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PAY-FOR-DELAY DEALS: LIMITING COMPETITION AND COSTING CONSUMERS

HEARING

BEFORE THE

SUBCOMMITTEE ON ANTITRUST, COMPETITION POLICY AND CONSUMER RIGHTS

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PAY-FOR-DELAY DEALS: LIMITING COMPETITION AND COSTING CONSUMERS

TUESDAY, JULY 23, 2013

U.S. SENATE,
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The Committee met, pursuant to notice, at 10:01 a.m., Room 226, Dirksen Senate Office Building, Hon. Amy Klobuchar, Chairman of the Subcommittee, presiding.

Present: Senators Franken, Blumenthal, Grassley, and Lee.

OPENING STATEMENT OF HON. AMY KLOBUCHAR, A U.S. SENATOR FROM THE STATE OF MINNESOTA, CHAIRMAN, SUBCOMMITTEE ON ANTITRUST, COMPETITION POLICY, AND CONSUMER RIGHTS

Senator KLOBUCHAR. Good morning, everyone. Welcome to today's hearing. We're going to examine the pay-for-delay settlement agreements. We welcome our witness and Federal Trade Commission Chairwoman Ramirez, who is appearing before our Subcommittee for the second time this year. So, we thank you for that.

Last year, analysts estimated that our country spent $325 billion on prescription drugs and they predict that drug sales will rise by more than four percent in the year 2014. Generic drugs, which can cost as much as 90 percent lower than brand-name drugs, help rein in the costs.

For example, a brand-name drug that costs $300 per month might be sold as a generic for as little as $30 per month, but for several years, pay-for-delay deals have robbed consumers of cost-saving generic drugs. At the very core, these deals involve collusion between brand and generic competitors to keep generic competition off the market.

Let's be very clear about what these deals are all about. A brand-name drug company pays—they pay—their generic competitor cash or another form of payment. In exchange, the generic delays its entry into the marketplace. That is why we call them pay for delay.

So the brand company wins because it gets to maintain its monopoly, and the generic company wins because they get paid more than they would have if they came to market. But American consumers and American taxpayers lose out on lower-cost generic drugs to the tune of billions of dollars each year, $3.5 billion according to the Federal Trade Commission.

Now, this wasn't always the case. From 2000 to 2004, after courts found these agreements to be illegal, there wasn't a single pay-for-delay deal among the settlements entered into between

brand and generic companies, not one, so pharmaceutical litigation can be settled without these cash sweeteners to delay generic competition.

It wasn't until 2005 when two Circuit Courts said these deals were not subject to antitrust scrutiny that we began to see dozens of pay-for-delay deals each year, directly related to those Circuit Court decisions.

The effect of these court decisions has been blunt. Last year, the number of pay-for-delay settlements ballooned 40 percent over the previous year. The FTC identified 40 pay-for-delay deals involving 31 different brand-name drugs, with combined annual U.S. sales of more than $8.3 billion.

These pay-for-delay deals are about more than drug companies and their lawsuits, they are about real people and they're about quality health care. Take Karen Winkler, for example. She suffers from multiple sclerosis and was prescribed the drug Profedil, which helps combat fatigue. Because a pay-for-delay agreement kept generic competition off the market for six years, the drug cost her $500 per month, even with insurance. As a result, she would skip pills or skip dosages.

In 2011, she had to stop taking it altogether, against her doctor's orders, because it got too expensive. Meanwhile, the CEO of the company that made the drug had this to say about the pay-for-delay deal: "We were able to get six more years of patent protection. That's $4 billion in sales that nobody expected."

Unfortunately, that $4 billion came out of consumers' pockets, including Karen's. This issue is also about taxpayers and the federal budget. Medicare is the largest buyer of prescription drugs. If pay-for-delay deals limit generic entry, then taxpayers get stuck with the bill for higher-priced brand-name drugs.

The Supreme Court's decision in *FTC* v. *Actavis* was a turning point. The court finally said what we have been saying for years, that pay-for-delay settlements harm consumers and deserve to be scrutinized under the antitrust laws.

The court said that the payments may provide "strong evidence that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market."

While this was a major step forward, there is still work that needs to be done. That is why Senator Grassley and I have introduced bipartisan legislation to further combat pay-for-delay agreements that keep cheaper generic drugs off the market.

Our bill would make these back-room sweetheart deals between brand-name and generic drug companies presumptively illegal. It does not make every agreement illegal, but it does require that drug companies prove to a judge that a deal in question is not anticompetitive. That is a measured approach that strikes the right balance to ensure that companies will have the ability to settle cases. They just can't do so without payments to delay competition and harm consumers.

So today we will hear from Chairwoman of the FTC, who has shown a steadfast commitment to fight for consumers and lower-cost drugs by challenging pay-for-delay agreements all the way to the Supreme Court. American consumers are counting on you to

fight these deals so that consumers have access to affordable generic drugs.

Ms. Ramirez, we look forward to hearing from our second panel, where I think we will have a lively debate about pay-for-delay deals, the need for legislation, and the contours of the Supreme Court's decision.

With that, I turn to our Ranking Member, Senator Lee, for his opening remarks. I know that Senator Grassley is going to make a few remarks, and Senator Franken, you're welcome to as well.

Senator Lee.

OPENING STATEMENT OF HON. MIKE LEE, A U.S. SENATOR FROM THE STATE OF UTAH

Senator LEE. Thank you, Madam Chair.

Pharmaceutical patents are extremely valuable and it's for good reason that they're valuable. On average, it takes 10 years and $1 billion to develop and gain FDA approval for a new drug. The intellectual property in that new drug allows developers and researchers to recoup their enormous investment.

Those drugs that gain approval and for which there is market demand have the potential not only to defray the initial outlays, but also to make their owners sizable profits as a reward for the risk undertaken in the process of securing both the patent and, later, the FDA approval.

Both this recoupment of investment and these profits are jeopardized by lawsuits that are filed by generics who seek to invalidate drug patents so that they can enter the market. Our laws incentivize these lawsuits by generics by granting the first generic challenger a period of dual exclusivity with the brand-name manufacturer.

