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Consequences Of Banning Reverse Payments

Law360, New York (April 09, 2009) -- A bipartisan group of Senators recently introduced a bill called "The Preserve Access to Affordable Generics Act" (S. 369).

The act seeks to make illegal any settlement of patent litigation which involves payments by a brand name drug maker to a generic drug manufacturer in exchange for the generic's agreement to delay market entry.

These agreements (often referred to as "pay for delay" or "reverse payment" settlements) would be illegal without regard to the strength of the patent, which is the subject of the litigation, and without regard to whether the settlement agreement in fact has any anti-competitive effect beyond the constitutionally mandated monopoly rights inherently conferred by a valid patent.

The proponents of the act argue that "reverse payment" agreements "are anti-competitive and contrary to the interests of consumers."

They theorize that any delay of generic entry hurts consumers because it delays the price reduction that immediately and irrevocably comes with the first generic on the market.

This act is the most recent chapter in a long-running story concerning the propriety of reverse-payment settlements of Hatch-Waxman litigation.

The Federal Trade Commission has kept the issue in the forefront by repeatedly challenging a series of appellate court decisions upholding reverse-payment settlements under the antitrust law.

Notably, the U.S. Department of Justice openly has disagreed with the FTC on the issue, accepting that certain reverse-payment agreements are permissible.

The act would ban reverse payments by making it unlawful "for any person, in connection with the sale of a drug product, to directly or indirectly be a party to any agreement resolving a patent infringement claim in which (1) the [generic company] receives anything of value; and (2) the [generic company] agrees not to research, develop, manufacturer, market or sell the [generic] product for any period of time."

The act expressly excludes from its scope settlements where the only "value" paid by a brand company is the generic's right to market its product prior to the expiration of the patent(s) involved in the litigation (so called "early entry" provisions).

Reverse payments are not a new development. According to the FTC, over half of the settlements between brand companies and generics between 1992 and 1999 included reverse payments.

In 1999, however, it was reported that the FTC was investigating the legality of reverse payments. According to the FTC, from the time of that announcement until 2005, the practice of reverse-payment settlements stopped completely.

The tide turned again in 2005 with the Eleventh Circuit's decision in Schering-Plough Corp. v. FTC and the Second Circuit's decision in In re Tamoxifen Citrate Antitrust Litig.

These decisions flatly rejected the FTC's long-standing position by finding certain types of reverse-payment agreements to be permissible under traditional antitrust and patent principles.

In general, Schering and Tamoxifen rejected the argument that reverse payments are per se antitrust violations, and instead focused on whether "the exclusionary effects of the agreement fall within the scope of the patent's protection."

The Federal Circuit essentially endorsed this rationale last October in In re Ciprofloxacin, when it ruled that a settlement agreement involving reverse payments did not violate antitrust law.

These decisions suggest that any anti-competitive effects arising from a reverse-payment agreement are likely to be considered lawfully within the scope of the patent's protection, subject to certain exceptions, including that:

1) the agreement does not prevent or restrain the introduction or marketing of unrelated or non-infringing products;

2) the agreement does not create a bottleneck on patent challenges, delay market entry by other generics or manipulate the 180-day exclusivity period granted to the first generic challenger;

3) the patent was not procured by fraud and is not clearly invalid; and

4) the litigation is not objectively baseless.

Needless to say, the FTC strongly disagrees with the approach taken by the courts in these decisions. Nonetheless, the industry has responded.

According to FTC reports, almost half (28 out of 61) of the brand-generic final settlements in fiscal years 2006 and 2007 included a reverse payment, compared to three in 2005 and none from after the announcement of the FTC's investigation in 1999 until 2005.

As recently as February 2009, the FTC announced that eliminating reverse payments, and stopping what it calls a worrisome trend, is "one of the most important objectives for antitrust enforcement in America today."

The FTC has embarked on a two-pronged strategy of (1) continued court challenges with the ultimate objective of obtaining a favorable Supreme Court ruling, and (2) legislation.

To date, the Supreme Court repeatedly has refused to consider the issue. Notably, the Supreme Court asked for the Solicitor General's opinion as to whether it should review the Schering and Tamoxifen decisions.

Both times, the Department of Justice urged the court not to take the cases — a position directly at odds with the FTC, which had encouraged review.

Among other things, the DOJ argued that the mere presence of a reverse payment in a settlement of Hatch-Waxman litigation is not sufficient to show that the settlement is illegal, because an appropriate legal standard should consider the relative likelihood of success of the parties' claims.

