IP LAW360

Portfolio Media, Inc. | 648 Broadway, Suite 200 | New York, NY 10012
Phone: +1 212 537 6331 | Fax: +1 212 537 6371 | customerservice@portfoliomedia.com

Drug Cos. Nervously Eye High Court In Landmark Case

Wednesday, May 24, 2006 --- One week after the Solicitor General recommended that the Supreme Court deny certiorari in the closely watched Schering-Plough case, the nation's highest court is still contemplating whether to allow the case to go forward – but the stakes for generic companies, brand-name drug makers and consumers are only getting higher.

In an amicus curiae brief filed last week, the Solicitor General recognized the important issues concerning potential antitrust violations in patent settlements, but 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."

Schering-Plough stands 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 they did not market a generic version of Schering's K-Dur heart medication until the patents expired in 2004.

The Federal Trade Commission 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 appealed the decision in the U.S. Court of Appeals for the Eleventh Circuit, which vacated the FTC's ruling. The Appeals Court 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."

The Supreme Court has yet to say whether it will do so, although some say the high court is likely to hear the case.

"The Supreme Court has recently shown a great deal of interest in patent cases," says Aaron F. Barkoff of McDonnell Boehnen Hulbert & Berghoff LLP. "In particular, the Court appears anxious to solve a perceived problem of 'vague' patents or those of 'suspect validity' being granted."

According to Barkoff, the Supreme Court may agree with the consumer groups that allowing reverse payment settlements in Hatch-Waxman litigation discourages generic drug companies from pursuing cases to completion.

And although the Solicitor General has recommended denial of certiorari, Barkoff says that is not necessarily a sign that the Court will take heed.

“Last year the Court asked the Solicitor General for his views on the Metabolite case and the Solicitor General recommended denying certiorari, but the Court granted it anyway,” he points out.

Even if the Supreme Court follows the Solicitor General's recommendation, however, the FTC is likely to seek review in similar cases, such as In re Tamoxifen Citrate Litigation, in the future – although some, like Barkoff, say the case may be too slow in coming, as it remains in the Second Circuit on petition for rehearing en banc.

“It might never reach the Supreme Court, and if it does, it could be a while before it gets there,” he warns.

The Schering case comes against the background of the FTC’s probe into anti-competitive practices in the prescription drug industry.

Last month, a report released by the agency said 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.

If approved by the Office of Management and Budget, the 190 subpoenas—including 80 brand-name drug companies, 10 authorized generic companies, and 100 independent generic manufacturers—will be distributed in the next six months, with a final report on the investigation's findings due out late next year.

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.

--By Erin Marie Daly, erin.daly@portfoliomedia.com
--Additional reporting by Anne Urda