Faced with even the remote prospect of losing their valuable patent, not to mention the substantial litigation costs, some brand-name manufacturers have chosen to settle lawsuits filed by generics instead of litigating to the merits of the issue of patent validity.

In some instances, these settlements involve the patent owner paying the challenger generic company millions of dollars and allowing it to enter the market before the expiration of the patent, all in exchange for simply dropping its lawsuit challenging the patent.

These patent settlements, or reverse settlements as they're sometimes called, are the subject of today's hearing. Opponents of reverse settlements have for several years argued that they're anti-competitive and that they should be subject either to a rule of per se invalidity or to a presumption of illegality.

Proponents of the agreements, on the other hand, have argued that the agreements can never properly be considered anti-competitive since the patent involved grants the owner a period of monopoly and the settlements do not extend or expand the term of that monopoly.

Both sides have found support in Circuit Court decisions, leading the Supreme Court to grant certiorari in a case presenting this very issue. In its recent ruling in *Activist*, the court rejected both sides' arguments as extreme because in the court's view reverse

settlements may sometimes be anti-competitive and sometimes not, a one-size-fits-all rule would be improper. Rather, the court held that courts should analyze reverse settlements on a case-by-case basis using what in antitrust law has long been called the Rule of Reason.

Federal courts have nearly a century of experience in applying the Rule of Reason to cases and controversies brought before them. Proper judicial administration of this approach protects consumer welfare, the touchstone of all of our antitrust laws.

In the event some pharmaceutical manufacturers are entering into patent settlements to shield a weak patent from scrutiny and to divide among themselves an invalid patent's unjustified monopoly, the Rule of Reason will ensure such agreements do not stand.

At the same time, the Rule of Reason comports with an objective, evidence-based approach to antitrust law. It ensures that social policies or other priorities apart from consumer welfare are not imported into antitrust analysis.

Where reverse settlements have pro-competitive effects by allowing generics to enter the market for a brand-name drug before the expiration of a properly granted patent, the Rule of Reason will wisely stay the government's hand. The Rule of Reason thus benefits consumers, both by protecting against high prices and by respecting intellectual property and preserving the innovation that leads to important advances in science and, in particular, in health care.

Any proposal with respect to reverse settlements must therefore be weighed against the proven ability of the Rule of Reason to balance and effectuate both of these important policies. I look forward to hearing from the witnesses, and I thank them for being here today.

Senator KLOBUCHAR. Thank you very much, Senator Lee.

Senator Grassley.

OPENING STATEMENT OF HON. CHARLES E. GRASSLEY, A U.S. SENATOR FROM THE STATE OF IOWA

Senator GRASSLEY. Yes. This is a very important hearing that we're having to learn more about pay-for-delay agreements. I think they harm drug competition. This is an issue I've been working on for a long time, and I'm surely pleased to have a teammate in Senator Klobuchar so that we can stop these abusive deals. We should be doing all we can to see that the American consumer has access to lower-priced drugs and do it in a way to get those lower prices as soon as possible.

The reality is that these deals between brand-name and generic pharmaceutical companies delay the entry of generic medicines into the marketplace, and I don't see how these agreements are competitive on how they—or how they benefit the consumer. In my opinion, they only end up keeping drug costs artificially high for consumers and the taxpaying public.

Further, these agreements threaten the long-term sustainability of federal health programs, particularly Medicare and Medicaid, so I commend the Federal Trade Commission for being vigilant in this area. I urge the Commission to continue protecting the American

consumer by continuing to take action against drug companies engaged in anti-competitive agreements.

Madam Chair, I have a written statement from Senator Vitter that I would like—that he'd like to have entered into the record. Senator Vitter also agrees that pay-for-delay settlements are a problem and would like to see Congress do something about it. I think he has ideas, but they're not dissimilar from what you and I are trying to accomplish.

Senator KLOBUCHAR. Very good. I appreciate your leadership on this issue, and Senator Vitter's statement will be included in the record.

[The prepared statement of Senator Vitter appears as a submission for the record.]

[The prepared statement of Senator Grassley appears as a submission for the record.]

Senator KLOBUCHAR. Senator Franken.

Senator FRANKEN. I'll save my opening for my question period. I think it will have more power.

[Laughter.]

Senator KLOBUCHAR. Thank you.

Senator Blumenthal, if you want to——

Senator BLUMENTHAL. As so frequently happens, I'm going to follow Senator Franken's lead, without seeking to emulate his sense of humor.

[Laughter.]

Senator BLUMENTHAL. But I just want to thank you, Madam Chairman, for having this hearing, and to our Ranking Member as well. This hearing is critical to our health care system and to American competitiveness.

Thank you very much.

Senator KLOBUCHAR. Well, thank you very much.

I would like to now introduce a distinguished witness on our first panel. Ms. Edith Ramirez is the Chairwoman of the Federal Trade Commission. She was sworn in as Commissioner of the FTC on April 5, 2010, and was designated as Chairwoman by President Obama on March 4 of this year.

Prior to joining the Commission, Ms. Ramirez was a partner in private practice in Los Angeles, representing clients in intellectual property, antitrust, and unfair competition suits.

Ms. Ramirez, if you could rise.

[Whereupon, the witness was duly sworn.]

Senator KLOBUCHAR. Thank you. Please begin with your statement.

STATEMENT OF HON. EDITH RAMIREZ, CHAIRWOMAN, FEDERAL TRADE COMMISSION

Chairwoman RAMIREZ. Chairman Klobuchar, Ranking Member Lee, and Members of the Subcommittee, thank you for inviting me to testify today about the Federal Trade Commission's effort to stop anti-competitive 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 blocking the development of lower-cost generic drugs.

Stopping these anti-competitive 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 that 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 11th 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 before the Supreme Court this spring in the Actavis case, where the Court considered the Commission's challenged patent settlements involving Solvay's billion-dollar testosterone replacement drug, Androgel.

The Commission alleged that Solvay agreed to pay three generic manufacturers hundreds of millions of dollars to abandon their patent challenges and delay roll-out of a generic version for nine years, until 2015.

