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Senate's Pay-For-Delay Bill Would Weaken Drug Patents

Law360, New York (February 14, 2013, 1:11 PM ET) -- This month several U.S. senators introduced the Preserve Access to Affordable Generics Act. The bill would expand Federal Trade Commission powers and alter the legal test governing drug patent settlements. See Preserve Access to Affordable Generics Act, S. 214, 113th Cong., 1st Sess. (2013). This bill is the most recent iteration of such legislation, and, aside from updated data, it mirrors bills introduced in 2009 and 2011. See S. 27, 112th Cong., 1st Sess. (2011); S. 369, 111th Cong., 1st Sess. (2009).

Key Points

- There is no similar bill pending in the U.S. House.
- The act revives legislative efforts to wipe out the majority court standard by treating "reverse payment" drug patent settlements as presumptively illegal.
- The FTC would enforce the act in administrative litigation and collect penalties valued at three times the violators' gains.
- Drug manufacturers would have to notify the FTC of additional agreements relating to patent settlements.

The State of the Law in 2013

Under the prevailing "scope of the patent" test, "reverse payment" settlements are lawful as long as (1) the terms of the agreement do not exceed the patent's scope, (2) the patent holder's claim is not objectively baseless, and (3) the patent had not been procured by fraud on the U.S. Patent and Trademark Office. The Second, Eleventh and Federal Circuits have adopted this test, rejecting challenges to "reverse payment" settlements where the restrictions in the settlement agreement fell within the scope of the patent with respect to duration and the products covered.[1]

Last year, the Third Circuit in In re K-Dur Antitrust Litigation rejected the "scope of the patent" test and treated reverse payment settlements as presumptively unlawful under a quick look rule of reason analysis, which is the test the FTC has advocated for many years.[2] Since the Third Circuit's K-Dur decision, the U.S. Supreme Court has granted certiorari in an FTC case against Watson Pharmaceuticals (now known as Actavis) to consider the legality of "reverse payment" settlements. That case is set for argument on March 25, 2013.

The Bill

New Legal Standard

The Preserve Access to Affordable Generics Act would establish a presumption of illegality whenever the accused infringer receives "anything of value" and "agrees to limit or forego research, development, manufacturing, marketing, or sales of" a drug "for any period of time." The term "patent infringement claim" in the act is not limited to claims made in litigation and extends to agreements in other settings.

To avoid liability for entering into a covered agreement, the settling parties must carry the burden of "demonstrat[ing] by clear and convincing evidence that the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement." In applying this "clear and convincing" test, the act prohibits the fact finder from presuming "that entry would not have occurred until the expiration of the relevant patent or statutory exclusivity" — a presumption that the majority of courts have adopted and that is consistent with the statutory presumption of patent validity provided under the patent laws.

The act would create an entirely new mode of antitrust analysis solely for covered settlement agreements. For one, the act reverses the burden of proof. The parties to the agreement would have the burden of proving that the agreement is not anti-competitive. Under traditional antitrust analysis, a party challenging an agreement has the burden of showing that it is anti-competitive. In addition, the act raises the standard of proof. Parties to the agreement must prove that the agreement is not anti-competitive with "clear and convincing" evidence, as compared to the lower preponderance of the evidence standard that is typically applied to other agreements.

The act contains some limited carve-outs. An agreement falls outside the act if the consideration received by the generic manufacturer consists of only one or more of the following: (1) "[t]he right to market the [product] in the United States prior to the expiration of" the patent; (2) "[a] payment of reasonable litigation expenses not to exceed $7,500,000"; or (3) "[a] covenant not to sue on any claim that the [generic product] infringes a United States patent."

The FTC's Enforcement Powers

The act is enforceable not by private parties but only by the FTC in proceedings before an administrative law judge. ALJ decisions are appealable to the full commission and then subject to judicial review in federal courts of appeals. The act also gives the commission authority to issue "regulations implementing and interpreting" the act.

Penalties

A company violating the act may face a civil penalty up to three times the value received that is reasonably attributable to the violation. This penalty is payable to the United States. The generic drug manufacturer would also forfeit any 180-day marketing exclusivity.

Expanded Notice Requirement

Through the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), Congress has required drug manufacturers to notify the FTC of drug patent settlements.[3] The pending bill would expand this notice requirement to include additional agreements — "any other agreement" the parties enter into within 30 days of entering into an agreement covered by the MMA. Moreover, the pending bill requires parties to such agreements to certify that they have reported "the complete, final, and exclusive agreement between the parties."

Likely Impact

If enacted, the Preserve Access to Affordable Generics Act would have the effect of gutting patent rights in a sector where innovation is vital to human health and welfare. The statutory presumption of patent validity would effectively disappear. Enforcing rights unquestionably within the scope of a patent may subject the patent holder to FTC litigation and large civil penalties. Moreover, this act would undermine the goal of enhanced competition and lower drug prices. Generic drug manufacturers will be more reluctant to challenge patents because of the significant constraints this act would place on the settlement options currently enjoyed by the parties to these disputes.

The effect of this act would also be felt in situations where parties consider entering additional agreements, such as cross-licensing, supply or co-promotion agreements. The act would not forbid such deals, but it would increase the associated risks. Parties would have to make sure that any payments involved in such agreements are consistent with the market value of the services or products. This should be well documented and easy to establish. Otherwise, the agreements might be characterized as disguised compensation for delayed entry, increasing the likelihood of an FTC enforcement action. Notably, the act's expanded notice requirement would ensure that the FTC receives notice of any agreement that the parties enter into within 30 days of settling their claims, which increases the chance that any such deal, even one that is independent, could be subject to government scrutiny.

Ongoing Counseling in this Area

Repeated past legislative efforts to weaken drug patents in this manner have been unsuccessful. Thus, ongoing counseling in this area should not be impacted by the pendency of this Senate bill. A U.S. Supreme Court decision will likely be the next major development in this area and one that will guide future counseling for companies that have earned drug patents. A Supreme Court decision is expected by June.

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[1] See, e.g., FTC v. Watson Pharma. Inc., 677 F.3d 1298, 1309-10 (11th Cir. 2012); Ark. Carpenters H. & Welfare Fund v. Bayer AG, 604 F.3d 98, 106 (2d Cir. 2010); In re Ciprofloxacin Hydrochlo-ride Antitrust Litig., 544 F.3d 1323, 1335-36 (Fed. Cir. 2008); In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 213-15 (2d Cir. 2006); Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1066 (11th Cir. 2005).

[2] In re K-Dur Antitrust Litig., 686 F.3d 197, 218 (3d Cir. 2012).

[3] See Pub. L. No. 108-173, §§ 1111-1117, 117 Stat. 2461-2463 (21 U.S.C. § 355 note).