Portfolio Media, Inc. | 648 Broadway, Suite 200 | New York, NY 10012 | www.law360.com
Phone: +1 212 537 6331 | Fax: +1 212 537 6371 | customerservice@portfoliomedia.com

Barring Pay-For-Delay, Reverse Payment Settlements

Law360, New York (October 28, 2009) -- On Oct. 15, 2009, the Senate Judiciary Committee voted to approve the Preserve Access to Affordable Generic Drugs Act (S.369).

The proposed act is meant to put a stop to pay-for-delay and reverse cash payments that were found to be legal in the Schering Plough Corp. v. Federal Trade Commission and In re Tamoxifen Citrate Antitrust Litig. litigations, and are currently being litigated in the In re Ciprofloxacin Hydrochloride Citrate Antitrust Litig. case.

While no vote on the full bill is scheduled and final legislation is not in sight, the Senate bill is in alignment with both the U.S. Department of Justice and the Federal Trade Commission positions and is hostile toward these agreements.

Companies that are involved in Hatch-Waxman Act Paragraph IV patent litigation, and that therefore may be involved in generic drug settlements, should begin paying closer attention to this bill.

Origins of the Bill

The Hatch-Waxman Act (as amended by the Medicare Prescription Drug, Improvement and Modernization Act of 2003) permits generic drug makers to challenge brand-name drug makers by certifying that any patent covering the branded drug is either invalid or not infringed.

Paragraph IV litigation (so-called due to a section of the Hatch-Waxman Act) results when a brand-name drug manufacturer reacts to such a certification by bringing an infringement suit.

The act permits the brand-name drug manufacturer to sue immediately, before the generic has entered the market, creating what is for patent litigation an unusual

situation: there are no infringement damages, meaning that a normal settlement bargaining chip is not available to the parties.

To induce the generic to settle, brand-name drug makers may opt for a settlement agreement including a “reverse payment” (a payment to the alleged infringer) to avoid the risk of invalidating the patent at the center of the litigation.

The FTC has labeled such agreements “pay-for-delay” and has opposed such agreements for many years in the appellate courts.

In Schering Plough, the FTC took the position that a settlement of Hatch-Waxman litigation violates the FTC Act and the antitrust laws if the settlement includes a payment to a generic drug maker that is meant to delay generic product market entry.

The Court of Appeals for the Eleventh Circuit rejected this position, stating that the law favors settlements and the courts should consider the strength of the patents challenged.

A similar result followed in Tamoxifen Citrate, where the Second Circuit held that a reverse payment not exceeding the scope of the patent does not violate antitrust laws.

In Cipro, the Federal Circuit likewise held that a patent holder may enter into a reverse payment agreement unless there was fraud on the U.S. Patent and Trademark Office or the patent holder engaged in sham litigation; however, in Arkansas Carpenters Health and Welfare Fund v. Bayer AG. (one of the three cases consolidated in the Cipro litigation that is still pending), the Second Circuit Court of Appeals invited the Executive Branch to weigh in on whether reverse settlements violate federal antitrust laws.

On July 6, 2009, DOJ filed a brief in the Cipro case, asserting that while these agreements are not illegal per se, the parties involved should be required to demonstrate that competition will not be harmed. The court has yet to rule on the issues presented.

The current bill is an effort to curtail the holdings of these cases and to empower the FTC to impose something close to an outright ban.

The Senate’s Position Aligns With the DOJ and FTC

The current version of the bill represents a compromise from a previously introduced bill under the same name, which did not make it out of the Judiciary Committee in the prior session of Congress.

The bill makes pay-for-delay agreements presumptively illegal, with a narrow, burden-of-proof shifting exception that allows such settlement agreements only if drug companies can prove with clear and convincing evidence that the deal will not harm competition.

The current bill also represents the position of the new administration and the Department of Justice's Antitrust Division.

"The Obama administration supports this bill, which certainly increases its chance of passage, although its prospects are still uncertain," notes Bingham partner Hill Wellford.

Under Christine Varney, the new Assistant Attorney General for Antitrust at the Department of Justice, DOJ has aligned its position with the FTC's. This represents a change from the Bush administration's tolerance for these types of agreements.

"The DOJ's change in position is significant because courts look carefully at the Antitrust Division's amicus briefs in deciding the issues before them," explains Wellford. This combination of support represents considerable forward movement on this issue.

Impact on Industry

The Generic Pharmaceutical Association reacted to the Judiciary Committee's action by releasing a statement expressing the organization's disappointment that the bill did not include a "score" from the Congressional Budget Office.

This score would allow members voting on the legislation to have a better understanding of its economic impact.

Kathleen Jaeger, GPhA's President and CEO, emphasized that "over the years, generic manufacturers have undertaken patent challenges that have ended in pro-competitive, pro-consumer settlements, generating tens of billions of dollars in savings for the American consumers."

She notes that "this bill would result in a de facto prohibition on patent settlements — a terrible result for consumers, businesses and the health care system."

If the legislation becomes law, the outcome of litigation in the Hatch Waxman arena will become less predictable because generic and branded drug companies will have fewer avenues for resolving their disputes.

As a result, "close attention should be paid to this bill's progress in order to best advise clients in the pharmaceutical realm," notes Bingham partner Jeff Boggs.

--By Hill B. Wellford (pictured) and Matthew L. Fedowitz, Bingham McCutchen LLP

Hill Wellford is a partner with Bingham in the firm's Washington, D.C., office and former chief of staff at the Antitrust Division of the U.S. Department of Justice. Matthew Fedowitz is an associate with the firm in the Washington office.

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