Applying the scope of the patent test, the 11th 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 11th Circuit ruling, the Third Circuit rejected the scope of the patent test in a private case involving another brand-name drug and held pay-for-delay agreements presumptively unlawful. This created a Circuit Court split that set the stage for the Supreme Court's review of the issue.

The *Actavis* decision was a significant victory for American consumers, taxpayers, and competition. The Supreme Court made 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 payment settlements have the potential for genuine anti-competitive 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, challenge reverse payment settlements, and decide them under a Rule of Reason standard. The Supreme Court ruled that courts must assess the drug company's justifications for the payments, including whether the payments were for something other than purchasing protection from potential competition. The Court was also clear that the anti-competitive effects

of a reverse payment settlement can typically be determined without litigating the underlying patent claim.

The Actavis decision is an important milestone, but the Commission's work is far from over. Harmful pay-for-delay settlements will not suddenly disappear, but there is now a path forward to stop them. To that end, we will continue to focus our resources on investigating and challenging those anti-competitive 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 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 a strong statement made by the Supreme Court in Actavis, will provide a significant deterrent effect. I look forward to continuing work with the Members of this Committee on how best to use the antitrust laws to promote the interests of consumers and gaining access to lower-cost generic drugs.

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

[The prepared statement of Chairwoman Ramirez appears as a submission for the record.]

Senator KLOBUCHAR. Thank you very much, Madam Chairwoman.

Earlier this year, the FTC released its annual report, as we mentioned, on pay-for-delay agreements that showed that in FY 2012 there were 140 settlements between brand and generic firms, and 40 of them involved pay for delay.

Now, you mentioned pursuing some of the cases, or the one that was in court in Philadelphia and some other ones. Just to make clear, what is the Commission now going to do in light of the Supreme Court decision with the 40 pay-for-delay agreements?

Chairwoman RAMIREZ. Chairman Klobuchar, the top priority for the agency will be to continue to press forward with two pending litigation matters in this area, as I mentioned, the Actavis case and the Cephalon case, so those will be the top priority. Our aim will be to prevail in those matters and show that the agreements at issue are in fact violative of the antitrust laws.

In addition, we intend to press forward with pending investigations that we have, as well as review settlements that have been previously filed with the agency pursuant to the *Medicare Modernization Act* and review them in light of the *Actavis* decision by the Supreme Court, as well as continue to vigilantly monitor any new agreements that are filed with the agency.

In addition, we do also aim to, as appropriate, file amicus briefs in connection with private litigation matters involving pay-for-delay settlements.

Senator KLOBUCHAR. Right. That's a lot and I assume that these are very complex agreements. Are you going to put additional resources in light of—how are you going to handle that, given sequestration and everything else?

Chairwoman RAMIREZ. This issue has been a top priority for the agency for many years, and we're going to continue to devote as many resources as necessary to achieve our aim to put an end to these practices.

Senator KLOBUCHAR. Would it be easier to do if the bill that Senator Grassley and I passed to make things clearer?

Chairwoman RAMIREZ. I want to emphasize that the *Actavis* decision was an important step forward and it has strengthened our ability to tackle these complaints. At the same time, these lawsuits are resource intensive and time consuming.

Litigating one of these suits to judgment can take many years. I do believe that the legislation that you have proposed, that you and Senator Grassley have sponsored, would create more of a bright-line rule and also create more of a deterrent effect and it could help further our effort to stop these practices.

Senator KLOBUCHAR. Yes. That's our focus here. Generic and brand-name companies—we're going to hear from them on the next panel—argue that pay-for-delay deals can be pro-competitive because the settlement may allow for entry for one to two years before the patent expires, and if the case was litigated to completion and the generic company lost, it would be five to 10 years until the patent expires.

What's your response to the criticism? Isn't generic competition one or two years prior to the patent expiring better than waiting until the patent expires?

Chairwoman RAMIREZ. The issue that we're concerned about here is that a reverse payment has the potential to "eliminate the risk of competition." That was the language that the Supreme Court used, and I agree with that. So the issue here is that a payment will distort the competitive process and lead to delayed entry of generic competition that otherwise would have existed absent the reverse payment.

Senator KLOBUCHAR. Exactly. I mean, I was just struck by the fact that there were settlements before, but not with the pay-for-delay element, until those Circuit Court cases came out.

Chairwoman RAMIREZ. Absolutely. Let me also emphasize that in our review of these settlements, we find that the vast majority of settlements in the pharmaceutical industry between pharmaceutical companies do not involve reverse payments, so the position that the FTC has taken does not impede the ability of these firms to settle.

Senator KLOBUCHAR. Exactly.

Chairwoman, drug companies say that having the ability to settle patent litigation is critical to promoting their ability to innovate and develop the next great miracles of modern medicine. What is your response? I assume it's along the lines of what you just said,

that the vast majority of these settlements don't involve the pay-for-delay.

Chairwoman RAMIREZ. Absolutely. The Supreme Court recognized this in the *Actavis* decision. What we are trying to stop are anti-competitive settlements. We're not trying to impede settlement of disputes that do not violate the antitrust laws.

Senator KLOBUCHAR. And do you think that limiting pay-for-delay settlements unreasonably restrains the ability of branded and generic firms to settle cases, and therefore taxes innovation?

Chairwoman RAMIREZ. I don't. Again, what we're trying to promote is competition. We want to promote innovation. We want to prevent any type of reverse payment settlement that would distort the competitive process.

Senator KLOBUCHAR. Exactly.

Then one last thing on a little different topic. While we're on this topic of pay-for-delay, another area where patent and antitrust law intersects is patent trolls. Last month, I sent a letter to the full Commission calling on it to approve your proposal for a 6(b) study to examine the unfair competition posed by patent trolls. What is the status of the Commission's review of the 6(b) proposal, and how soon do you think they can get the study under way?

Chairwoman RAMIREZ. I agree that a study would be a valuable mechanism that could be used to evaluate both the harms and efficiencies of patent assertion entity. The agency is in the process of evaluating whether such a study would be valuable. If the Commission determines that it is, then we're going to proceed expeditiously.

