

CLIENT ALERT

What Does *FTC v. Actavis Inc.* Mean for Hatch-Waxman Litigation?

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What's next for pharmaceutical companies now that the Supreme Court in *Federal Trade Commission v. Actavis Inc.* has held that "reverse payment" settlement arrangements in the pharmaceutical industry—that is, a payment from the brand patent owner to the generic infringer—can sometimes violate the antitrust law? The Supreme Court heard the case after a circuit split where the Second and Eleventh Circuits held that reverse payment settlements are lawful as long as they do not exceed the scope of the underlying patent, contrasting with the Third Circuit, which has rejected the "scope of the patent" test in favor of a structured "rule of reason" analysis. In so doing, the Court set forth a new, four part test for reverse payment settlement agreements that essentially provides a roadmap for antitrust challenges to such agreements. As a result, the way forward for using reverse payments in settling brand versus generic patent litigation is far from clear.

Rather than fully embrace or outlaw reverse payment arrangements, the Supreme Court adopted a middle ground "rule of reason" analysis for evaluating whether this type of settlement of Hatch-Waxman litigations violate the antitrust laws. The FTC had advocated a "quick look" test, which would have barred almost any settlement involving a reverse payment; the Court declined to take this position.¹ Likewise, the Court also rejected the "scope of the patent" test, which would have permitted the reverse payment settlement so long as the settlement terms gave the patent owner no more than it could have obtained by successfully enforcing the patent where the underlying patent claim was not a sham.²

In an opinion authored by Justice Stephen Breyer, the Court held that the settlement arrangements should be evaluated under the "rule of reason" balancing test, writing that the "likelihood of a reverse payment bringing about anticompetitive effects depends upon (1) its size, (2) its scale in relation to the payor's anticipated future litigation costs, (3) its independence from other services for which it might represent payment, and (4) the lack of any other convincing justification."³ The Court declined to specify further how the rule of reason should be applied in this context, and expressly left the particulars of implementation to the lower courts.⁴ The Court did in a number of places in its decision indicate that due to the suspicious nature of "reverse payment" settlements, defendants accused of thereby violating the antitrust laws will have the burden of justifying the payment as not anticompetitive. This could be hard to do unless the payment is relatively small compared to the cost of litigation or unless the payment is fair compensation for some other consideration supplied by the defendant, such as distribution services, or the transfer of other valuable IP or product development rights to the plaintiff. This four-part reverse payment test will be the focus of future litigation in this area.

So what does this mean for industry stakeholders? The FTC has been scrutinizing every component of these settlements for years now, and private plaintiff challenges were common, but some firms were willing to take that risk in light of a run of court decisions most of which had been favorable to the defense. But the government scrutiny -- and direct purchaser and consumer class action exposure -- will grow now that the Supreme Court has rejected the "free pass" that many lower courts had given to patent settlements. Third-party "pay-for-delay" anti-trust litigation, brought by both direct and indirect purchasers, and state attorneys general, will become more common if these settlements continue to be made. Indeed, any time there is a substantial reverse payment, "pay-for-delay" plaintiff's lawsuits will likely follow. And these cases will be harder to dismiss at the motions

stage because the "rule of reason" test is highly fact specific. As a result, litigation costs will go up. What is also clear is that pharmaceutical companies have to consider balancing the cost of continuing patent litigation with defending the validity of any reverse payment agreement in "pay-for-delay" antitrust litigation.

Can pharmaceutical companies settle patent disputes with some element of compensation to the generic company and a continued patent enforcement for some period less than the full patent term and still minimize their antitrust exposure? The actual answers will be hammered out by the lower courts in the coming years before an eventual return to the Supreme Court. The four part reverse payment test is very fact specific, but there are some guideposts:

1. **Size matters**—simply put, the larger the reverse payment, the riskier the settlement from an antitrust perspective. The Court did not, though, give us a point of reference for assessing "size" other than comparison to legal costs to be avoided. It would appear that size relative to profits or sales to be made on the drug could also be an indicator of a situation where the brand manufacturer is arguably paying off a likely lawful entrant, rather than an infringing entrant.
2. **Settle early**—one of the elements of the four part reverse payment test is the "scale in relation to the payor's anticipated future litigation costs." The Court acknowledges that some of the benefit that a patentee gets from settlement is a reduction in litigation costs. A party's anticipated future litigation costs will be highest at the outset of litigation. Interestingly, it should be noted that recoupment of the generic company's past litigation costs does not appear to be part of Justice Breyer's legitimate settlement costs, but it should be.
3. **Settlements in competitive markets should be easier to defend**—the Court explained that there is less antitrust concern if the payor-patent holder does not have substantial market power in the particular market for the drug or other product. In competitive markets, such as for heartburn medication or oral contraceptives, where there are numerous competing products and prices and profit margins are low, the Court indicated that the payor is unlikely to have substantial market power to defend, and any paid-for exclusion of one generic competitor is less likely to have an anticompetitive effect.
4. **Payments should be for services rendered, not to stay out of the market**—brand and generic companies will have to be diligent in assuring that dollars paid to the defendant for the provision of services, rights to other drugs or intellectual property are fair value and so documented. These can include distribution agreements, marketing agreements, and other business arrangements that offer value to the payor and legitimate justification any payments to the generic firm in under the settlement.
5. **No "unexplained" payments**—parties should from the outset have a contemporaneous documented explanation for every dollar of each settlement. Justice Breyer's opinion noted that the "size of the unexplained reverse payment" can serve as a proxy for a patent's weakness and thus the likely anti-competitive nature of the settlement. Parties should retain economic experts to provide analysis that explains the settlement in pro-competitive terms. This addresses the fourth element of the Actavis Test—"the lack of any other convincing justification."

A potential pitfall will be companies retreating from outright reverse cash payments as consideration for the settlement,

substituting a variety of side deals that may be camouflaged as reverse payments. Issues, in that event, will turn on proof questions, building on the still somewhat unformed framework of *Actavis* analysis.

A final mystery under the *Actavis* decision is the nature of balancing that the courts are to do. It is clear enough that the plaintiff will have the burden of proving a likelihood of anticompetitive effects. But if that threshold is satisfied, it is not at all clear what procompetitive considerations are, in the Court's view, available to be offered in defense of a payment that has enough "size" to be of concern.

¹ See *FTC v. Actavis Inc.*, No. 12-416, 2013 U.S. LEXIS 4545, at *38 (U.S. June 17, 2013).

² *Id.* at *29.

³ *Id.* at *39-40.

⁴ *Id.* at *40.

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