

3rd Circ. Keeps K-Dur Ruling In Place As FTC Fights IP Deals

By **Melissa Lipman**

Law360, New York (August 17, 2012, 5:18 PM ET) -- The Third Circuit on Friday refused to put a hold on its ruling that pay-for-delay patent settlements are presumptively anti-competitive while the defendant drugmakers ask the U.S. Supreme Court to hear the case, making it easier for the Federal Trade Commission to challenge other pharmaceutical patent settlements in the meantime.

Defendants Merck & Co. Inc. and generics maker Upsher-Smith Laboratories Inc. had urged the court to stay its ruling in the dispute over settlements relating to patents for blood pressure medication K-Dur 20 while the companies file a petition for certiorari with the Supreme Court. But the panel refused that request in a brief order, noting that the companies could still go ahead with their cert bid.

The FTC has already urged one district court within the Third Circuit to interpret the K-Dur decision to cover no-authorized-generic deals as well as traditional reverse payment settlements, and attorneys said the panel's refusal to stay the case would likely allow the agency and private plaintiffs to try to expand the decision's reach.

"As a practical consequence ... this will keep the FTC and private plaintiffs free to continue trying to use K-Dur as a platform to go after patent settlement agreements in the Third Circuit and elsewhere, whereas if the stay motion had been granted it might have made that effort a bit more difficult," Dechert LLP antitrust and life science co-chair George G. Gordon said.

After spending more than a decade campaigning against pay-for-delay settlements with little success in the courts, the July K-Dur decision marked a major victory for the FTC even though it was not a party to the case.

FTC Chairman Jon Leibowitz quickly lauded the panel for having "gotten it just right" by holding that any payment from a patent-holding pharmaceutical company to a generics maker for delaying market entry amounted to prima facie evidence of an antitrust violation.

A few weeks later, the agency moved to expand the reach of the Third Circuit's ruling to a suit challenging patent settlement over antidepressant Effexor, even though the K-Dur defendants had already indicated that they planned to ask the Supreme Court to hear the case. In a proposed amicus brief, the agency told the New Jersey district court that it didn't matter whether the "payment" in the challenged settlement was a straight cash offering or a different type of consideration, such as a promise from the brand company not to launch an authorized generic.

Attorneys said they weren't surprised to see the FTC continue its aggressive campaign against the deals, given its tenacity in the face of years of courts ruling that the settlements were generally legal as long as they did not exceed the duration or substance of the patent.

"I expect that the commission will press its agenda aggressively, and seek to have the Third Circuit's approach in K-Dur adopted both in other courts within the circuit and in courts around the country, wherever it can find the opportunity to do so," Kaye Scholer LLP antitrust practice group co-chairman Saul P. Morgenstern said.

In their motion to stay the ruling, Merck and Upsher-Smith themselves cited the "active role" that both the FTC and the U.S. Department of Justice "have played in pharmaceutical patent antitrust cases" as proof of the importance of the pay-for-delay dispute.

"The court's decision, which diverges from the most recent federal appellate decisions on the legality of reverse payments, has altered settled expectations in the industry," the defendants wrote. "As the law now stands, whether such settlements run afoul of the antitrust laws will now depend on which forum addresses the issue, leading to great uncertainty as to how to resolve ongoing patent litigation."

The companies argued that that uncertainty merited both Supreme Court review and a stay of the mandate until the justices decide whether to take up the case.

Merck spokesman Ronald Rogers declined to comment on the stay decision, but noted that the company was still free to move ahead with a cert petition. Representatives for the other parties were not immediately available for comment Friday.

Despite the circuit split — which encompasses not only the general issue of whether the settlements are legal but also an explicit dispute between the Third and Eleventh circuits over whether the exact same K-Dur patent settlements pass antitrust muster — it makes sense that the Third Circuit would refuse to put a hold on the K-Dur case, according to Baker & McKenzie LLP partner Charles H. Critchlow.

"While this decision is clearly a prime candidate for review given the split in circuits, we all know the Supreme Court marches to its own somewhat unpredictable drummer," Critchlow said. "And the Third Circuit could readily conclude, based on the firmness of its conviction that its view is correct, that the K-Dur case should proceed forward in the meantime."

Still, attorneys said that a stay would have given pay-for-delay defendants fodder to discourage other courts from applying the K-Dur panel's logic to other cases brought by the FTC or private plaintiffs.

"[The decision] would still be the law, but if the Third Circuit had stayed the mandate, it would be sending a signal ... that it's uncertain enough about what the outcome of this is going to be at the Supreme Court that it wants to put everything on hold," Gordon said.

But with the stay denied, the path is open for the FTC to try to use the K-Dur decision as widely as it can in other cases, attorneys said.

"The FTC has strongly advocated for many years that so-called pay-for-delay settlements are harmful to consumers," Critchlow said. "Having had that position vindicated in the Third Circuit, I would be very surprised if the FTC did anything other than press it vigorously in other proceedings."

Still, attorneys said that given the agency's determination to pursue pay-for-delay deals, it likely would have pressed other courts to adopt the K-Dur panel's logic with or without a stay, especially in cases like Effexor within the Third Circuit.

"This is an opportunity for the FTC to try to extrapolate from K-Dur with a district court within the Third Circuit and to try to get that district court to take the extra step of holding that K-Dur somehow reaches no-authorized-generic agreements," said Mayer Brown LLP partner Christopher J. Kelly. "It makes perfectly good sense that the FTC has an incentive to do things like this while it can."

Circuit Judges Dolores Sloviter and Thomas Vanaskie and District Judge Lawrence Stengel sat on the panel for the Third Circuit.

Hangley Aronchick Segal Pudlin & Schiller represents individual plaintiffs Rite Aid Corp. and CVS Caremark Corp. The direct purchaser plaintiff class is represented by Cohn Lifland Pearlman Herrmann & Knopf LLP, Garwin Gerstein & Fisher LLP and Berger & Montague PC, among others.

Merck and its Schering-Plough unit are represented by McCarter & English LLP, Baker Botts LLP and John W. Nields Jr. of Covington & Burling LLP.

Upsher-Smith is represented by White & Case LLP, Wolff & Samson PC and Gordon Arata McCollam Duplantis & Eagan LLC.

The case is In re: K-Dur Antitrust Litigation, case numbers 10-02077, 10-02078 and 10-02079, in the U.S. Court of Appeals for the Third Circuit.

--Editing by Elizabeth Bowen and Cara Salvatore.

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