The plaintiffs in In re Ciprofloxacin have until late March to seek Supreme Court review in that case.

The Supreme Court's refusal to address the issue, at least so far, apparently again prompted Congressional leaders to take action by introducing the act.

Similar legislation introduced during the previous sessions of Congress (notably co-sponsored by then Senator Obama) died without a vote.

Vigorous lobbying efforts by both generic and brand companies contributed to the defeat (a rare show of unity by two constituencies naturally at odds with each other).

Whether the result will be different with a new Congress and administration that are likely to be less sympathetic to the industry remains to be seen.

The act purportedly is intended to enhance competition in the pharmaceutical market, “lead to greater innovation, and inure to the general benefit of consumers.”

Whether the act actually will accomplish this purpose very much is an open question. There is a very real risk that the legislation will chill innovation by reducing the willingness of companies to engage in cutting edge research where the prospective returns are most uncertain.

Also, some argue that the ban on reverse payments will discourage, rather than encourage, aggressive patent challenges by generics under Hatch-Waxman.

Although not perfect, current practice allows Hatch-Waxman litigants to achieve some degree of certainty by fashioning settlements that are based on the merits of the case, the likelihood of success and the risks of receiving an unfavorable judgment after expensive litigation.

An absolute ban on reverse payments has the potential to unduly constrain efforts to negotiate mutually beneficial deals, thereby magnifying the uncertainty and risk that is always present in high stakes patent litigation.

In this respect, these cases would be treated differently than every other patent case where the parties are encouraged to work out appropriate settlements that eliminate risk and uncertainty and allow patent holders to realize the full benefit of their patent rights.

Brand-name drug makers, like all companies, seek certainty, particularly when making decisions concerning the investment of hundreds of millions of dollars for research and development.

While they have to accept certain risks, such as whether the science ultimately will prove successful, they always look to limit uncertainty with respect to patent protection, which is fundamental to ensuring a return on their R&D investment.

A consequence of the new act could be that brand companies are faced with the Hobson’s choice of either litigating to the very end (with all of the associated expense and uncertainty) or giving up the valuable exclusivity afforded by their patent rights.

The result may well be investment only in less risky science, where periods of patent exclusivity may be more predictable. This very real concern was recognized by the Schering and Tamoxifen courts, and by the Department of Justice, as one reason for rejecting a blanket ban on reverse payments.

The act also could have a chilling effect on the number of patent challenges initiated by generics under Hatch-Waxman.

In the current environment, many Hatch-Waxman patent challenges are brought by smaller companies that typically do not have the resources to litigate cases to a judgment, and then through appeal.

If parties are limited in their ability to fashion settlements, many of these companies may simply decide to stay on the sidelines because they cannot afford to go the distance.

At the very least, all but a handful of the largest generic companies would be forced to be more selective when deciding which patents to challenge, thereby reducing the frequency of patent challenges, a result contrary to the policy behind the Hatch-Waxman Act itself.

While more targeted legislation aimed at truly anti-competitive behavior (i.e., parking 180-day exclusivity to block all generic competition) might accomplish the stated objectives of the act, there are many reasons why a blanket prohibition of reverse payments is both unwise and unnecessary.

Traditional remedies afforded by antitrust law and principles of patent misuse already provide a meaningful safeguard against settlements that are truly anti-competitive.

Existing case law does not prohibit the FTC or private parties from challenging agreements involving reverse payments where, for example, the generic's covenant not to compete clearly extends beyond the scope of what the patent protects or the patent clearly is invalid.

To the contrary, the FTC can and should continue to challenge such settlements.

Notably, on Feb. 2, 2009 — the day before the act was introduced in the Senate — the FTC announced that it had filed a complaint against Solvay Pharmaceuticals Inc., Watson Pharmaceuticals Inc. and Par Pharmaceutical Companies Inc., alleging that Solvay's payment to the generics to delay competition with Solvay's branded drug AndroGel violates antitrust laws.

The FTC and Congress should avoid creating inflexible rules, like the blanket prohibition contemplated by the act, that undermine legitimate, valuable patent rights and that are just as likely to chill competition as to prevent illegal agreements.

The United States pharmaceutical and biotechnology industries have a long history of unparalleled success in developing innovative life-saving therapies.

The delicate balance struck by the Hatch-Waxman Act has helped to foster that success by ensuring that strong patents can be fairly enforced, while also clearing the path for timely generic entry.

Upsetting that balance by foreclosing reverse-payment settlement agreements in all circumstances, without regard to whether they actually have an adverse effect on innovation and competition, risks doing more harm than good.

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