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Key Takeaways

Antitrust Roundtable Series

Reverse-Payment Settlements – What Now? | A Discussion on the Implications of the *FTC v. Actavis* and *Lundbeck* Decisions

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Skadden recently hosted a webinar — "Reverse-Payment Settlements: What Now?" — with presenters from the firm's antitrust and intellectual property litigation groups. Listeners received an overview of the recent U.S. Supreme Court decision in *FTC v. Actavis, Inc.* and the European Commission decision in *Lundbeck*, both of which addressed the antitrust standards to be applied to reverse-payment pharmaceutical patent litigation settlements.

In *Actavis*, the Supreme Court was faced with a Federal Trade Commission complaint alleging that brand-name manufacturer Solvay, in settling Paragraph IV Hatch-Waxman patent litigation over the drug AndroGel, had unlawfully "paid to delay" generic entry by its potential generic competitors using contemporaneous business agreements to disguise the compensation. The Supreme Court by a 5-3 vote reversed the U.S. Court of Appeals for the Eleventh Circuit, rejecting the scope-of-the-patent test that had been applied below, and ruling that reverse-payment settlements should instead be subject to rule-of-reason review. How the rule-of-reason inquiry is to be structured was left to the lower courts, but the Court set out "five considerations" that informed its analysis. These include ascertaining whether the payment to the generic manufacturer was "large and unjustified," and envisioning the use of such a payment as a proxy for patent strength and market power. Finally, the Court emphasized that the burden of proving significant anti-competitive effects flowing from reverse-payment settlements remains with the plaintiff.

In *Lundbeck*, the European Commission issued a decision imposing fines totaling more than €145 million on pharmaceutical company Lundbeck and a number of generic pharmaceutical manufacturers for patent settlement agreements that were deemed infringements of Article 101 of the Treaty on the Functioning of the European Union. The commission's decision, like the U.S. Supreme Court's decision, clearly rejected the scope-of-the-patent test. Under the commission's approach the existence of a "payment" is considered decisive in the legal analysis to determine whether the agreements infringe Article 101, even if the restrictions on entry imposed remain within the scope of the patent. The decision finds that the inclusion of a payment can be sufficient to find an infringement by object also if the amount of the payment only "comes close" to the generic manufacturer's anticipated profits. In addition, the commission took the view that the generic manufacturers are in principle to be considered potential competitors, in particular after expiry of the compound patent, and that generics suppliers may be required to investigate the existence and availability of non-infringing processes.

In its decision, the commission also took the position that the presumptive validity of patents does not preclude an assessment under competition law of the possibility of challenging the validity of the patent in court, which the decision considered an "essential part of the competitive process," and which highlights the relevance of contemporaneous documents assessing the patent and litigation risk in the commission's analysis.

The webinar panel discussed the similarities and differences in the U.S. and EU approaches, as well as the open questions that remain in the wake of these two landmark decisions and the arguments that can be raised in defending existing settlements. Looking forward, the panel also addressed considerations in planning for patent litigation in the post-*Actavis* and *Lundbeck* era. The panel concluded with a discussion of factors to be considered in contemplating future patent litigation settlements.