Senator KLOBUCHAR. Okay. I liked your quote when you talked about this and the need for the study. You said that the use of patent trolls "allows operating companies to exploit the lack of transparency in patent ownership to win a tactical advantage that could not be gained with a direct attack."

Could you talk about the harm that that does to consumers and competition? We're going to be having a hearing on a related matter on standards next week on this Subcommittee.

Chairwoman RAMIREZ. We are concerned with examining the increased litigation activity of patent assertion entities that there may be significant tax on competition by virtue of their exploiting flaws in the patent system. So it's an issue that does raise complicated questions and I want to make sure that I'm not condemning all patent assertion activities. That's why I believe that a study would be appropriate so that we can more fully understand the competitive impact of these activities.

Senator KLOBUCHAR. Okay. Thank you. I just want to again thank you for your work. When that court decision came out I couldn't help but think of all the work that it's going to be for lawyers, but also work for the FTC, which is already strapped with some of the resource issues we have.

I'm not here to talk about that; I'm more trying to figure out how we can (1) help consumers, and (2) make this work the best possible. To me, it's passing this bipartisan legislation to make it clearer what the rule is. Again, we're not including all settlements between pharmaceuticals and generics, we are just simply looking at these pay-for-delay settlements, as you so well point out.

So, thank you very much, and I will turn it over to Senator Lee.

Senator LEE. Thank you very much for joining us today, Madam Chairwoman. I appreciate your testimony and your insight on these issues.

I want to talk just a little bit about our use of the term "pay for delay" today. This causes me some concern that we use this term this broadly because in your testimony you used the term pay for delay to refer to a whole category of reverse settlements among pharmaceutical manufacturers without qualifying that term further.

Now, it is my understanding that these settlements do not extend the term of the patent, but in fact most of the time they end up shortening of the patent by allowing the generic manufacturer to enter the market before the generic manufacturer would otherwise be able to enter the market, assuming that the patent itself is valid.

In fact, it would make no sense for a brand-name manufacturer to make such an attempt, to attempt to extend the length of the patent on the underlying drug, because in order for that to work, in order for that to be effective, they would have to settle with every possible potential competitor out there who might choose to enter the market on that drug once the patent term expires, and doing that is not something that's allowed under our patent law and would present, plainly, anti-competitive impacts which would create actionable antitrust problems. So, that's really not a possibility.

So, with respect to the reverse settlements that we're discussing today, one can argue that the agreements delay the entry of the market—of the generic into the market if, and only if, we assume that the generic is entitled to enter the market immediately, that is, prior to the expiration of the patent.

But to assume that requires us to assume at the outset that the patent is, in fact, invalid. So do you agree that none of the agreements that we're talking about today extend, first of all, the terms of the patent beyond the life of the patent?

Chairwoman RAMIREZ. I agree with that.

Senator LEE. Okay.

Chairwoman RAMIREZ. But I don't agree with the rest of your assertions.

Senator LEE. Okay. So why is it then appropriate to use the term pay for delay with respect to a reverse settlement that applies to a drug, the patent attached to which is, in fact, valid? How is that paying for delay if the generic is not entitled to enter the market prior to the expiration of the patent term?

Chairwoman RAMIREZ. I believe that pay for delay is an accurate characterization of these types of anti-competitive reverse payment settlements, and the reason is that a reverse payment allows a brand to, as the Supreme Court put it, eliminate the risk of competition and induce a generic to agree to a date of entry that would not otherwise have taken place in the absence of a particular payment.

So our position does not assume that there would be immediate generic entry, it merely raises a concern from an antitrust perspec-

tive about the way that a reverse payment can distort that negotiation process and the normal competitive process.

Senator LEE. Right. But if you assume the patent's validity, then you would agree that the generic manufacturer is not going to be able to enter the market until the end of the patent term, right?

Chairwoman RAMIREZ. Correct. But your assumption is, in fact, that the patent is valid. The objective of the Hatch-Waxman Act is—one of them is to incentivize generic companies to challenge weak patents in order to introduce lower-cost generic drugs. So one can't assume that the patent is necessarily valid, and that's precisely what the concern is, that the payment will, in fact, induce a generic challenger to abandon a claim of invalidity and a claim of non-infringement, and that's what raises the competitive concern.

Senator LEE. But our legal system in the world of intellectual property, our laws, creates a statutory presumption as to the patent's validity. Would you agree with that statement?

Chairwoman RAMIREZ. I agree with that.

Senator LEE. Okay. So if, in fact, our laws create a statutory presumption of the patent's validity, then why are you so quick to assume that all of these so-called reverse settlements can appropriately be described as pay for delay?

Chairwoman RAMIREZ. Well——

Senator LEE. Wouldn't they just as appropriately be described—or more appropriately be described—as pay for resolution of uncertainty as to the patent's validity? I mean, we do, in fact, have this presumption and if that presumption is valid, if it's called for by law, I don't know why you would want to presume the opposite. I think you have to presume that the patent is invalid in order, legitimately, to call it pay for delay.

Chairwoman RAMIREZ. I disagree. I'm not presuming—I'm not making any particular assumption as between those two. The concern—and I'm not—I'm also not saying that every single reverse payment settlement is in fact anti-competitive, rather that there is a category of them, and I believe there is a tendency for these types of settlements to, in fact, likely lead to anti-competitive consequences.

So the concern here is a payment that is intended to, again, induce a generic patent challenger to abandon a claim and to delay its entry into the market.

Senator LEE. Okay. Okay. So——

Chairwoman RAMIREZ. And the inquiry is precisely to ascertain—the inquiry that we would engage in is to ascertain whether the reverse payment was in fact for purposes of delay, as opposed to for other legitimate—other legitimate reasons.

Senator LEE. Right. Okay. Okay.

So the use of the term "pay for delay" then refers to the fact that you could, in some circumstances, have some of these that are collusive. Perhaps the patent is invalid and what they're paying for is something nefarious, it's something that they're not entitled to.

Chairwoman RAMIREZ. What they're paying for is delayed generic entry. These types of payments permit and incentivize the brand-name firm and the generic firm to split monopoly profits. It's ad-

vantageous and more profitable for them to do that than to simply proceed with the litigation.

