

Supreme Court Passes On Schering-Plough Appeal

Monday, June 26, 2006 --- In a move that could open the floodgates for controversial patent settlement deals between brand-name and generic drug companies, the nation's highest court Monday turned down the U.S. Federal Trade Commission's appeal in the closely watched Schering-Plough case.

The U.S. Supreme Court's rejection came after months of debate between the FTC and the U.S. Solicitor General's office as to whether the justices should hear the case amid the FTC's wider probe into anti-competitive practices in the prescription drug industry.

Christopher M. Curran, partner at White & Case LLP, the firm representing co-defendant Upsher-Smith during the trial and appeal process, said his client is "pleased to put this case behind it."

"Upsher-Smith is gratified to be vindicated," said Curran. "It has felt all along that its settlement with Schering-Plough was reasonable, legal and pro-consumer. The FTC was misguided in challenging the settlement, as the court system has shown. Indeed, it was the FTC's own administrative law judge who first declared that there was nothing wrong with the settlement."

Schering-Plough stood accused of violating unfair competition laws after it agreed to pay Upsher-Smith Laboratories American Home Products (now Wyeth) millions of dollars in royalties if it did not market a generic version of Schering's K-Dur heart medication until the patents expired in 2004.

"Settlements of this kind raise serious antitrust concerns if the payments from the patentee are in fact pay-offs to potential generic competitors to induce them to abandon patent challenges and delay their entry," the FTC said in its court filing.

The FTC took action against the company in a move to bar similar conduct in the future, issuing an order which broadly prohibits litigation settlements under which a generic manufacturer "receives anything of value" and agrees to defer its own research and development, production or sales activities.

Schering consistently maintained that the patent litigation settlements complied with the law and benefited consumers by allowing generic products to enter the market two to five years before the expiration of the relevant patent.

The company appealed the decision in the U.S. Court of Appeals for the Eleventh Circuit. A three-judge panel vacated the FTC's 2003 ruling that the companies had entered into illegal agreements to keep generic versions of

K-Dur off the market.

In setting aside the FTC's ruling, the appeals court also vacated the agency's cease-and-desist order.

"The Commission's inflexible (...) theory neglects to understand that '[r]everse payments are a natural by-product of the Hatch-Waxman process,'" the appeals court wrote in its opinion. "A prohibition on reverse-payment settlements would 'reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive.'"

The appellate decision prompted the FTC to file the petition with the Supreme Court.

"Review of this error is urgently needed because the ruling below could seriously impede the Commission's law enforcement efforts on behalf of consumers nationwide," the petition says. "In light of the large number of leading drugs that are the subject of patent challenges, the economic stakes for the American consumer in this issue are staggering."

But the Solicitor General recommended against greenlighting the Schering-Plough case, saying it "does not present an appropriate opportunity for this court to determine the proper standards for distinguishing legitimate patent settlements."

Although the dismissal marks a moment of defeat for the FTC, the move is not likely to deter the agency from going after similar cases in the future, says Steven H. Sklar of Leydig, Voit & Mayer, Ltd.

"The FTC is not going to put its tail between its legs," he says. "Some people might think this gives free reign to companies to settle these patent cases however they want, but every case is different. The FTC is still there, and it's still going full steam ahead to make parties more cautious of these types of deals."

Sklar points to the recent late-reached deal between Sanofi-Aventis, its U.S. partner Bristol-Meyers Squibb and Canadian generic rival Apotex, which over the weekend altered an earlier settlement deal over Plavix that had raised the FTC's concern for similar issues.

"That may be a sign that companies are paying attention to the FTC's concerns," he says. "There's too much money at risk for companies not to take note."

While the rejection may have sparked disappointment among those who were closely following the case, the issue of authorized generics is no less controversial, says Richard W. Cohen, shareholder and head of the antitrust practice at Lowey, Dannenberg, Bemporad & Selinger, P.C.

“The motives and consequences of these deals are obvious,” says Cohen. “They hurt consumers and health insurers. But what was extraordinary about the FTC’s appeal in this case is that the DOJ opposed its application, marking a rare split between the agencies.”

While Cohen says the Supreme Court’s denial is “a non-event,” the bigger news may be on the Plavix front.

“This may signal a prevailing sentiment that companies will simply adjust their deals by a few months until the FTC agrees to accept,” says Cohen. “In the process of compromise, they may start to feel immunized by taking that sort of action.”

Given the Solicitor General’s decision to inform the Court not to take the case, the ruling is unsurprising, says Michael Halfenger, partner at Foley & Lardner.

“What it means going forward is that there remains a great deal of uncertainty as to which antitrust principles will apply in settlements in which there are payments going from the brand-name companies to the generic companies, and whether those deals will be lawful,” says Halfenger. “Some recent case law, including the case below, suggests that such settlements are perfectly lawful and indeed encouraged.”

On other hand, adds Halfenger, the FTC isn’t likely to slow its attempts to examine the issue of authorized generics anytime soon.

“The FTC has been quite clear that it continues to see problems with such deals,” he says. “The agency is likely to continue to pursue its attempts to litigate against those settlements it thinks may harm consumers.”

