Reverse payment settlements:  
The U.S. Supreme Court weighs in

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On June 17, 2013, the U.S. Supreme Court released its decision in Federal Trade Commission v. Actavis, Inc., in which it considered the presumptive validity (or invalidity) of so-called reverse payment settlement agreements between branded pharmaceutical manufacturers and their generic competitors. FTC v. Actavis Inc., No. 12-416, 133 S. Ct. 2223 (June 17, 2013).

The Actavis case concerned a patent infringement settlement between Solvay Pharmaceuticals, which had obtained a patent for its brand name drug AndroGel, and Watson Pharmaceuticals (a predecessor of Actavis), which had filed an application for approval to manufacture and sell a generic version of AndroGel based on the alleged invalidity of Solvay’s patent. However, after receiving regulatory approval to do so, Watson entered into a settlement agreement with Solvay under which Watson agreed not to market generic AndroGel until 2015 — five years before the expiry of the AndroGel patent — and to promote AndroGel sales to doctors. Solvay agreed to share a portion of its AndroGel profits with Watson, which could result in an annual payment to Watson of up to $30 million per year.

For years, the U.S. Federal Trade Commission (FTC) has taken the view that reverse payment settlements are tantamount to an agreement to pay a competitor to stay out of the market and, therefore, presumptively unlawful. However, U.S. appeals court jurisprudence held that reverse payment settlements are immune from antitrust challenge as long as the settlement does not impose an exclusion that is greater than the exclusivity conferred by the relevant patent. In Actavis, in a 5 to 3 decision, the U.S. Supreme Court held that, while reverse payment settlements are not presumptively unlawful, they are also not immune from antitrust challenge. Rather, the Court held that these settlements can sometimes violate antitrust laws and can be challenged in appropriate — but not clearly defined — circumstances. The Court sent the case back to the appeals court for further consideration.

IMPLICATIONS OF THE ACTAVIS DECISION

For pharmaceutical manufacturers carrying on business in the United States, the Actavis decision will exacerbate the uncertainty around patent litigation settlements, which, while not presumptively unlawful, can now clearly be challenged by the FTC. Since the lawfulness of each settlement — particularly those involving significant payments to a generic — will need to be considered on its particular facts, the Actavis decision may both discourage settlements that include such payments and, where such payments are made, encourage challenges by the FTC and private parties.

The Actavis decision could have one important positive spillover implication in Canada for pharmaceutical manufacturers seeking to settle patent litigation.

Canada’s Competition Bureau has expressed ongoing interest in the pharmaceutical industry including, among other things, reverse payment settlements. However, under the Competition Act (Canada), it is an unresolved issue whether such a settlement could be challenged under the criminal competitor agreements provision (Section 45) as a per se agreement to allocate markets or restrict product output.

If the U.S. Supreme Court’s reasoning in Actavis is followed in Canada, bona fide patent litigation settlements — even those involving payments to a generic — should not be regarded as presumptively unlawful and, therefore, should not be subject to challenge under Section 45. They would remain subject to review under the civil competitor agreements provision (Section 90.1).

Otherwise, the significant differences between the Canadian and U.S. patent, litigation and competition law frameworks should limit the relevance of the Actavis decision in Canada. For example, unlike in the United States, a generic competitor in Canada whose allegations of non-infringement and patent invalidity are justified and who has been improperly excluded from the market by a patent holder may claim damages under the Patent Act for its resulting losses. This should provide branded and generic manufacturers with scope to agree on monetary payments designed to settle claims for these amounts.

Jay Holsten is the chair of Torys LLP’s competition and antitrust practice group in Toronto. His practice is focused on complex merger review and the competition law aspects of other strategic business arrangements for clients such as Bank of Nova Scotia, Brookfield, Cameco, Pfizer, Thomson Reuters and TD Bank. He has developed expertise in the pharmaceutical sector, where he advises numerous pharma and biotech clients on a broad range of antitrust issues. This commentary was originally published in the firm’s Competition and Antitrust Bulletin on June 22. Reprinted with permission.