Prepared Statement of
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Before the
United States Senate
Committee on the Judiciary
Subcommittee on Antitrust, Competition Policy and Consumer Rights

on

Pay-for-Delay Deals: Limiting Competition and Costing Consumers

Washington, D.C.
July 23, 2013

Chairman Klobuchar, Ranking Member Lee, and Members of the Subcommittee, thank you for the opportunity to appear before you today. I am Edith Ramirez, Chairwoman of the Federal Trade Commission, and I am pleased to testify about one of the Commission's top priorities: ending anticompetitive "pay-for-delay" settlements in the pharmaceutical industry.[1]

As this Subcommittee is well aware, pay-for-delay settlements (also known as "exclusion payment" or "reverse payment" settlements) are settlements of patent litigation in which the brand-name drug firm pays its potential generic competitor to abandon a patent challenge and delay entering the market with a lower cost, generic product. As the Supreme Court recently explained, "there is reason for concern that settlements taking this form tend to have significant adverse effects on competition."[2] The core concern with these agreements—what the Court termed "the relevant anticompetitive harm"—is that they will allow the brand to "prevent the risk of competition" by splitting monopoly profits with the prospective entrant.[3]

Anticompetitive pay-for-delay agreements violate the antitrust laws and undermine the goals and spirit of the Hatch-Waxman Act,[4] which seeks to prevent weak patents from obstructing the development of lower-cost, generic competition. Consumers, federal and state governments, and other purchasers of prescription drugs, all of which are already struggling to contain increasing health-care costs, pay a substantial price for these deals.[5]

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[1] This written statement represents the views of the Federal Trade Commission. My oral presentation and responses to questions are my own and do not necessarily reflect the views of the Commission or of any other Commissioner.
[2] *Federal Trade Commission v. Actavis, Inc.* ("*Actavis*"), No. 12-416, 570 U.S. __ (2013), slip op. at 8.
[3] *Id.* at 19.
[4] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended 21 U.S.C. § 355 (1994)). For a discussion of the Act's statutory background, see "Protecting Consumer Access to Generic Drugs: The Benefits of a Legislative Solution to Anticompetitive Settlements in the Pharmaceutical Industry," FTC Testimony before the Subcommittee on Trade, Commerce, and Consumer Protection, Committee on Energy and Commerce (May 2, 2007) at 8-9, *available at* http://ftc.gov/os/testimony/P859910%20Protecting_Consume_%20Access_testimony.pdf. For a discussion of the Act's statutory scheme, see *Actavis*, No. 12-416, 570 U.S. __ (2013), slip op. at 2-5.
[5] Fed. Trade Comm'n, Pay For Delay: How Drug Company Pay-Offs Cost Consumers Billions (Jan. 2010), *available at* http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf. ("Pay-for-Delay Report").

For these reasons, the Commission has long recognized that stopping anticompetitive pay-for-delay deals is a matter of pressing national concern. Since this issue first arose in 1998, every single member of the Commission, past and present—whether Democrat, Republican, or Independent—has supported the Commission's challenges to these agreements. The Commission remains united today in its determination to end these illegal pay-for-delay agreements.

The Commission appreciates the concern that Chairman Klobuchar, Senator Grassley and this subcommittee have expressed about pay-for-delay agreements and your important work to protect consumers from anticompetitive settlements. We, of course, are aware of Chairman Klobuchar, Senator Grassley, and others' bill to address pay-for-delay agreements and appreciate your efforts in this important area. For its part, the Commission will continue to investigate and challenge these agreements. My testimony today focuses on the Supreme Court's recent ruling and its impact on the Commission's pay-for-delay enforcement agenda.

The Supreme Court's decision last month in *FTC v. Actavis, Inc.*,[6] is an important victory for consumers and a vindication of basic antitrust and free market principles. With it, the Commission achieved one of its top competition priorities: overturning the so-called "scope-of-the-patent" test, which had been adopted by some courts and virtually immunized pay-for-delay settlements from antitrust scrutiny.[7] Because of the *Actavis* decision, we are in a much stronger position to protect consumers from anticompetitive drug-patent settlements that result in higher drug costs.[8] The decision and the Commission's enforcement agenda should deter many

[6] No. 12-416, 570 U.S. __ (2013).
[7] Under the "scope-of-the-patent" test, "absent sham [patent] litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent[.]" *FTC v. Watson Pharm., Inc.*, 677 F. 3d 1298, 1312 (2012).
[8] It is important to note that most pharmaceutical patent settlements do not raise antitrust concerns. *See infra* p. 10 (noting number of settlements without compensation to the generic challenger).

companies from entering into anticompetitive agreements. This, in turn, will help consumers, employers, and taxpayers who would otherwise suffer from reduced competition and higher prices.

