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Competition

Supreme Court Agrees to Review Decision On 'Pay-for-Delay' Deals; Should Resolve Split

In a much-anticipated move, the U.S. Supreme Court Dec. 7 agreed to review a federal appeals court decision that upheld against a Federal Trade Commission challenge a so-called reverse payment deal that resolved a drug patent dispute (*FTC v. Watson Pharmaceuticals*, U.S., No. 12-416, *review granted* 12/7/12).

The Supreme Court—in an action in which Justice Samuel A. Alito Jr. did not participate—granted a petition in which the FTC asked the high court to review a federal appeals court decision that found a branded drugmaker did not violate federal antitrust laws in paying two generic drugmakers to delay introduction of their generic version of AndroGel as part of a patent litigation settlement (21 HLR 1423, 10/11/12).

Practitioners who spoke to BNA said that the case has important implications for pharmaceutical companies and consumers—including federal health care programs, health insurers, employers, and other payers—because the reverse payment practice costs billions of dollars annually. Also, ''the underlying antitrust policy is a critical focal point for the FTC, for which the issue has been a *bête noire*,'' Stephanie W. Kanwit, a health care attorney and consultant based in Washington, said.

The decision to take up the case means that the Supreme Court finally will have an opportunity to decide whether agreements between branded and generic drugmakers that call for payments and delayed generic drug entry as part of a patent litigation settlement should be considered presumptively illegal. The high court's ruling should resolve a circuit split and a long-standing dispute over whether such ''pay-for-delay'' deals are presumptively anti-competitive.

''This will be a landmark argument,'' antitrust lawyer David A. Balto, who formerly served as assistant director for policy and evaluation in Federal Trade Commission's Bureau of Competition, told BNA Dec. 7. ''It's crystal clear the Supreme Court needs to step up to the plate. The courts clearly have taken inconsistent positions, and the stakes for the taxpayer and consumers couldn't be higher since these settlements cost consumers over $3.5 billion a year.''

Another attorney suggested that, depending on the breadth of the high court's ultimate decision, the court could address other allegedly anti-competitive practices such as when branded and generic drugmakers enter into supply and licensing agreements, which delay generic entry, and ''product hopping,'' in which a branded drugmaker makes minor, nontherapeutic modifications to a drug in order to extend an exclusivity period.

Subject to Per Se Rule? Reverse payment settlements generally involve payments from companies that hold patents on brand-name drugs to settle patent infringement litigation brought by or against generic drug companies. They have the effect of delaying competition among brand-name and generic manufacturers in the pharmaceuticals market, the FTC claims.

The question presented by FTC's petition is whether reverse payment agreements are lawful under federal antitrust laws—unless the underlying litigation was a sham or the patent was obtained by fraud—or whether they instead are presumptively anti-competitive.

FTC has for many years been a vocal opponent of pay-for-delay agreements and has been actively seeking Supreme Court review of the agreements. Indeed, FTC Chairman Jon Leibowitz has characterized such agreements as ''sweetheart deals'' that are presumptively anticompetitive.

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—James M. Burns, Dickinson Wright PLLC

In the underlying case, the U.S. Court of Appeals for the Eleventh Circuit found Solvay Pharmaceuticals, owner of a drug patent for AndroGel, as well as two generic competitors—Watson Pharmaceuticals Inc. and Paddock Laboratories Inc.—with which Solvay had entered reverse payment settlement agreements, were not subject to liability under federal antitrust laws.

The court relied on three prior rulings by the Eleventh Circuit that ''establish the rule that, 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.''

FTC's petition to the high court argued that the Supreme Court should embrace the approach adopted by the U.S. Court of Appeals for the Third Circuit, which found that a reverse payment from a branded drug manufacturer to a generic competitor can be a per se violation of antitrust laws (21 HLR 1045, 7/19/12).

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Branded drug company Merck & Co. (No. 12-245) and generic drug company Upsher-Smith Laboratories Inc. (No. 12-265) have sought high court review of that ruling, which involves the blood pressure drug K-Dur, but those petitions now appear to be on hold.

Balto told BNA that the high court may decide to hear only the AndroGel case because it is a cleaner case than the K-Dur case. ''The justices don't have to struggle with the facts nearly as much,'' he said. Moreover, AndroGel comes to the court as a ruling on a motion to dismiss, while there was a full trial in the K-Dur case.

In addition, Balto said, the AndroGel case may have been attractive to the high court because it is a government case. ''The FTC as a plaintiff has lots of credibility,'' he said.

How Far Will Court Go? James M. Burns, in Dickinson Wright PLLC's Washington office, agreed that the high court's decision to grant certiorari in the case is very significant. ''The Supreme Court could potentially rule in a manner that brings clarity to a host of pharmaceutical industry practices that are allegedly designed to slow generic competition,'' he told BNA.

