

***Federal Trade Commission v. Actavis, Inc.* and reverse-payment or pay-for-delay settlements**

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An imminent US Supreme Court ruling should resolve one of the thorniest legal issues facing pharmaceutical companies today.

On March 25, 2013, the US Supreme Court heard arguments in *Federal Trade Commission v. Actavis, Inc.* The Court's decision, which will likely come out in June, should resolve one of the thorniest legal issues facing pharmaceutical companies today: whether brand pharmaceutical manufacturers can settle patent lawsuits with generic drug makers by paying them to delay entering the market after the generics' approval but before any of the brands' relevant patents expire. Typically, payments to delay competitors' entry in a marketplace violate antitrust laws as being anticompetitive. But the matter is complicated when patents are involved. Because patents are simply the right to prevent someone else from practicing the patented invention, paying someone to delay doing so could also be seen as pro-competitive if it grants a right to enter the marketplace earlier than the patent would normally allow. Nonetheless, there is a concern that these reverse payments or pay-to-delay settlements are little more than two competitors divvying up a very lucrative market. And the purpose of the Hatch-Waxman Act, the complicated regulatory framework concerning the US Food and Drug Administration's approval of generic drugs blocked by patents, is to "encourage patent challenges as a way of increasing consumer access to low-cost drugs"¹.

Because the Hatch-Waxman Act says little about whether reverse-payment settlements violate the antitrust laws, the lower courts of appeal have adopted a variety of—and sometimes conflicting—approaches to analyzing these settlements in an antitrust context.

Whether the Supreme Court's ruling will have a significant impact on the pharmaceutical industry will likely depend on how the Court resolves these conflicts.

Under one theory, the Supreme Court may conclude that reverse-payment settlements are always or *per se* permissible as long as the generic drug enters the market before any relevant patents expire. Adopting this 'scope of the patent' test will likely be a major boon to brand pharmaceutical companies. Historically, reverse-payment settlements by brand pharmaceutical manufacturers have allowed generics to enter the market, on average, 90.2 months before the protecting patents expire, at an average sales revenue loss to the brand of \$1.31 billion (ref. 2). A scope-of-the-patent approach, however, would allow brand pharmaceutical manufacturers to structure settlements that essentially delayed generic entry until days or weeks before any relevant patents expire. This would ensure brand pharmaceutical companies supracompetitive profits for longer—and more predictable—periods of time.

At the other extreme, the Supreme Court may conclude that reverse-payment settlements are *per se* impermissible, regardless of the duration or scope of the delay relative to the patents. But because the Hatch-Waxman Act generally requires brand pharmaceutical companies to sue their generic competitors or forgo market exclusivity, brand pharma would often be placed in the peculiar situation of litigating patent lawsuits against generics even if such cases are in neither parties' best interests. Where a brand's patents are weak, forced litigation will more likely result in the patents' invalidation, and a resulting flood of generic competitors. This would be good for consumers but bad for both brand and generic companies. Each additional generic entrant tends to substantially decrease the profits of both brand

and generic companies³. Where a brand pharma's patents are strong, however, forced litigation will likely keep generic competitors off the market until the patents' expiration. This would be good—although costly—for brand pharma, and obviously bad for consumers. In addition, smaller or start-up brand pharma—who are particularly sensitive to the validity of their patents—would be forced to shoulder the costly burden of litigation.

The Supreme Court may, however, take a more nuanced view than either of these two extremes. Rather than determining that reverse-payment settlements are *per se* permissible or impermissible, the Court may conclude that such settlements are only presumptively impermissible. Brand and generic pharma that wish to settle patent litigation may overcome this presumption by proving to the trial court that a proposed settlement is pro-competitive because it also includes unrelated business services, structures itself around expected litigation costs or involves other unusual circumstances. This nuanced view of reverse-payment settlements has broad appeal in the legal community. It is currently supported by the Federal Trade Commission, the American Antitrust Institute, and in a friend-of-the-court brief filed by 118 academics in law, economics and business^{4,5}.

The effect of this nuanced rule on the pharma industry, however, would be unclear. With the diminishment of reverse payments as an option, only large generic manufacturers will be able to afford expensive patent lawsuits against brand pharma, which average \$5 million through trial⁶. In the event that a business services settlement could be reached, this would similarly benefit larger generic manufacturers that have more assets and access to services than smaller manufacturers. Nonetheless, it is unclear whether this

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size-specific effect would ultimately be more beneficial to consumers or brand pharma than the current state of affairs.

Irrespective of the rule adopted by the Supreme Court, it is also possible that Congress could step in and create a rule of its own. Congress has recently taken an extraordinary interest in innovation policy despite the current political deadlock. It passed the America Invents Act in 2011, the first major substantive change to the patent statute in over 30 years. New bills focusing on some of the current ills of patent law are now frequently introduced. And California congressman Henry A. Waxman,

one of the Hatch-Waxman Act's sponsors, filed a friend-of-the-court brief in *Actavis* calling for a ban on reverse-payment settlements⁷. *Actavis's* legacy may be a political rather than a judicial one.

Ultimately, the effect of the *Actavis* ruling on the pharmaceutical industry will depend on the rules the Supreme Court adopts in analyzing reverse-payment settlements. Those rules may disproportionately affect larger pharmaceutical companies—both brands and generics—at the expense of smaller ones. But even then, Congress may very well have something to say about it.

COMPETING FINANCIAL INTERESTS

The author declares no competing financial interests.

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