To achieve those ends, the Commission will continue to:

- pursue pay-for-delay matters currently in litigation and seek appropriate relief for consumers;
- monitor private litigations alleging pay-for-delay agreements and leverage Commission experience and expertise by filing *amicus* briefs where appropriate;
- investigate pending pay-for-delay matters;
- examine new settlements that companies file with the Commission pursuant to the Medicare Modernization Act of 2003 ("MMA") and investigate those that raise anticompetitive concerns;[9] and
- issue regular reports on pharmaceutical settlements filed with the Commission pursuant to the MMA.

In addition, the Commission will re-examine settlements previously filed with the Commission in light of the *Actavis* decision to determine whether they merit further investigation.[10]

When determining whether to pursue a case, the Commission will consider the seriousness of the violation, the potential consumer harm, the Commission's ability to remedy the harm, the legal principle at stake in each matter, and the potential deterrent effect of an enforcement action. Where there is a violation, the Commission has a number of remedial tools at its disposal, including prospective restrictions to prevent future violations, rescinding the illegal agreement, and taking other actions to help expedite generic entry.[11]

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[9] Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug Improvement and Modernization Act (FY 2012), *available at* http://www.ftc.gov/os/2013/01/130117mmareport.pdf. ("2012 Report"). For an explanation of the MMA filing requirements, *see* Pub. L. No. 108-173, §§ 1111-1118.

[10] *See infra* p. 12.

[11] In addition, under the Hatch Waxman Act, a generic company automatically forfeits its entitlement to the 180-day exclusivity period that is otherwise available to first filing generics if it is found to have violated the antitrust laws or the Federal Trade Commission Act. Amended 21 U.S.C. § 355(j)(5)(D)(i)(V) (2003).

I. Preventing Anticompetitive Pay-for-Delay Settlements Remains a Top Commission Priority

Pay-for-delay settlements increase the cost of prescription drugs for consumers, employers, and taxpayers and have become an increasingly common phenomenon. In FY 2004, the first year that pharmaceutical companies were required to file their agreements with the antitrust agencies, there were no such deals. According to our most recent data, by FY 2012, however, there were 40 potentially anticompetitive patent settlements between brand-name and generic drug companies. This number represents a significant increase over the 28 potentially anticompetitive deals filed in FY 2011. Overall, the FY 2012 agreements covered 31 different brand-name pharmaceutical products with combined annual U.S. sales of more than $8.3 billion.[12] *See* Chart 1.

