Testimony of

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Statement on "Pay-for-Delay Deals: Limiting Competition and Costing Consumers"

Before the

Subcommittee on Antitrust, Competition Policy and Consumer Rights
Committee on the Judiciary
United States Senate

July 23, 2013

I. Introduction

A. Reverse-payment settlements are one of most important antitrust issues of 21st century.
B. They directly affect health of millions of Americans.
C. Congressional action is still needed after Supreme Court's decision in *FTC v. Actavis*.

II. My Background

A. I have focused on antitrust and intellectual property (IP) since my time at Covington & Burling.
B. As academic, have written 400-page book and 50 articles on antitrust and IP (especially "reverse payments").
C. Wrote reverse-payment amicus briefs in appellate courts and co-authored, on behalf of 118 professors and American Antitrust Institute, brief cited by Justice Breyer in *Actavis*.

III. Antitrust Alarm Bells

A. In past decade, brand drug companies have paid generics tens (or hundreds) of millions of dollars not to enter market.
B. One of most concerning types of business conduct: one company pays another not to enter market.
   1. Market division is per se violation of antitrust laws.
   2. Patent complicates analysis, but not if delay based on payment, not patent.
C. These settlements reveal perversion of Hatch-Waxman Act (HWA), Congress's resolution of patent and antitrust law in pharmaceutical industry.
   1. HWA provides 180-day exclusivity to first generic to challenge brand's patent, claiming it is invalid or not infringed.
   2. But period does not begin to run until generic enters market.
   3. By paying first generic to delay entering market, brand can delay entry by other generics for years.
   4. One potential solution: expand universe of parties eligible for 180-day exclusivity.
D. Reverse-payment settlements have alarming consequences.
   1. They cost consumers billions of dollars.
   2. They cover drugs treating heart disease, cancer, reflux, depression, anxiety, and others.
   3. They force patients to split pills in half or skip taking their medications, leading to worsening symptoms and even death.

IV. *Actavis* Reinvigorated Antitrust Scrutiny

A. Despite severe concerns presented by reverse-payment settlements, most appellate courts had blessed the activity, relying on presence of patent and policy supporting settlements.
B. In *Actavis*, Supreme Court made clear that reverse-payment settlements had "significant anticompetitive effects" and could be "unjustified."
   1. Court also found that large payment could demonstrate market power.
   2. And Court explained that parties can settle in ways other than with reverse payments.

C. Court called for Rule-of-Reason analysis that considered payment's "size," "scale in relation to . . . future litigation costs," "independence from other services," and "lack of any other convincing justification."

V. Need for Clarity

A. Reverse-payment settlements present complicated issues of antitrust, patent, and HWA law.
B. Drug firms have lamented lack of guidance from decision.
   1. PhRMA was "disappointed" that Court "failed to provide clear and unambiguous guidance" as to which settlements would "avoid antitrust exposure."
      a) PhRMA also lamented "degree of uncertainty" making it "less likely" that brands and generics "will be able to settle these disputes."
   2. GPhA worried that decision "will require generic companies to take on a greater administrative burden to pursue a patent challenge."
   3. Actavis lamented that ruling imposes "additional and unnecessary administrative burden" on industry.
      a) Actavis announced its "plan[s] to continue to defend the propriety of such settlements against any further legislative or judicial challenges."
C. Enactment of S. 214 would clarify Congress's position on reverse-payment settlements.
   1. In *Actavis* dissent, Chief Justice Roberts refused to rely on procompetitive purposes of HWA since "Congress has repeatedly declined to enact legislation" addressing these settlements.
   2. "Findings" section of S. 214 confirms that HWA's intent "has been subverted" and that the settlements "result in consumers losing the benefits" the Act "was intended to provide."
   3. "Purposes" section of S. 214 makes clear that competition would be "enhance[d]" by "stopping anticompetitive agreements" that "limit, delay, or otherwise prevent competition from generic drugs."
   4. These findings and purposes would provide assistance to courts in determining legality of the settlements.

VI. S. 214 and Presumptive Illegality

A. S. 214 provides chief enforcer challenging settlements, Federal Trade Commission (FTC), with important new tools.
B. Most important, creates framework of presumptive illegality applying when generic "receives anything of value" and delays "research, development, manufacturing, marketing, or sales."
C. S. 214 allows settling parties to rebut presumption based on factors such as timing and amount of payment.
D. "Limitations" section provides important reminder that generic entry could occur before patent expiration and that pre-expiration entry is not necessarily procompetitive.
   1. As I have previously explained, brands have used settlements to block generic entry while they switch market to new version of drug.
      a) So even if generics can enter before end of patent term on *old* version, this does not constrain brand, which is enjoying monopoly profits on *new* version.
E. Presumptive illegality would have several important benefits.
   1. Would make clear that *Congress* believes the settlements are anticompetitive.
   2. Would help *FTC* prove its cases against anticompetitive settlements in court.
   3. Would counter *drug firms'* claims that anticompetitive settlements are reasonable.
   4. Would help *courts* organize the multiple factors in the antitrust analysis.

VII. Conclusion

A. S. 214 would confirm hazards of reverse-payment settlements.
B. S. 214 would provide framework allowing FTC to challenge the settlements.
C. S. 214 would help save consumers money and improve public health.