JONES DAY

SEPTEMBER 2010

PENDING U.S. LEGISLATION TO BAN "REVERSE PAYMENT" SETTLEMENTS WOULD BRING FUNDAMENTAL CHANGE (AND UNCERTAINTY) TO DRUG PATENT LITIGATION

Soon—perhaps by the time you read this—Congress may pass a bill designed to declare so-called "reverse payment" settlements of patent litigation presumptively unlawful. The Federal Trade Commission has long attacked such settlements as anticompetitive but repeatedly has been rebuffed by the courts. Since 2006, the Commission has been asking Congress to enact the ban on such settlements that the courts would not decree. If Congress does so, as now seems likely, the behavior of all drug companies, branded and generic, engaged in the approval process for generic drugs will change fundamentally.

The proposed Preserve Access to Affordable Generics Act would amend the Federal Trade Commission Act to grant the FTC broad new authority to bring enforcement proceedings against parties choosing to settle certain types of patent infringement litigation brought under the federal framework governing approval of generic drugs, popularly known as the Hatch-Waxman Act. Shortly before its August recess, the Senate Appropriations Committee approved the Fiscal Year 2011 Financial Services and General Government Appropriations Bill (S. 3677). At the same time, the Committee agreed, by the narrowest possible margin, to include in the report accompanying the bill the Preserve Access to Affordable Generics Act. Identical versions of the bill have been passed by the full House of Representatives on multiple occasions, most recently in July 2010 as an amendment, ultimately removed in the Senate, to the War Funding Bill, H.R. 4899.

BACKGROUND ON "REVERSE PAYMENT" AGREEMENTS

"Reverse payment" settlements are a byproduct of the Hatch-Waxman Act, the statute governing the process by which the Food and Drug Administration approves new branded and generic drugs. If a generic drug manufacturer files an Abbreviated New

Drug Application (or "ANDA") that seeks to market a copy of a branded drug prior to the expiration of any patent claiming the branded drug, the generic manufacturer must certify that the patent in question is either invalid or not infringed by the proposed generic copy. The branded drug company may file a patent infringement lawsuit against the generic manufacturer within 45 days of its receipt of such a certification. If it does so, the FDA may not approve the proposed generic application for 30 months (unless the court rules sooner).

"Reverse payments" arise in the event the branded and generic manufacturer settle the patent litigation prior to the resolution of the claims. In these arrangements, the generic drug company agrees not to enter the market for a period of time. In exchange, the branded drug company provides a benefit (in the form of payments, licensing agreements, or the like) to the generic company. This arrangement is considered a "reverse payment" because the compensation flows *from* the patentholder to the generic manufacturer, as opposed to traditional license agreements, where payments flow *to* the patentholder.

The FTC long has viewed these settlement agreements as anticompetitive, and it has taken aggressive steps, both in administrative proceedings and in the courts, to attempt to prevent litigants from settling their disputes in this manner. But its efforts repeatedly have failed in the courts: the Second Circuit (twice), the Eleventh Circuit (twice), and the Federal Circuit all have held that the key to determining whether any settlement agreement runs afoul of the antitrust laws is not the direction of the payments made, but rather the scope of the settlement agreement. As long as the terms of the settlement fall within the "exclusionary scope" of the patent (in other words, as long as the settlement does not restrain any more competition than the patent itself), a "reverse payment" injures neither competition nor consumers. Even the Sixth Circuit, to date the only federal appeals court to rule in favor of antitrust plaintiffs attacking a patent settlement involving payments, found that the particular settlement agreement in that case actually *exceeded* the exclusionary scope of the challenged patent, by excluding noninfringing drugs.

The clear majority rule in the circuit courts therefore is that "reverse payment" settlement agreements that restrain competition only within the existing scope of the challenged patent do not harm consumers—unless the patent is so weak that the infringement claim was "objectively baseless." But that is a rule that Congress can change by legislation and, after years of prompting by the FTC, it now seems poised to do so.

THE (POSSIBLE) NEW FEDERAL REQUIREMENTS FOR DRUG PATENT SETTLEMENTS

The proposed Preserve Access to Affordable Generics Act would empower the FTC to bring an enforcement action against parties who choose to "resolv[e] or settl[e], on a final or interim basis, a patent infringement claim, in connection with the sale of a drug product." The Commission would treat as presumptively anticompetitive any settlement in which:

- The generic manufacturer receives "anything of value" and

- The generic manufacturer "agrees to limit or forgo research, development, manufacturing, marketing or sales" of its product "for any period of time."