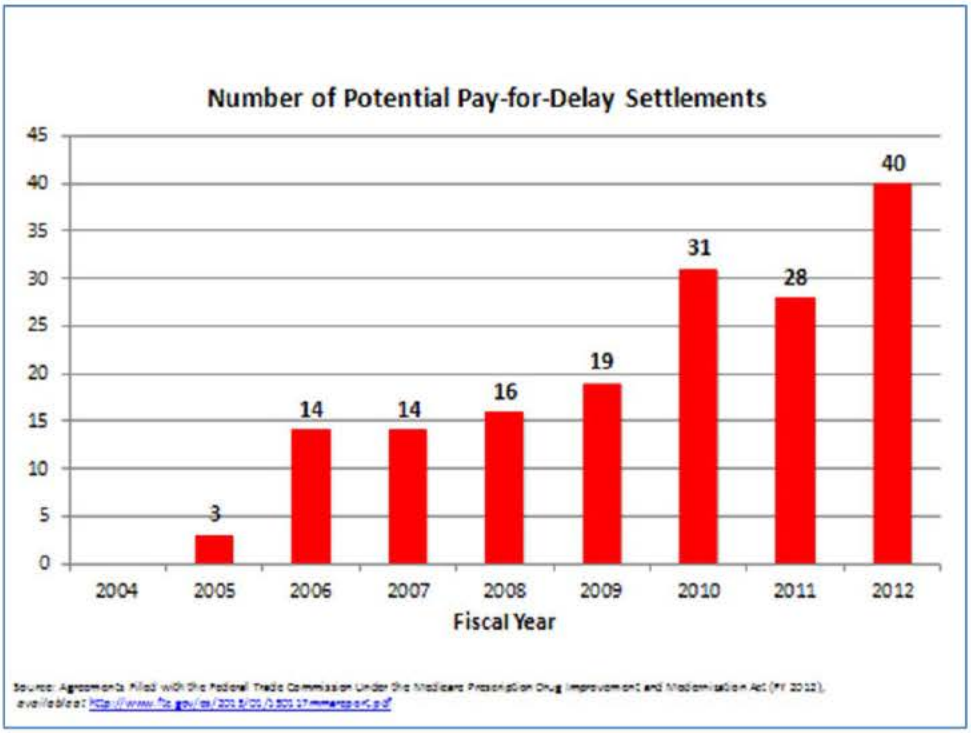

Chart 1

[12] Press Release, FTC Study: In FY 2012, Branded Drug Firms Significantly Increased the Use of Potential Pay-for-Delay Settlements to Keep Generic Competitors off the Market (Jan. 17, 2013), *available at* http://www.ftc.gov/opa/2013/01/mmarpt.shtm.

These deals have occurred with increasing frequency in the pharmaceutical industry for two reasons. First, they are highly profitable for both the brand-name drug firm and the generic drug company. The brand-name version of a drug sells at a monopoly price, but the generic versions sell at a significant discount. Typically, the first generic sells at a 20 percent discount off the branded price, and a discount of as much as 85 percent is common in a mature generic market with multiple generic entrants.[13] Lower-priced generic competitors take significant market share from the brand-name company as a result. Because the generic is priced substantially lower, the profits the brand-name drug company stands to lose are typically far greater than the profits the first generic entrant stands to gain from the sales of its product.

Consequently, it will generally be more profitable for both parties if the brand-name manufacturer pays the generic manufacturer to settle the patent dispute and defer generic entry. By eliminating the potential for competition by a generic product, the parties can share the monopoly profits preserved by the delayed entry, appropriating for themselves the consumer savings that would have resulted if the firms had instead competed. Under these circumstances, the parties are resolving their dispute at the expense of consumers. *See* Figure 1.

[13] *See* Pay-for-Delay Report, *supra* note 5; *see also*, Congressional Budget Office, How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry (July 1998) (hereinafter "CBO Study"), *available at* http://www.cbo.gov/showdoc.cfm?index=655&sequence=0.

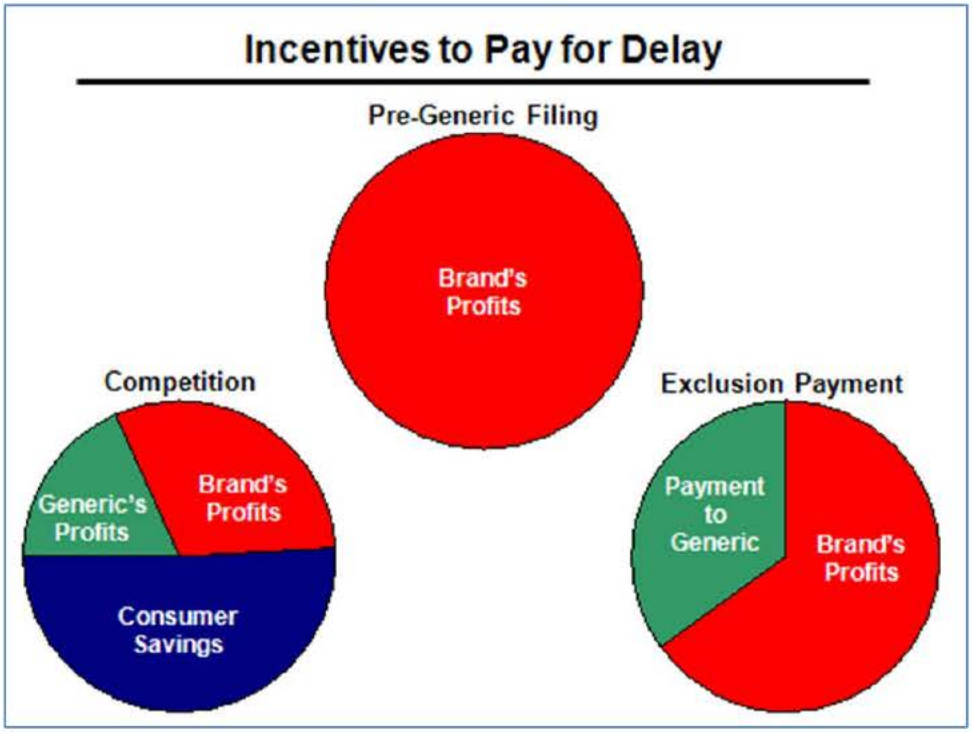

Figure 1

Eliminating the potential for early generic entry imposes enormous costs on consumers, for the federal and state governments, and for employers and other purchasers. As an example, generic entry following successful patent challenges involving just four major brand-name drugs (Prozac, Zantac, Taxol, and Platinol) is estimated to have saved consumers more than $9 billion overall.[14]

