**Statement of Chairwoman Edith Ramirez**
**Committee on the Judiciary**
**Subcommittee on Antitrust, Competition Policy & Consumer Rights**
**U.S. Senate**
**Washington, DC**
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Chairman Klobuchar, Ranking Member Lee, and Members of the Subcommittee: Thank you for inviting me to testify today about the FTC's efforts to stop anticompetitive "pay-for-delay" patent settlements among pharmaceutical companies.

As members of this Committee are well aware, these agreements not only raise substantial antitrust concerns, but also undermine the goals and spirit of the Hatch-Waxman Act, which seeks to prevent weak patents from obstructing the development of lower-cost, generic drugs. Stopping these anticompetitive patent settlements has been a top bipartisan priority at the Commission for many years.

The reason the Commission has been so concerned about these settlements is because there is so much at stake for consumers. FTC economists have found that, on average, these settlements cost consumers $3.5 billion each year, and taxpayers ultimately bear a significant portion of this burden because of the increased costs to Medicare, Medicaid, and other government health programs.

The FTC has taken aggressive action to combat these harmful agreements, beginning in 2000 with our administrative litigation against Schering-Plough. That case ended up before the Eleventh Circuit, which adopted the overly permissive "scope-of-the-patent" test, effectively immunizing pay-for-delay settlements from antitrust scrutiny.

Even though the Commission lost that case, and other courts also adopted the "scope of the patent test," we continued to investigate and litigate pay-for-delay cases. The Commission's

ongoing efforts culminated in a matter before the Supreme Court this spring, *FTC v. Actavis*, in which the Court considered the Commission's challenge to patent settlements involving Solvay's billion-dollar testosterone replacement drug AndroGel. The Commission alleged that the brand-name drug manufacturer agreed to pay three generic manufacturers hundreds of millions of dollars to abandon their patent challenges and delay rollout of a generic version for nine years, until 2015. Applying the scope-of-the-patent test, the Eleventh Circuit had affirmed the district court's dismissal of our case because the settlements did not prevent competition beyond the challenged patent's expiration date.

Soon after the Eleventh Circuit ruling, the Third Circuit, however, rejected that approach in a private case involving another brand-name drug and held that pay-for-delay agreements are presumptively unlawful. This created a circuit court split that set the stage for the Supreme Court's review of the issue.

The Supreme Court's decision in *Actavis*, announced last month, was a significant victory for American consumers, American taxpayers, and competition. The Supreme Court has made it clear that pay-for-delay agreements between brand and generic drug companies are subject to antitrust scrutiny. Although the Court did not declare reverse-payment settlements to be presumptively illegal, it did find that reverse payments have the potential for genuine anticompetitive effects because they permit a brand-name drug company to eliminate the risk of competition, maintain a monopoly, and share the benefits of that monopoly with its potential competitor.

In light of the Supreme Court's decision, federal courts must now consider antitrust claims challenging reverse payment patent settlements and decide them under a rule of reason

standard. The Supreme Court ruled that courts must assess the drug companies' justifications for the payments, including whether the payments were for something other than purchasing protection from potential competition, such as avoided litigation costs or for services provided by the generic company. The Court was also clear that the anticompetitive effects of a reverse payment settlement can typically be determined without litigating the underlying patent claim, using the brand's payment to the generic as a proxy for its belief about the viability of its patent claims.

The *Actavis* decision is an important milestone, but the Commission's work is far from over. Harmful pay-for-delay patent settlements will not suddenly disappear. But now there is a path forward to stopping them.

To that end, we will continue to focus our resources on investigating and challenging those anticompetitive settlements likely to cause the most consumer harm. These efforts will begin with our two pending pay-for-delay cases – *Actavis* and the *Cephalon* case pending in federal district court in Philadelphia – in which we will seek to prove that the agreements at issue violate the antitrust laws. We will also continue to review the pharmaceutical patent settlements filed with the agency pursuant to the Medicare Modernization Act and report to Congress and the public on trends and developments, as well as investigate those settlements we believe violate the law.

In addition to enforcement work, we will look for opportunities to utilize the Commission's extensive experience and expertise in this area by filing amicus briefs in private litigation in order to assist courts that are deciding pay-for-delay matters. We believe that all of

these efforts, together with the strong statement made by the Supreme Court in *Actavis*, will provide significant deterrent effect.

I look forward to continuing to work with the members of this Committee on how best to use the antitrust laws promote the interests of consumers in gaining access to lower-cost generic drugs.

I am happy to answer any questions you may have. Thank you.