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Antitrust

Third Circuit Says Reverse Payments In Drug Patent Cases Presumptively Illegal

In a precedential decision issued July 16, the U.S. Court of Appeals for the Third Circuit ruled that reverse payment settlements between branded and generic drug manufacturers are presumptively unlawful restraints of trade (*In re K-Dur Antitrust Litigation*, 3d Cir., No. 10-2077, 7/16/12).

In its ruling, which some antitrust experts are already calling a ''landmark'' decision, a Third Circuit panel reversed the decision of a New Jersey federal trial court in a case involving the high blood pressure medication K-Dur 20, and found that a reverse payment from a branded drug manufacturer to a generic competitor is a per se violation of antitrust law.

The case involves pay-for-delay or reverse payment settlements, which often include payments from brand-name drug manufacturers to generic drug manufacturers in an effort to delay competition from generic drugs. Such settlements have been challenged in the courts as anti-competitive by the Federal Trade Commission and by drug payers, such as employers, benefit funds, and drugstore chains.

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—James M. Burns, Dickinson Wright PLLC

While holding that a reverse payment is ''prima facie evidence of an unreasonable restraint of trade,'' Judge Dolores Korman Sloviter of the U.S. Court of Appeals for the Third Circuit, writing for the panel, said that patent holders ''may attempt to rebut the prima facie case by demonstrating that the reverse payment offers a competitive benefit that could not have been achieved in the absence of a reverse payment.''

This possible defense ''attempts to account for the—probably rare—situations where a reverse payment increases competition,'' she said.

For example, the judge wrote, ''a modest cash payment that enables a cash-starved generic manufacturer to avoid bankruptcy and begin marketing a generic drug might have an overall effect of increasing the amount of competition in the market.''

Class Action Revived. The appeals court's decision reinstates a class action lawsuit brought by private party direct purchasers against Schering-Plough Corp. (now part of Merck & Co.), and the generic drug companies Upsher-Smith and ESI, over the companies' patent settlements over the blood pressure treatment K-Dur 20 (potassium chloride).

The appeals court said that drug companies must show that the reverse payment patent settlement has pro-competitive effects in order not to run afoul of antitrust laws.

In 2010, Judge Garrett E. Brown Jr. of the U.S. District Court for the District of New Jersey dismissed the private payers' class action, finding that the patent settlements between the branded and generic drug companies over K-Dur 20 did not violate antitrust laws.

''The decision is probably the second most important health care decision in many years, eclipsed only by the Supreme Court's recent decision on the constitutionality of PPACA [the Patient Protection and Affordable Care Act],'' James M. Burns, an antitrust attorney in the Washington office of Dickinson Wright PLLC, told BNA July 16.

And David A. Balto, an antitrust lawyer in Washington who formerly served as an FTC policy official, told BNA July 16, ''This is a landmark decision that clarifies why these pay-for-delay deals violate mainstream antitrust law.''

Win for FTC. The panel's ruling is a huge win for FTC, which filed an amicus brief to the Third Circuit in 2011 urging the appellate court to reverse the district court's K-Dur decision. FTC argued that the district court's analysis conflicted with basic antitrust principles, as well as patent law and the policies of the Hatch-Waxman Act.

In a July 16 statement, FTC Chairman Jon Leibowitz praised the ruling, saying ''the Third Circuit Court of Appeals seems to have gotten it just right: These sweetheart deals are presumptively anticompetitive.''

While the FTC consistently has taken the position that pay-for-delay settlements are presumptively anticompetitive, up to this point, the commission had little luck in convincing courts of that position. Indeed, most courts have held that the right to enter into reverse payment agreements falls within the terms of the exclusionary grant conferred by the branded drug manufacturer's patent. The U.S. Court of Appeals for the Eleventh Circuit's decision in *Schering-Plough Corp. v. FTC*, the Second Circuit's decision in *In re Tamoxifen Cit-*

rate, and the Federal Circuit's decision in *In re Ciprofloxacin Hydrochloride Antitrust Litigation* allowed such settlements unless they exceeded the scope of the patent's protection.

Prior to the Third Circuit panel's decision, only the U.S. Court of Appeals for the Sixth Circuit, in *In re Cardizem CD Antitrust Litigation*, had agreed with FTC that these deals are illegal.

Supreme Court Review Likely. FTC had been actively seeking to try to create a circuit split so that the U.S. Supreme Court would have no choice but to resolve it, and experts agreed that the Supreme Court is highly likely to be the ultimate arbiter in the case.

''The case immediately becomes 'one to watch' for the Supreme Court's next term,'' Burns said, adding that ''the ruling seems to present a circumstance where the Supreme Court is virtually compelled to accept the case and create a uniform rule on reverse payments.''

''Because the decision conflicts with decisions from the Second, Eleventh, and Federal Circuits, the U.S. Supreme Court is highly likely to review today's decision.''

—Richard Samp, Washington Legal Foundation

And Richard Samp, chief counsel for the Washington Legal Foundation, a free enterprise group that filed a brief urging affirmance of the district court's dismissal of the suit, agreed. ''Because the decision conflicts with decisions from the Second, Eleventh, and Federal Circuits, the U.S. Supreme Court is highly likely to review today's decision,'' Samp said in a July 16 statement.

Samp said the Third Circuit's decision ''fails to account for the patent law's inherently anticompetitive nature; Congress has determined that society benefits when inventors are provided monopoly profits for a finite number of years, thereby encouraging innovation.'' Indeed, Samp said, ''So long as a patent settlement does not prevent competition for a period that exceeds the life of a patent, the antitrust laws should be deemed inapplicable.''

Generic Drug Industry Response. Ralph G. Neas, president and chief executive of officer of the Generic Pharmaceutical Association in Washington, echoed Samp's point.

In a July 16 statement, Neas said, ''GPhA believes the Court's decision is inconsistent with previous federal court rulings, which have time and again found patent settlements to be a lawful and valuable tool for bringing affordable medicines to market sooner than otherwise would be possible,'' he said. And he added, ''Pro-consumer patent settlements have never prevented competition beyond a patent's expiration. Indeed, they have resulted in making lower-cost generics available months and even years before patents have expired, saving consumers billions of dollars.''

Meanwhile, Balto lauded the decision as one that ''will finally reverse the past decade of misguided decisions that have cost consumers billions in higher drug prices.''

Sitting on the panel with Sloviter were Third Circuit Judge Thomas I. Vanaskie, and Judge Lawrence F. Stengel of the U.S. District Court for the Eastern District of Pennsylvania, sitting by designation.

The case was argued before the panel on Dec. 12, 2011, by David Francis Sorensen, of Berger & Montague in Philadelphia, and Steve D. Shadowen, of Hangley Aronchick Segal Pudlin & Schiller in Harrisburg, Pa., for appellants (the companies that paid for the drug). John W. Nields Jr., of Covington & Burling in Washington, argued for appellees (drug companies).

Malcolm E. Stewart, of the Office of Solicitor General, Department of Justice, in Washington, argued on behalf of the government.

By Dana A. Elfin

The opinion is at http://op.bna.com/hl.nsf/r?Open=deln-8w9q5w.