The second reason pay-for-delay settlements of pharmaceutical patent litigation have become more common is that prior to the Supreme Court's decision in *Actavis*, three federal appellate courts had adopted an overly lenient legal rule, the so-called "scope-of-the-patent"

[14] *Generic Pharmaceuticals Marketplace Access and Consumer Issues: Hearing Before the Senate Commerce Comm.*, 107th Cong. (Apr. 23, 2002) (statement of Kathleen D. Jaeger, President & CEO, Generic Pharmaceutical Ass'n) at 12, *available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107_senate_hearings&docid=f:90155.pdf.

test.[15] Under this standard, a brand company, except in rare circumstances, could buy off generic competition until the day of patent expiration and face no antitrust scrutiny. The adoption of this permissive rule further encouraged companies to enter deals delaying generic entry. As we explained in our briefing to the Supreme Court in *Actavis*: "Given the profitability of reverse-payment agreements, if this court were to adopt the scope-of-the-patent approach as the applicable nationwide rule, brand-name manufacturers would have little reason not to offer their potential generic competitors payments not to compete, and the generic manufacturers would have little reason to refuse."[16] Because of the tremendous costs imposed on consumers by these anticompetitive settlements, the Commission has been resolute in its efforts to prevent them.

II. The Supreme Court's Decision in *FTC v. Actavis*

In 2009, the Commission challenged two patent settlements involving AndroGel, a testosterone replacement drug with annual sales exceeding a billion dollars. As alleged by the Commission, Solvay Pharmaceuticals, Inc. (now AbbVie, Inc.) agreed to pay generic drug makers Watson Pharmaceuticals, Inc. (now Actavis, Inc.) and Par Pharmaceutical Companies, Inc. to delay generic competition. According to the February 2009 complaint, Solvay provided payments of hundreds of millions of dollars to Watson and Par collectively to induce the generic companies to abandon their patent challenges and agree to forbear bringing a generic AndroGel product to market for nine years until 2015. Applying the scope-of-the-patent test, the Eleventh Circuit affirmed a dismissal of the suit because the settlement did not prevent competition beyond the patent's expiration date.

[15] Note that not all circuit courts adopted the scope-of-the-patent test. *See In re K-Dur Antitrust Litig.* ("*K-Dur*"), 686 F.3d 197 (3d Cir. 2012); *Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799 (D.C. Cir. 2001).
[16] Brief for the Petitioner at 18, *Actavis*, No. 12-416, 570 U.S. __ (2013).

Shortly after the Eleventh Circuit decision, the Third Circuit in *K-Dur* rejected the scope-of-the-patent approach and held reverse-payment settlements presumptively anticompetitive.[17] This January, the Supreme Court granted certiorari in *Actavis* to resolve the resulting conflict between the circuit courts. In its June decision, the Court found no basis to support the scope-of-the-patent standard. It refused to treat the patent as if it had been adjudicated valid and infringed, as the industry had urged: "to refer, as the [Eleventh] Circuit referred, simply to what the holder of a valid patent could do does not by itself answer the antitrust question."[18] Instead, the Supreme Court ruled that pay-for-delay agreements are appropriately subject to rule of reason scrutiny, the standard applied in most antitrust actions, under which courts consider evidence that the agreement harms consumers.

Although not declaring reverse-payment settlements presumptively illegal, the Supreme Court agreed with the Commission that pay-for-delay settlement agreements can harm consumers and violate the antitrust laws, and explicitly rejected arguments urged by those

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[17] 686 F.3d at 214-18.

