Statement Of Senator Patrick Leahy (D-Vt.),
Chairman, Senate Judiciary Committee,
Subcommittee Hearing, "Pay-for-Delay Deals: Limiting Competition and Costing Consumers"
July 23, 2013

Today, the Subcommittee on Antitrust and Consumer Protection considers an issue that has long been of interest to this Committee: patent litigation settlements that have the potential to harm consumers by delaying the entry of generic drugs into the market.

The Committee first began its examination of this issue over a decade ago. Unfortunately, a report published by the Federal Trade Commission earlier this year suggests that drug companies are continuing to enter into such agreements at significant cost to consumers and taxpayers.

In 2003, Congress enacted legislation that I introduced to require brand and generic pharmaceutical companies to disclose agreements to the Federal Trade Commission and Department of Justice if they relate to a generic drug's entry into the market. The purpose of the law was to increase oversight and transparency of such arrangements to ensure that pharmaceutical companies were not inappropriately foreclosing generic competition at the expense of consumers. A series of discouraging court decisions, however, limited the ability of the antitrust authorities and consumers to effectively challenge these agreements under the antitrust laws.

I am pleased that the Supreme Court's recent decision in *FTC v. Actavis* made clear that agreements between brand-name pharmaceutical companies and generic challengers can be reviewed under the antitrust laws to determine whether they harm consumers. That is an appropriate and fair outcome. Our patent system incentivizes innovation by protecting the rights of inventors, but those rights should not shield patent holders who engage in anticompetitive behavior. This is especially important in the market for prescription drugs, where generic competitors play a vital role in ensuring consumers have access to affordable medicines.

In addition to the question of patent settlements, I hope that today's discussion will touch upon another area in the prescription drug market that may be subject to anticompetitive abuse: the use of product redesign to extend the life of a patent simply to delay generic entry, without real therapeutic benefits to consumers. As in the patent settlement context, these cases must be reviewed on their facts to distinguish between arrangements that benefits consumers, and those that inappropriately delay generic entry and stifle competition. Our antitrust authorities can play an important role in this exercise, and I urge them to continue their strong oversight.

I welcome Chairwoman Ramirez and the other witnesses to today's hearing. I look forward to their testimony.

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