Senator LEE. Okay. And if you're presuming that such a thing could happen but you're not presuming that it's always the case with all of these reverse settlements in this context, isn't that an appropriate occasion to use the Rule of Reason analysis?

Chairwoman RAMIREZ. I agree with the holding of the Supreme Court. I mean, we're fine testing these settlements under the Rule of Reason. At the same time, I believe that litigating these cases can be costly and time consuming, and I also believe that a bright-line rule, such as one that was proposed by the legislation that Chairman Klobuchar and Senator Grassley are proposing, would create more of a deterrent effect.

Again, my concern is that these types of payments, which are unusual and only seen in the pharmaceutical context, and even within that context are only a small minority of settlement agreements, these elevate the antitrust risks and pose a significant detriment to competition. So that's the concern and that's why I believe that while the Rule of Reason standard is an appropriate test and we intend to apply that going forward, I do believe that declaring them to be presumptively invalid would also further help us to put a stop to these types of settlements.

Senator LEE. My time's expired. Thank you very much.

Senator KLOBUCHAR. Thank you very much, Senator Lee. And just to make clear, as the Chairwoman has stated, this bill that Senator Grassley and I have that has bipartisan support would not affect the vast majority of the drug settlements, and even for the pay-for-delay settlements it creates a presumption that they are invalid and illegal, which can be overcome if the pharmaceuticals and generics are able to prove that somehow the pro-competitive benefits outweigh the anti-competitive harm. So while we call it a bright-line rule, which it is because it says they're presumptively illegal, it does have some exemptions that can be proven in court.

So that's how it works, because we are aware of all these unique characteristics of these agreements. We just feel that right now the Supreme Court has opened the doors, which is great, but we still have a reason to want to make clear what the presumption is here instead of putting it as a burden on the FTC.

Chairwoman RAMIREZ. Yes. Thank you for that.

Senator KLOBUCHAR. Yes. I thought you'd like that answer, Chairwoman Ramirez.

Senator Franken.

Senator FRANKEN. Thank you, Madam Chairwoman, for your work on this. I will be, in the next panel, asking Professor Carrier about sort of this very issue. In his brief, I believe, to the Court—the Supreme Court, he said that figure approaches 75 percent in litigation that these patents, when they're challenged, turn out to be invalid. But I'll ask in the next panel.

I've really enjoyed working with the Chairwoman on this legislation to bring down prescription drug costs for Minnesota Senators—seniors and Senators.

[Laughter.]

Senator FRANKEN. It's an issue that we both care about deeply. I'm proud to sponsor the *Klobuchar-Grassley Preserve Access to Af-*

fordable Generics Act. It's a good bipartisan bill and I know that you've taken great care—both of you, great care—and effort in drafting it. I am also—I'm grateful for your support, Madam Chair, for the *Franken-Vitter Fair Generics Act*.

What our bill would do is fairly simple. It provides subsequent filers with an exclusivity period if the first filer relinquishes that privilege in a pay-for-delay deal. Making this change to the law will diminish the incentive for patent holders to enter into these pay-for-delay agreements in the first place, and fewer pay-for-delay deals will result in more prescription drugs on the market, which in turn will drive down prices.

Chairwoman Ramirez, the FTC reported that in Fiscal Year 2012 there were 40, as we have heard, pay-for-delay settlement agreements. That's a record high. In your view, what accounts for the increase in these deals, and do you anticipate that they will remain prevalent in the coming years unless Congress and the FTC acts?

Chairwoman RAMIREZ. I think there are two main reasons why we've seen a steady rise in these types of settlements over the years. The first, is that there is an incentive for the brand-name manufacturer and the generic manufacturer to split monopoly profits, so that's one powerful incentive in which the two firms end up gaining at the expense of consumers.

Second, I also believe that the scope of the patent test, which had been adopted by a number of courts over the years, led to an overly permissive standard that encouraged these types of settlement agreements. My hope is that with the strong statement that's been made by the Supreme Court, that in and of itself will prove to be a strong deterrent against these types of settlements.

We certainly intend to enforce the law aggressively under the standard that's been set by the Supreme Court, so my hope is that the combination of those things will help put an end to these types of settlements.

Senator FRANKEN. In the *Actavis* case, as we've heard, the court said that pay-for-delay agreements need to be analyzed on a case-by-case basis, or a middle-ground approach. As the FTC begins litigating cases under the *Actavis* decision, what kinds of evidence will it use to show that pay-for-delay agreements are anti-competitive in particular cases, and what sorts of things will the FTC look for in the patent settlements that are filed with the Commission?

Chairwoman RAMIREZ. I believe that the Supreme Court provided some useful guidance in the *Actavis* decision. The kinds of issues that we're going to be addressing are: Is there a payment or other form of compensation, what is the size of that payment, what's the purpose of the payment, is there a legitimate justification for the payment? We're also going to be examining the competitive effects of any such agreement. So those are the issues that we would be looking at and litigating under the Rule of Reason standard that's been set out by the Court.

Senator FRANKEN. Would it consider pay-for-delay—whether the pay-for-delay settlements have a disproportionate effect on seniors? Is that——

Chairwoman RAMIREZ. That's certainly a concern of ours and one of the reasons that we're seeking to put an end to pay-for-delay agreements because, to the extent that seniors do share a dis-

proportionate burden when it comes to drug charges, they clearly are impacted. So that's a concern of ours and certainly one of the reasons that we are trying to combat these.

Senator FRANKEN. Thank you.

Thank you, Madam Chair.

Senator KLOBUCHAR. Thank you very much, Senator Franken, and thank you for your work in this area.

Senator Grassley.

Senator GRASSLEY. Yes. And thank you, Madam Chairwoman, for coming to help us with this important issue.

Supporters of pay-for-delay settlements claim that legislation to establish a presumption of illegality for these kinds of settlements is "unnecessary and inconsistent with longstanding principles of antitrust and patent law."

So, Chairwoman, do you believe that pay-for-delay legislation like the Klobuchar-Grassley bill is "unnecessary and inconsistent with longstanding principles of antitrust and patent law"? Why or why not?