[18] *Actavis*, No. 12-416, 570 U.S. __ (2013), slip op. at 8. Certainly, real-world experience has long shown that, when litigated to judgment, many patents do not prevent generic entry, and successful patent challenges have occurred on blockbuster drugs. Paul Janicke & Lilan Ren, *Who Wins Patent Infringement Cases?* 34 AIPLA Q.J. 1, 20 (2006) (finding that, between 2002 and 2004, generic challengers had a 70 percent success rate in the Federal Circuit in cases deciding the merits of a pharmaceutical patent claim – *i.e.*, validity, infringement, or enforceability); *see also* Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, 19-20 (July 2002), *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf (finding that, based on all patent litigation initiated between 1992 and 2000 between brand-name drug manufacturers and generic applicants and litigated to a decision on the merits, the generics prevailed in cases involving 73 percent of the challenged drug products.). For specific examples, *see, e.g.*, *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, No. 2007-1280, 2008 WL 2039065 (Fed. Cir. May 14, 2008) (patents covering blood-clotting drug Lovenox held unenforceable), *petition for cert. filed*, 77 U.S.L.W. 3441 (U.S. Jan. 23, 2009) (No. 08-937); *Aventis Pharma Deutschland GmbH v. Lupin Ltd.*, 499 F.3d 1293 (Fed. Cir. 2007) (patent covering high blood pressure drug Altace found invalid); *Daiichi Sankyo Co., Ltd. v. Apotex Inc.*, 501 F.3d 1254 (Fed. Cir. 2007) (patent covering method of treating ear infections with ofloxacin held invalid); *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348 (Fed. Cir. 2007) (patent covering hypertension drug Norvasc held invalid); *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312 (Fed. Cir. 2006) (product-by-process patent covering anti-depressant drug Paxil was invalid); *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286 (Fed. Cir. 2006) (claims of patent related to extended release urinary incontinence drug Ditropan XL held invalid and not infringed). Indeed, the Commission's challenge to the alleged anticompetitive settlements in *Cephalon* involves a patent covering a multi-billion dollar drug that the Federal Circuit found to be invalid and unenforceable. *Apotex, Inc. v. Cephalon, Inc.*, No. 2012-1417, 2013 U.S. App. LEXIS 7018 (Fed. Cir. Apr. 8, 2013). For a description of the Commission allegations in *Cephalon*, *see infra* note 32.

defending these settlements as virtually always lawful. In so ruling, the Court provided some useful guidance showing how reverse-payment settlements may violate the antitrust laws.

First, the Court found that a reverse payment has the potential for "genuine adverse effects on competition" because it enables the brand company to use its monopoly profits to induce the generic to abandon its claim and thereby allow the brand to "prevent the risk of competition."[19] The threat posed by such a sharing of monopoly profits with a would-be competitor is the primary concern the Commission has raised about these deals.

Second, the Supreme Court explained the need to assess the justifications offered for the payment.[20] The Court stated, "Where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of non-infringement."[21] Thus, companies "may show in the antitrust proceeding that legitimate justifications are present."[22]

Third, the Supreme Court recognized that a brand-name drug manufacturer likely has the power to bring about anticompetitive harm in practice—*i.e.*, it likely has market power.[23] As the Court explained, "a firm without that power" is unlikely "to pay 'large sums' to induce 'others to stay out of its market.'"[24]

Fourth, the Supreme Court held that "it is normally not necessary to litigate patent validity" to determine the anticompetitive effects of the settlement.[25] As the Court explained,

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[19] *Actavis*, slip op. at 14.
[20] *Id.* at 17.
[21] *Id.*
[22] *Id.* at 18.
[23] *Id.*
[24] *Id.* (quoting 7 Areeda ¶ 2046, at 351). The Court also relied on a study cited by the Commission "showing that reverse payment agreements are associated with the presence of higher-than competitive profits—a strong indication of market power." *Id.* (citing Brief for Petitioner at 45).
[25] *Id.*

"prevent[ing] the risk of competition"—even where the patentee's risk of losing the patent suit may be small—is "the relevant anticompetitive harm."[26] Consequently, companies cannot defend their agreements by merely arguing that the brand-name drug company would likely have prevailed had the patent case been fully litigated or that the settlement provided for entry prior to patent expiration.

