerpiece of its antitrust agenda in the health care field. The decision creates a razor-sharp conflict within the circuits that the Supreme Court will now almost certainly have to resolve.

Underlying Settlements Between the Brand-name and Generic Drug Companies

The Third Circuit case involved Schering-Plough's ("Schering") brand-name drug, K-Dur 20, an extended release formulation of potassium chloride used to treat potassium deficiencies. Schering held a formulation patent, U.S. Patent No. 4,863,743 ("the '743 patent"), granted on September 5, 1989 for the controlled release coating applied to the potassium chloride crystals. The '743 patent was set to expire on September 5, 2006.

In August 1995, long before the expiration of the '743 patent, Upsher-Smith Laboratories, Inc. ("Upsher") sought regulatory approval to manufacture and market a generic version of K-Dur by filing an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration. Upsher's ANDA included a so-called Paragraph IV certification, named after 21 U.S.C. § 355(j)(2)(A)(vii)(IV), which asserted that the '743 patent was either invalid or will not be infringed by Upsher's actions. In accordance with the requirements of the Hatch-Waxman Act,[1] Upsher provided Schering notice of the filing of an ANDA with a paragraph IV certification.

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Under the Act, filing suit by the patent holder within 45 days of receiving notice effects an automatic stay that prevents the FDA from approving the ANDA until the earlier of (1) 30 months from the date of receipt of the notice letter or (2) the court hearing the patent challenge finds that the patent is invalid, not infringed, or unenforceable.[2]

Within the required 45 days, Schering sued Upsher for patent infringement in the District of New Jersey. On June 18, 1997, hours before the District Court was set to rule on pending motions for summary judgment, Upsher and Schering agreed to settle the case. The settlement provided that Upsher would refrain from marketing its generic potassium chloride supplement or any similar product until September 1, 2001, at which point it would receive a non-exclusive license to make and sell a generic form of K-Dur. Additionally, Upsher granted Schering licenses to make and sell several pharmaceutical products Upsher had developed. In return, Schering promised to pay Upsher at least sixty million dollars ($60,000,000) over three years.

The FTC's Campaign

The FTC has been challenging so-called pay-for delay settlements for more than a decade. At the beginning of the last decade, it entered into several consent decrees with pharma companies under which they agreed to forgo the practice. When Schering refused to settle one of those cases, the agency pursued litigation, which ultimately ended up in the Eleventh Circuit.[3] In a 2005 ruling, the Eleventh Circuit upheld the agreements, rejecting the FTC's argument that a reverse payment should be presumed unlawful. The Supreme Court declined to hear the case.

Earlier in the decade, the D.C. Circuit and the Sixth Circuit had ruled in favor of the FTC approach.[4] However, in the years following the Eleventh Circuit decision in *Schering-Plough*, the Second and Federal Circuits sided with the pharma companies on the issue[5], and the Eleventh Circuit in April reaffirmed its earlier ruling in rejecting another FTC case, this one involving the drug Androgel.[6] On July 18th, the Eleventh Circuit rejected the agency's request for an *en banc* hearing.

The FTC has put the reverse settlements in the bull's eye of its enforcement priorities. They have been a particular focus for Chairman Jon Leibowitz, who has pushed for legislation and directed the agency's Bureau of Economics to quantify the damages from reverse payments. A 2010 analysis by the FTC found that reverse payment settlements cost consumers $3.5 billion annually in increased costs for drugs.[7]

The Third Circuit Ruling

The *K-Dur* case involves the same drug and patent settlement that was at issue in the 2005 Eleventh Circuit case. While not a direct party in the Third Circuit action, the FTC, along with the Justice Department, filed an amicus brief and the Solicitor General was granted a slot in the oral argument.

In February 2009, the district court granted summary judgment under the "scope of patent" rule articulated by the Eleventh, Second, and Federal Circuits. Under that rule, Hatch-Waxman settlements are unlawful only if (1) they exceed the scope of the patent; (2) the underlying patent infringement suit was objectively baseless; or (3) the patent was procured by fraud. The Third Circuit reversed, rejecting the use of the "scope of patent" test for these types of settlements, and endorsing the FTC's longstanding position that payments for delay are "*prima facie* evidence of an unreasonable restraint of trade."[8]

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The precise holding is that "any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market [is] *prima facie* evidence of an unreasonable restraint of trade, which could be rebutted by showing that the payment was (1) for a purpose other than delayed entry or (2) offers some pro-competitive benefit."[9] The court also agreed with the FTC that "there is no need to consider the merits of the underlying patent suit…"[10]

The court rejected the notion that the mere existence of a patent granted to the brand-name company should confer a presumption of validity for that patent, reasoning that a presumption of validity assumes away the question being litigated in the underlying patent suit, *i.e.,* the validity of the patent at issue, and improperly assumes that the patent holder would have prevailed in litigation.[11] The court noted that, "[w]hile persons challenging the validity of a patent in litigation bear the burden of defeating a presumption of validity, this presumption is intended merely as a procedural device and is not a substantive right of the patent holder."[12] The court found persuasive several studies showing that brand-name companies' patents are found invalid in a majority of ANDA litigation cases. Also, it considered its position "supported by a long line of Supreme Court cases recognizing that valid patents are a limited exception to a general rule of the free exploitation of ideas."[13]