Chairwoman RAMIREZ. I don't agree with that statement. As I've indicated, we see the *Actavis* decision as a victory for American consumers and we're pleased to move forward, seeking to put a stop to anti-competitive reverse payment settlements under the Rule of Reason that the Supreme Court has set forth.

At the same time, my view is that it is, again, resource intensive, time consuming to litigate these cases to judgment, and I believe that the proposed legislation that declares reverse payment settlements, anti-competitive reverse payment settlements to be presumptively invalid, but at the same time allows settling parties to overcome that presumption, would be a quicker way of putting an end to these types of settlements.

Senator GRASSLEY. On another point, in your written testimony you state that "the Medicare Modernization Act is purely a notice and filing provision. Alone, it does not grant the agencies the power to deny or block settlements. With the *Actavis* decision, the MMA's filing requirement is more likely to serve its intended purpose of preventing anti-competitive agreements from escaping antitrust scrutiny."

As you probably know, I worked hard to make sure that this notice and filing provision was included in that legislation. We wanted to deter drug companies from entering into anti-competitive pay-for-delay settlements, and also empower the FTC with the knowledge of when these kinds of problematic settlements could be occurring.

So, Madam Chairwoman, with the statement from your written testimony that I just quoted, are you saying that the MMA filing and notice requirement is not a sufficient enough deterrent to anti-competitive behavior? And before you answer, if so, are there any improvements to this provision that you would suggest? Are you suggesting that we consider giving the FTC Commission greater ability to block or delay settlements that are seen to be potentially abusive?

Chairwoman RAMIREZ. Let me simply clarify that the statement that you quoted from the written testimony merely states that the MMA provisions under which pharmaceutical companies are re-

quired to file settlements with the antitrust agencies didn't alter the substantive antitrust standards.

It's an important provision and it allows us to actually see what firms are doing when we review these agreements. So it's an absolutely important provision and our point was merely that now that we have the Actavis decision we are going to be in a position to more effectively combat those settlements that we believe to be anti-competitive.

Senator GRASSLEY. So then there don't need to be any changes in MMA from your point of view?

Chairwoman RAMIREZ. Not with respect to what you're quoting, that's correct.

Senator GRASSLEY. Okay.

Given the rate at which pay-for-delay settlements have increased, what do you think is the best approach to address the problem? How does FTC plan to move forward with respect to the Supreme Court's decision in that case, and are there any FTC policies that you believe need to be changed in response to the Court's ruling?

Chairwoman RAMIREZ. I believe that the Supreme Court itself has sent a very strong message to industry indicating, again, that these settlements are subject to antitrust scrutiny. We intend to vigorously apply the standard that has been set forth by the Supreme Court and, as I mentioned, my aim is to prevail in the two pending lawsuits that the FTC has involving pay-for-delay settlements.

In addition, we're going to be reviewing settlements that have been previously filed with us pursuant to the MMA—reviewing them in light of the *Actavis* decision, also trying to be as vigilant as possible when it comes to the filing of new agreements, and submitting amicus briefs where appropriate in connection with private lawsuits.

So we intend to be very active in this area, and we believe that the combination of our enforcement and other efforts, along with the strong message that's been sent by the Supreme Court, my hope is that that will end up being a deterrent, hopefully putting an end to these types of anti-competitive agreements.

Senator GRASSLEY. You might be aware or you might not be aware that I worked closely with the FTC and Chairman Lebowitz on this issue. I look forward to working with you. According to the 2010 Federal Trade Commission report entitled "Pay For Delay: How Drug Companies Payoffs Cost Consumers Billions," these settlements cost consumers approximately $35 billion over 10 years. The report recommended that Congress pass legislation to protect these anti-competitive agreements.

Do you plan to make pay-for-delay settlements a priority at the Federal Trade Commission under your leadership?

Chairwoman RAMIREZ. Combating pay-for-delay settlements has been a priority for over 15 years at the Commission. It continues to be a priority and we're going to put whatever resources we need to in order to seek to put a stop to these.

Senator GRASSLEY. Yes. I will yield back my time. Thank you, Madam Chairwoman.

Senator KLOBUCHAR. Thank you very much, Senator Grassley.

Senator Blumenthal.

Senator BLUMENTHAL. Thank you, Madam Chairwoman. Again, my thanks to you and to the Chairwoman and Senator Grassley for their bill, which I would anticipate joining. I'll be interested in hearing from the next panel about the arguments opposed to this measure, but I think it's a good pro-consumer measure and I would expect that I will be joining in support of it as a co-sponsor.

Let me understand a little bit more about the process that will follow the FTC investigation under this bill. As I understand it, the FTC can then initiate action, either in Federal District Court or before an administrative judge, if it finds that there is no justification for this pay for delay or compensation for delay. Perhaps you could enlighten us as to how the FTC will choose between those two fora, the District Court or the administrative judge.

Chairwoman RAMIREZ. It can depend on a number of factors. We often proceed administratively, but we do have the ability to move forward in federal court. So it depends on the circumstances of the case. It may also depend on the type of relief that the agency would be seeking.

Senator BLUMENTHAL. And how would that determine the outcome, the type of relief?

Chairwoman RAMIREZ. For instance, if the agency were to seek equitable monetary relief we would want to proceed in federal court.

Senator BLUMENTHAL. As State Attorney General, I was among the States that frequently dealt with abuses and misuses of patents, so I have seen firsthand the difference that it can make, the very grave harm that it can do to consumers not only in terms of delaying the availability of a drug, but also the affordability. So I feel very strongly that your determination is welcome, and I want to thank you for it.

Can you give us examples of circumstances where a pay-for-delay agreement might be justified through the FTC investigation process? Are there such circumstances, if any, when you can anticipate some payment would be exempted from the presumption against it?

Chairwoman RAMIREZ. Sure. And the Supreme Court spoke to this in the *Actavis* decision. So, for instance, if a payment merely reflects anticipated litigation costs that would be avoided, that would be one instance where we would not conclude that the payment was for anti-competitive purposes.