Finally, the Supreme Court recognized that parties in the pharmaceutical industry can and routinely do settle patent litigation without reverse payments, specifically rejecting the defendants' argument that such payments are necessary for settlement.[27] Over 75 percent of patent settlements since fiscal year 2005 have *not* contained both compensation to the generic and the generic's agreement to delay entry.[28] As the Court recognized in *Actavis*, parties "may, as in other industries, settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point."[29]

III. The Commission's Enforcement Priorities in Light of *Actavis*

In *Actavis*, the Supreme Court emphasized the need for antitrust scrutiny of pay-for-delay agreements. To that end, the Commission will continue to pursue its two current pay-for-delay litigations—*Actavis* and *FTC v. Cephalon*.[30] We expect that the *Actavis* case will be remanded to the federal district court in the Northern District of Georgia for further proceedings. Because

[26] *Id.* at 19.
[27] *Id.*
[28] 2012 Report, *supra* note 9.
[29] *Actavis*, slip op. at 19.
[30] *FTC v. Cephalon, Inc.*, No. 08-cv-2141 (E.D. Pa. complaint filed Feb. 13, 2008) ("*Cephalon* Compl."), *available at* http://www2.ftc.gov/os/caselist/0610182/080213complaint.pdf. The Commission has alleged that Cephalon entered into anticompetitive pay-for-delay agreements to prevent generic competition to its leading product, Provigil. Provigil treats excessive sleepiness caused by narcolepsy and sleep apnea, and has annual sales of more than $800 million. The Commission charges that Cephalon agreed to pay in excess of $200 million to settle patent litigation with four manufacturers of generic versions of Provigil, in order to induce them to abandon their plans to sell generic Provigil for six years, until 2012. Cephalon's CEO observed shortly after entering these agreements: "We were able to get six more years of patent protection. *That's $4 billion in sales that no one expected*." *Id.* at 2 (emphasis added).

the district court previously granted a motion to dismiss, the case will now proceed through the usual steps of litigation. *Cephalon* is in a different posture. The Commission filed suit in February 2008 and the parties had conducted much of the necessary discovery prior to the district court's stay of the proceedings pending the outcome of the *Actavis* decision. Earlier this month, the district court held a status conference and has asked the parties to propose a schedule for moving forward by July 31. Our goal is to resolve these pending matters as quickly as possible and show that these pay-for-delay settlements violate the antitrust laws.

In addition to our active litigation, we will also continue to monitor private actions involving possible pay-for-delay deals. These can provide opportunities for the Commission to file *amicus* briefs on a variety of issues raised by pay-for-delay settlements.[31] We can use our significant experience and expertise regarding pharmaceutical matters to provide necessary background that may assist a court in deciding a matter.

The *Actavis* standard laid down by the Supreme Court will also allow the Commission to challenge other pay-for-delay deals that are anticompetitive. To that end, we will continue to pursue and assess a number of open investigations.

We will also continue to review the pharmaceutical patent settlements that companies are required to file with the antitrust agencies. In response to concerns about pay-for-delay agreements, Congress, as part of the MMA, required branded and generic companies that enter into patent litigation settlements to file those settlement agreements with the FTC and the Department of Justice for antitrust review.[32] The MMA is purely a notice and filing provision; alone, it does not grant the agencies the power to delay or block settlements. With the *Actavis*

[31] *See, e.g.*, Federal Trade Commission Brief as *Amicus Curiae, In re Lamictal Direct Purchaser Antitrust Litig.*, No. 2:12-CV-00995-WHW-MCA (D.N.J.) (Oct. 5, 2012).
[32] *See supra* note 9 (discussion of MMA filing requirements).

decision, the MMA's filing requirement is more likely to serve its intended purpose: preventing anticompetitive agreements from escaping antitrust scrutiny.

In light of the *Actavis* decision, we are also re-examining settlement agreements previously filed with the Commission. A single anticompetitive agreement can easily increase prescription drug costs by many millions of dollars, and Commission staff plan to determine whether previously filed agreements now merit additional investigation and possible legal action.

Finally, we will continue to study the effects of pharmaceutical settlements and issue reports of our findings. Those reports provide valuable information on the frequency of compensation and delay, and the rate of settlement without those troubling features.[33] We expect future reports to continue to provide useful information to Congress, the public, and the industry.

Conclusion

Anticompetitive pay-for-delay agreements undermine the policy goals of the Hatch-Waxman Act, harm consumers, and violate the antitrust laws. For almost fifteen years, the Commission has dedicated significant resources to prevent these deals because it believes that these settlements can significantly harm consumers and competition. The Supreme Court's decision in *Actavis* confirms that these settlements harm consumers and competition, and the Commission will continue to aggressively prosecute these anticompetitive settlements.

Thank you for this opportunity to share the Commission's views. The Commission looks forward to working with the Subcommittee to protect consumers from anticompetitive pay-for-delay settlements that cost taxpayers billions of dollars.

[33] *See supra* note 9 (discussion of 2012 report).