Burns, however, said a crucial question is just how far the Supreme Court's decision might go and whether it might be broad enough to apply to other similar forms of potentially anti-competitive conduct in the pharmaceutical industry as well. ''While the FTC has been fighting the reverse payment phenomenon for a long time now, the fact of the matter is that pharmaceutical companies also engage in other practices—such as product hopping and authorized generics—that some contend are also designed to delay generic entry, which is really what the FTC is concerned about,'' Burns said.

''I expect amicus briefs filed with the court will bring these practices to the court's attention, so it will be interesting to see whether the court issues a decision that is limited to the reverse payment issue alone or one that provides guidance on how the patent and antitrust laws intersect and can be applied more broadly to other practices that also, arguably, delay generic entry and raise consumer prices,'' Burns said.

Joel M. Cohen, of Davis Polk & Wardwell LLP, New York, agreed that guidance is needed. ''I think that most practitioners and companies are hopeful that the Supreme Court will clarify the law in this area,'' Cohen said.

''It is much needed. To many companies, and to practitioners, the inconsistency and lack of clarity can be almost as frustrating as results that go against them. The spectacle of forum shopping hopefully will be unnecessary going forward,'' he said.

High Stakes Battle. Arthur N. Lerner, with Crowell & Moring LLP in Washington, said the case is important ''because the stakes are very high, the disagreement has been sharp, and the implications for consumers could be great.'' He noted that the antitrust consequences of ''pay for delay'' settlements of patent disputes between brand and generic drug manufacturers have been debated for over a decade.

''The FTC view and the view of some plaintiff-side claimants is that, where the dispute is settled with a payment to the generic company in exchange for it dropping its defense against the patent infringement action and not entering the marketplace, consumers are forced to pay brand drug prices, with the brand and generic drug makes effectively splitting the profits,'' he noted. ''The drug companies respond that, so long as the settlement does not extend the original life of the patent, these settlements should be left to the parties to work out.''

''Though for a while the drug companies had been winning most of these antitrust challenges, the recent decision by the Third Circuit has brought the issue even more to the forefront. Depending on the Supreme Court's decision, we might also see Congress revisit the issue,'' he said.

Kanwit agreed that the high court's decision in the case could have important implications for the pharmaceutical industry and consumers.

''The Commission has argued for years that these 'reverse payments' cost consumers billions, and has even asked Congress for legislation outlawing them,'' Kanwit said. ''The Third Circuit's July decision, reversing a years-long trend by a number of circuit courts blessing these arrangements, called them into question, holding that they should be presumed anticompetitive and violative of the Sherman Act unless proven otherwise.''

''Although the high court did not agree to review that decision, opting instead to review the Eleventh Circuit's ruling against the FTC and in favor of Watson Pharmaceuticals, it will nonetheless have an opportunity to resolve the conflict created by these two rulings and determine whether the Third Circuit's conclusion, that the Hatch-Waxman Act was intended to increase competition between brand-name and generic manufacturers, represents the better view,'' she said.

Kanwit also noted that the administration's 2013 fiscal year budget included prohibiting ''pay for delay'' agreements for generics and biologics in its menu of health savings, indicating that a legislative resolution to the issue might be possible. One legislative proposal introduced in 2011, sponsored by Sens. Herbert Kohl (D-Wis), chair of the Senate Aging Committee, and Chuck Grassley (R-Iowa), of the Senate Judiciary Committee, would have deemed drug patent settlements presumptively illegal, citing significant savings to both the federal government and consumers on drug prices, Kanwit observed.

Strength of Patent. Robert F. Leibenluft, with Hogan Lovells, Washington, said the case ''may well be a close decision for the justices,'' who must decide whether to accept the premise—adopted by three circuit—that absent sham litigation or fraud, a settlement agreement within the scope of the patent is valid. ''The alternative view, espoused by the FTC and adopted by the Third Circuit, is that a reverse payment is prima facie illegal since it is presumed to have been made in return for an agreement by the generic for a later entry date,'' he said.

One thing to watch for, Leibenluft said, is to what extent, if at all, the Court requires consideration of the strength of the underlying patent. Prior decisions generally have shied away from making such an inquiry, out of concern that it could require a patent ''mini-trial'' in the context of the antitrust litigation. ''But ultimately whether any agreement actually could have an anticompetitive effect is related to whether the generic otherwise would have been barred by the patent,'' he said.

Moreover, Leibenluft cautioned that a decision in favor of the FTC will not necessarily provide private plaintiffs with a clear road to recovery in reverse settlement cases. ''Plaintiffs will still be required to show

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damages—that the agreement caused delay and that the generic would have entered the market but for the anti-competitive settlement—and that may be very difficult to prove," he said.

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