Senator BLUMENTHAL. And if that claim were made, how would you determine whether in fact it was factually justified, the magnitude of the payment, the nature of the agreement? What would you look to?

Chairwoman RAMIREZ. It would be a fact-specific determination, so we would be looking very closely, comparing, yes, the size of the payment in relation to anticipated future litigation expenses. That would certainly be a key factor, but we would be looking again closely at all of the relevant facts.

Senator BLUMENTHAL. And aside from litigation costs, can you anticipate or describe other circumstances that might justify these types of payment?

Chairwoman RAMIREZ. There may be services that might be provided that are entirely independent of any desire to make a pay-

ment to induce abandoning a patent challenge in order to delay generic entry, so in that circumstance a payment may be justified. But again, all of this would depend very much on the specifics of any particular case, so it is an intensive—fact-intensive inquiry.

Senator BLUMENTHAL. Would it be lengthy?

Chairwoman RAMIREZ. These do take time to evaluate, yes.

Senator BLUMENTHAL. But presumably they could be put on a fairly fast track if the presumption indicated that they should be, in effect, barred or pursued through legal means?

Chairwoman RAMIREZ. I can assure you that we're going to be pursuing and evaluating these agreements and pursuing pending investigations as expeditiously as possible. At the same time, we want to be careful only to move forward with regard to anti-competitive agreements that do cause serious harm.

Senator BLUMENTHAL. In your experience, are these pay-for-delay agreements increasing in number and importance? I know the number is 100 out of 140 did not involve, over the recent past, pay-for-delay kinds of settlements, but in your experience are they increasing? Should we be more and more concerned about them?

Chairwoman RAMIREZ. Yes. Over the course of the time that we have been examining these settlement agreements, we have seen a steady increase. In Fiscal Year 2012 we saw 40 reverse payment settlements that are potentially anti-competitive, so we have seen a steady increase. And again, our hope is that now that there's a standard that's been set by the Supreme Court, that will create a deterrent effect.

Senator BLUMENTHAL. Thank you.

Thank you very much.

Senator KLOBUCHAR. Thank you very much, Madam Chairwoman. We appreciate your testimony.

Do you have anything more? Senator Lee, okay.

Senator LEE. Just to follow up on where we were a few minutes ago, so suppose, as I understand as has happened on a couple of occasions, you have had a reverse payment settlement in one of these scenarios and that settlement allows the generic manufacturer to enter the market prior to the expiration of the patent term, thereby introducing competition, but in a subsequent challenge to the validity of the patent there was in fact a finding that the patent was valid.

In that circumstance it appears that you actually introduced competition earlier and there appear to have been some price-moderating influences as a result of that earlier entry. Wouldn't you have to concede that then in that circumstance you've got pro-competitive effects?

Chairwoman RAMIREZ. When a brand-name manufacturer has a strong patent it is likely to prevail in litigation. That's absolutely fine with us. As you've noted, it's absolutely appropriate for the manufacturer of a pioneer drug to recoup its investment if it has a strong patent that withstands scrutiny and is deemed to be valid. That's an absolute fine result from an antitrust perspective.

The concern that we have, again, is evaluating agreements from the time that they're entered into whether the objective is, in fact, to eliminate the risk of competition and induce a generic patent challenger to abandon the patent challenge when we don't know

what the outcome would have been and to agree to a delayed rollout of a generic product. So that's what the concern is.

Senator LEE. Okay. And again, is it your position that Rule of Reason analysis is itself inadequate to the degree that it makes this legislation necessary?

Chairwoman RAMIREZ. I don't believe the Rule of Reason standard is inadequate. My point in backing the proposed legislation is simply to say that—that in my view—because of the significant concern that these types of agreements raise, in my view it would be appropriate to have a presumption which can then be rebutted because it would create greater clarity and it would create more of a deterrent effect and would help the agency more quickly eliminate anti-competitive reverse payment settlements.

Senator LEE. Okay. Thank you.

Senator KLOBUCHAR. Thank you very much. I would just note again for the record, when you have a CEO talking about the fact that we were "able to get six more years of patent protection, that's $4 billion in sales that nobody expected."

To me, when you look at the numbers and the change since those Circuit Court decisions, this is more than just about some patent litigation, this was about a deliberate effort to delay these drugs onto the market to increase profits on the backs of consumers.

That's why we are trying to do something that's reasonable, that will still not upset the market with innovation, which I don't think it will in any way, and we're focused on this very narrow category that I know the FTC has been focused on of these pay-for-delay deals. Narrow as it may be in a litigation standpoint, it's not narrow for the consumers that have been having to foot the bill. So, thank you very much, Madam Chairwoman.

Now we will bring up our second panel. Thank you.

Chairwoman RAMIREZ. Thank you.

Senator KLOBUCHAR. All right. I'd like to introduce the distinguished witnesses on our somewhat large second panel, and we'll start with Mr. Robert Romasco. He is the president of AARP. Before becoming president, he served as board secretary and treasurer and chairs the organization's Audit and Finance Committee. Mr. Romasco was previously the president and chief executive officer at J.C. Penney Direct Marketing Services.

Next, we have Ms. Diane Bieri. She is a partner at Arnold & Porter, working with the firm's health care and antitrust practice groups. She's also worked for the Pharmaceutical Research and Manufacturers of America as their executive vice president and general counsel.

Next, we have Mr. Michael Carrier, that I believe Senator Franken referred to, who is a professor at the Rutgers University School of Law and a leading authority in antitrust, copyright, and patent law. He is a member of the Board of Advisors at the American Antitrust Institute and a past chair of the Executive Committee of the Antitrust and Economic Regulations Section of the Association of American Law.

Next, we have Mr. Jonathan Orszag. I know your brother and I was at his wedding. He is a senior—I assume you were there.

Mr. ORSZAG. So was I.

Senator KLOBUCHAR. Okay. That's good. I was a little nervous to ask that, but I'm glad you were there. That's a good thing. Is a senior managing director and member of the Executive Committee at the economic consulting firm Compass Lexecon, LLC. Previously he served as an economic policy advisor to President Clinton's National Economic Council, and also served as the assistant to the U.S. Secretary of Commerce. Additionally, Mr. Orszag is a Senior Fellow at the Center for American Progress and a Fellow at the University of Southern California's Center for Communication Law and Policy.