The statute is made broad by the terms "anything of value," which would appear to apply to all Hatch-Waxman settlements, and "patent infringement claim," which is not limited to claims made in litigation but applies to any "allegation" that a drug product infringes a patent. Thus, the FTC may apply the statute and its presumption of illegality to any license with an ANDA filer, even if it arises from private discussions outside of litigation.

Settlement agreements that fall within the statute would avoid liability only if the settling parties could demonstrate by "clear and convincing evidence that the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement." Failure to meet this burden would subject the settling parties to penalties of up to three times the value received by the generic manufacturer under the agreement. The generic company would also forfeit any 180-day marketing exclusivity to which it would have been entitled under the Hatch-Waxman framework.

In addition to placing the burden on the settling parties to justify the settlement, the bill expressly prohibits the presumption—unambiguously adopted by a majority of the circuit courts that have considered the issue—that absent a successful challenge to the patent, the generic manufacturer's product would not have entered the market until the expiration of the patent. (The statute would not prohibit the fact finder from reaching that conclusion on the basis of the evidence presented.) Strangely, the statute also forbids the "presumption" that the generic would not have entered the market prior to the expiration of the branded drug's "statutory exclusivity" under the Food, Drug and Cosmetic Act, even though there is no doubt that the FDA could not approve the generic during that period. The statute further forbids the fact finder from presuming the agreement to be procompetitive solely because it allows generic entry prior to patent expiration.

The statute does purport to contain a "safe harbor" for settling parties. The settlement will not be considered unlawful if the consideration (or "value") granted by the pioneer company to the generic manufacturer consists only of one or more of the following:

- The right of the generic manufacturer to market its product prior to the expiration of any patent or other exclusivity that would prevent such marketing,
- A payment of "reasonable litigation expenses not to exceed $7,500,000," or
- A "covenant not to sue on any claim that the [generic product] infringes a United States patent."

Essentially, the terms of a "safe" license must be limited to an entry date for the generic drug and a payment of attorney fees. Any other terms, including such common terms as mutual releases and making the license exclusive, would not satisfy the statute and would be deemed presumptively illegal.

Finally, the bill would compel parties settling these lawsuits not only to notify the FTC of the terms of any and all agreements between the parties, but it would also require their chief executive officers to certify that the notice represents "the complete, final, and exclusive agreement between the parties."

WHAT CAN PHARMACEUTICAL COMPANIES DO?

Should the proposed Act pass both houses and become law, it would both overrule the clear weight of circuit court authority in this area and make the FTC the effective arbiter of the propriety of all Hatch-Waxman settlements, if not all license agreements between branded companies and generics that have filed an ANDA with the FDA. The consequences will be significant.

Pharmaceutical companies would need to be sensitive to the implications of the new Act, not only when they settle a case, although that will be a critical moment, and we expect to see the absolute number of settlements decline as a result. But generic applicants also would need to think hard about challenging branded drugs in the first place, knowing that they might have to choose between litigating to the bitter end or satisfying the FTC's concerns with any settlement they contemplate. And those "concerns" may be quite difficult to predict. Recall that the FTC has yet to persuade a court that there is a genuine competitive problem arising from a settlement within a patent's scope. The FTC has even redefined "reverse payments" to include settlements with no payments at all, such as those in which the generic's license is made exclusive. Generic company witnesses have testified to Congress that the number of ANDA challenges necessarily will decline under this statute, and there is little reason to doubt them.

Finally, the statute may even affect the earlier decision of the branded company to list a given patent with the FDA, given the possible consequence of having to litigate any resulting challenge to conclusion in order to avoid dealing with the FTC down the line. Some may prefer not to list the patent at all, but that choice will be complicated by FDA regulations that arguably mandate the listing of all patents that might be infringed by a generic product. In the end, while the number of challenges made, lawsuits filed, and settlements entered may decline, the many who have no choice but to litigate will face a difficult and highly uncertain process that will be measured in years.

Finally, much will depend on the way in which the statute is interpreted by the FTC in any regulations it adopts, and by the courts in the cases they decide. For now, the proposed legislation raises far more questions than it answers for pioneer and generic drug manufacturers attempting to navigate the Hatch-Waxman process. In the words of former Justice Robert Jackson, who dissented from a similarly dramatic change in the way the antitrust laws were applied to the insurance industry: "What will be irretrievably lost and what may be salvaged no one can now say, and it will take a generation of litigation to determine."

Jones Day will continue to monitor this topic and report on any significant developments.

LAWYER CONTACTS

For further information, please contact your principal Firm representative or one of the lawyers listed below. General email messages may be sent using our "Contact Us" form, which can be found at www.jonesday.com.

Kevin D. McDonald
Washington
+1.202.879.3743
kdmcdonald@jonesday.com

Christopher R. Farrell
Washington
+1.202.879.7632
crfarrell@jonesday.com