The Court’s decision does not mean that the FTC’s opposition against authorized generic deals is now dead in the water, says Doug Olson at Paul, Hastings, Janofsky & Walker.

“It simply means that the FTC methodology incorrectly set the bar too high for the settlement of patent infringement suits between innovators and generic drug manufacturers,” says Olson. “But despite the setback, the FTC will continue to scrutinize these kinds of deals.”

According to Olsen, the Court’s refusal to take the case suggests that it felt that the legal analysis by the Eleventh Circuit was correct, meaning that future settlements between generic drug manufacturers and innovators will most likely be evaluated using the lower court’s approach.

“The Eleventh Circuit put great weight on the value of the patent and upon a careful analysis of the facts and credibility of witnesses,” says Olsen. “Subsequently, it is likely that future agreements between innovators and generic drug manufacturers will be structured to fit within the guidelines of the Eleventh Circuit decision. The FTC will likewise adjust their investigations

to pursue settlements and agreements that do not fit within those guidelines.”

According to Barry Pupkin, partner at Squire, Sanders & Dempsey LLP, the FTC will continue to press the issue.

"The FTC will continue to look for cases that it thinks are examples of illegitimate patent settlements, especially where the case is a more obvious example of an effort to improperly restrain trade rather than minimize unnecessary litigation," he says. "Even the DOJ, which opposed the FTC, said that the FTC's case raised important issues about the treatment under the antitrust laws of settlements in patent cases."

Pupkin adds that the decision not to take the case could have broader implications.

"According to the FTC, the Court of Appeals decision resulted in an increasing number of similar settlements struck between brand-name and generic drug companies," he says. "Companies had stopped entering into such deals in the late 1990s, following FTC legal challenges. The Supreme Court decision could affect the outcome of litigation involving generic versions of Lipitor, Protonix, and other top-selling brands."

Hatch-Waxman lawsuits are rarely settled, and the few exceptional settlements have raised concerns about antitrust issues.

However, courts have been moving toward a legal stamp of approval for settlements between brand-name drug makers and their generic competitors.

Last year, a federal court in New York rejected an antitrust challenge to Barr Pharmaceuticals' 1997 settlement with Bayer Corp. of patent litigation related to the antibiotic Cipro.

The High Court's rejection came as the FTC has been focusing on possible anti-competitive practices in the prescription drug industry, with a report released earlier this year finding that brand-name drug makers are increasingly collaborating with generic rivals to stall the introduction of cheaper generic drugs to the detriment of consumers.

The study analyzed the 20 agreements that were filed by generic and brand-name drug manufacturers with the FTC in fiscal year 2005.

Of those deals, 11 represented final settlements of patent litigation between a branded and generic company, five were interim agreements that occurred during patent litigation between a brand and a generic company, but that did not resolve the litigation, and four were deals between a first-filer generic company and a subsequent generic filer, according to the report.

Between 1992 and 1999, over half of the settlement agreements between brand-name companies and generic first-filers compensated generic companies while placing restrictions on their marketing rights, said the report.

But after the FTC launched an investigation into such agreements in 1999 for possible anti-competitive violations, the practice virtually disappeared, with neither the six settlements entered in 2000 and 2001 nor the 14 settlements reported in fiscal 2004 containing such provisions.

In fiscal 2005, however, the trend made a comeback, with three agreements filed including both compensation and marketing restrictions.

In a sign that the practice is not waning, at least seven such agreements have already been reached so far in fiscal 2006, according to the report.

Earlier this year, the FTC said it plans to subpoena nearly 200 pharmaceutical companies to determine whether they are stifling competition by releasing authorized generics of brand-name drugs to stave off generic challengers made by competitors.

Under the Hatch-Waxman Act, the first generic maker to challenge patents on a drug wins six months of exclusive marketing rights. After the exclusivity period expires, other challengers can seek approval for generic versions.

But under "authorized generics" agreements, a brand drug maker licenses its product to a generic firm, which launches the authorized equivalent drug during another generic firm's 180-day marketing exclusivity period for the same product. The generic firm with the authorized product then splits the sales with the brand firm.

This loophole has led to the increasingly widespread practice of authorized generics arriving on the market simultaneously with those of generic challengers, which depend on the exclusivity period for profit margins.

The FTC is concerned that a rise in the authorized generic practice is precluding generic drug companies from challenging patents in the first place, which keeps drug prices high.

As part of its probe, the FTC also announced earlier this year that it will conduct a study of short- and long-term competitive effects of authorized generics in the prescription drug marketplace.

The study will examine wholesale prices of brand-name and generic drugs, both with and without competition from authorized generics.

It will also review factors relevant to the decisions of generic firms about whether and under what circumstances to seek entry prior to patent expiration, business reasons that support authorized generic entry, and licensing agreements with authorized generics, said the FTC.

The Supreme Court case is *FTC v. Schering-Plough*, case number 05-273, in the U.S. Supreme Court. The appellate case is *Schering-Plough Corp. & al. v. Federal Trade Commission*, case no. 04-10688, U.S. Court of Appeals for

the Eleventh Circuit.

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