Implications

The Third Circuit decision creates a stark split among the circuits as to the legality of these settlements. Now, both the Eleventh Circuit and Third Circuit have addressed the legality of the exact same settlement agreement between Schering and Upsher and have come to diametrically opposed conclusions. The disagreement between the circuits is likely to continue. Last Wednesday, July 18th, the Eleventh Circuit again upheld the use of the scope-of-patent test to approve the use of a reverse settlement between Solvay Pharmaceutical Inc. and a number of manufacturers of generic Androgel by refusing to re-hear en banc an appeal by the FTC challenging the settlement.[14] Only a decision by the Supreme Court can resolve this split and this matter is likely to appear before the Court soon. It is possible that the Court may postpone addressing this issue for the time being, however, as it has already granted *certiorari* to consider a separate antitrust issue brought by the FTC that relates to the limits of the state action doctrine to protect otherwise anticompetitive conduct from antitrust liability.[15]

But apart from Supreme Court possibilities, the FTC now has a friendly venue in which to pursue its challenges to reverse payments. Expect to see new lawsuits being filed in the Third Circuit. At the same time, brand-name pharmaceutical companies will presumably avoid the Third Circuit in bringing their ANDA challenges. Until recently, the majority of these cases were brought in New Jersey or Delaware, but with the In re K-Dur holding, this is likely to change.

Bear in mind, however, that even under the FTC's approach, now the law of the Third Circuit, these cases will still be extremely complex and time-consuming. While early reverse payments took the form of outright cash flows from the branded to the generic company, once the FTC began bringing cases the payments went underground, so to speak, in the form of complex commercial arrangements between the companies. The problem, in other words, is that "thing of value" is complicated.

That was true in part in the Schering case itself, and in the agency's two pending cases in federal court. In both of the pending FTC cases, the claim is that the branded company is effectively channeling a reverse payment to the generic company by entering into commercial relationships such as co-promotion agreements that are greatly tilted in favor of the generic company. The generic company, under this theory, is getting its pay for delay in the form of a commercial relationship with terms greatly in excess of fair market value. Thus, for example, in the case involving Androgel, the

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FTC is alleging that the branded company's business deals with the generic companies "make economic sense only as payments to defer generic entry." And the complaint includes a lengthy review of the facts supporting the agency's contention that the business deals are "not independent business transactions"—that is, normal arms-length transactions. For a further discussion of this issue, see Kenneth Glazer and Jenee Desmond-Harris, "Reverse Payments: Hard Cases Even Under Good Law," Antitrust (Winter 2010).[16]

The Third Circuit expressly stated that its ruling was not intended to discourage settlements of patent suits under the Hatch-Waxman Act, just those involving the alleged agreements to delay entry into the market. "We also emphasize that nothing in the rule of reason test that we adopt here limits the ability of parties to reach settlements based on a negotiated entry date for marketing of a generic drug…"[17] Pharma companies have continued to settle these cases and are free to continue to do so in the future. Also, the FTC is very unlikely to go after any settlements that fall under the $2 million safe harbor laid out in the 2003 consent decree in FTC v. Bristol-Myers Squibb Co.[18], for payments to compensate for potential future litigation costs. We would advise clients that even after the K-Dur decision, payments of that magnitude are still safe.

Finally, the FTC argues that if it is successful in eliminating the use of reverse settlements, it could lead to more of these ANDA cases being decided on the merits and increased availability of generic drugs to consumers.[19] However, the pharmaceutical industry warns that the elimination of the option to enter into reverse settlements will actually have the opposite effect, raising the costs and risks of ANDA patent litigation and discouraging generic manufactures from filing ANDAs challenging the validity of the patents for brand-name drugs.[20] Time will tell.

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[1] 25 U.S.C. § 355(j)(2)(B)(iii)(I).
[2] *Id.* § 355(j)(5)(B)(iii)(I).
[3] The case was *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005).
[4] *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). These cases have since been distinguished because the settlements at issue manipulated the 180 day exclusivity given to first-to-file ANDA applicants to prevent any other generic company from entering the market for the drugs at issue in the cases.
[5] *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187 (2d Cir. 2006); *In re Ciprofloxacin Hyrdocholoride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008).
[6] *FTC v. Watson Pharma. Inc. et al.*, 10-12729 (11th Cir. April 25, 2012).

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[7] FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 2 (2010) available at http://www.ftc.gov/os/2010/01/1000112payfordelayrpt.pdf.
[8] *In re K-Dur Antitrust Litig.* Opinion at 33.
[9] *Id.*
[10] *Id.*
[11] *See id.*
[12] *Id.* (citing *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed. Cir. 1983).
[13] *Id.* at 29.
[14] *FTC v. Watson Pharmaceuticals Inc. et al*., No. 10-12729, (11th Cir. July 18, 2012).
[15] *FTC v. Phoebe Putney Health Sys. Inc.*, 793 F.Supp.2d 1356 (M.D. Ga. 2011), *aff'd*, 663 F.3d 1369 (11th Cir. 2011), *cert. granted*, 2012 WL 985316 (U.S. June 25, 2012).
[16] http://www.americanbar.org/content/dam/aba/publishing/antitrust_source/glazer_desmond_harris_Anti_Spring2010_4.authcheckdam.pdf
[17] *In re K-Dur Antitrust Litig.* Opinion at 32. Further stating that "the only settlements subject to antitrust scrutiny are those involving a reverse payment from the name brand manufacturer to the generic challenger."
[18] C-4076, 135 F.T.C. 444, 2003 FTC LEXIS 59 (2003) (consent order).
[19] The Third Circuit noted that FTC studies show that generic companies succeed in these cases more than 50% of the time.
[20] http://www.gphaonline.org/media/press-releases/2012/gpha-appeals-court-ruling-threatens-consumer-access-safe-and-effective-gen