Next, Mr. Mike Russo. He is the U.S. Public Interest Research Group's Federal program director. From 2010 to 2012, he was U.S. policy analyst for health care, and prior to that he served as CALPER's health care advocate. Mr. Russo has authored and co-authored numerous reports on health care policy.

Finally, Mr. Sumanth Addanki is currently the senior vice president of NERA Economics, where he specializes in antitrust, intellectual property, and the evaluation of commercial damages. He has analyzed the competitive consequences of mergers in a wide range of industries and addressed the liabilities involving predatory pricing and monopolization. Thanks to all of you for appearing at our Subcommittee's hearing to testify today. I ask you to rise so I can administer the oath.

[Whereupon, the witness was duly sworn.]

Senator KLOBUCHAR. Thank you very much.

Mr. Romasco, if you could begin with your opening statement.

STATEMENT OF ROBERT G. ROMASCO, PRESIDENT, AARP, WASHINGTON, DC

Mr. ROMASCO. Thank you, Chairman Klobuchar, Ranking Member Lee. On behalf of AARP's more than 37 million members, we thank you for holding this hearing on pay-for-delay agreements.

My name is Rob Romasco. I am a member of AARP's all-volunteer board of directors and I am honored to serve as AARP's president.

Older Americans use prescription drugs more than any other segment of the U.S. population. These drugs play a critical role in their health and financial security. Two-thirds of people 65 and older report using three or more prescription drugs within the past month, 40 percent used five or more. Unfortunately, retail prices for brand-name drugs continue to rise faster than inflation.

In contrast, generic prescription drugs are considerably less expensive. In fact, retail prices are actually falling. Generic drugs have proven to be one of the safest, most effective ways for consumers to lower their prescription drug costs. They have been essential to the recent slowdown in health care spending.

AARP believes that eliminating pay-for-delay agreements will result in additional savings for consumers and taxpayers. Pay-for-delay agreements provide financial benefits to prescription drug manufacturers at the expense of consumers.

The Federal Trade Commission estimates that pay-for-delay agreements cost consumers and taxpayers $3.5 billion a year. If nothing changes, that's $35 billion over the next 10 years. The FTC has found pay-for-delay agreements keep generics off the market

for an average of nearly 17 months longer than patent settlement agreements without such payments. In the meantime, consumers must pay brand-name drug prices, typically 80 to 85 percent higher than generics.

This substantially raises the costs for consumers, businesses, and taxpayer-funded health programs such as Medicare and Medicaid. Putting an end to these agreements will not only save consumers and taxpayers money, but will also help prevent patients, including older Americans, from foregoing needed medications because of the high cost of brand-name drugs.

Researchers have found that the cost is one of the primary reasons why older adults do not fill prescriptions, skip doses, or take smaller doses. When people do this, they ultimately use more expensive urgent care and expensive inpatient hospital services later on. This results in extra health care costs, estimated to be as much as $290 billion each and every year, not to mention the toll on the individuals' health and lives.

Unfortunately, pay-for-delay agreements are increasing. Given that the pharmaceutical faces an unprecedented number of patent expirations, this trend will continue and is likely to accelerate.

Several of the top 10 leading medicines, including Nexium, Celebrex, and Crestor, are set to lose patent protections over the next few years. A recent report by AARP's Public Policy Institute examined events as the popular anti-cholesterol drug, Lipitor, first faced generic contribution, including a reported pay-for-delay agreement.

The report found that the retail price of Lipitor increased by 17.5 percent in 2011. Lipitor is raising its price while the alleged pay-for-delay was in place. The average annual retail price of Lipitor increased by roughly $300 between 2010 and 2011. I hear from our members just how punishing brand-name drugs' prices can be. John Charles from Greenwood, Indiana, is one example. A long-time Lipitor user, he was paying $70 out of pocket for a three-month supply. Now, with the generic, he only pays $15 for that same three months' supply. This may not sound like much, but to John and for millions of older Americans, particularly those on fixed incomes, this reduction made, in his words, "a dramatic difference."

AARP has filed a Friend of the Court brief in the recent Supreme Court challenge on pay-for-delay. We supported the FTC's argument that pay-for-delay agreements are anti-competitive. The Supreme Court decision represents a major step forward with more antitrust claims against pay-for-delay likely to go to court and receive the scrutiny they deserve.

However, experts generally agree that pay-for-delay agreements, while now more legally risky, will continue unless Congress intervenes. We believe legislative solution is needed to eliminate these agreements and save money for consumers, businesses, and taxpayers.

We urge Congress to take action on Senate bill 214, the *Preserve Access to Affordable Generics Act*, a bipartisan bill sponsored by Senator Klobuchar and Grassley. The CBO, as we know, expects this legislation would accelerate the availability of generic drugs and save $4.7 billion over 10 years.

We are also a strong supporter of another bipartisan bill, Senate bill 504, the *Fair and Immediate Release of Generics Act*, sponsored by Senators Franken and Vitter. The CBO estimate of savings for that is $3.8 billion over 10 years.

We are committed to working to further lower the cost of prescription drugs through the enactment of responsible changes that improve access and reduce costs for consumers, businesses, and Medicare and Medicaid.

We look forward to working with Members of Congress from both sides of the aisle to address pay-for-delay agreements. We seek to ensure that each and every American has access to affordable prescription drugs. Thank you very much.

Senator KLOBUCHAR. Very good. Thank you very much.

[The prepared statement of Robert G. Romasco appears as a submission for the record.]

Ms. Bieri.

STATEMENT OF DIANE E. BIERI, PARTNER, ARNOLD & PORTER LLP, WASHINGTON, DC

Ms. BIERI. Senator Klobuchar, Ranking Member Lee, Members of the Subcommittee, good morning. My name is Diane Bieri and I'm a partner in the law firm of Arnold & Porter. I'm appearing today on behalf of the Pharmaceutical Research and Manufacturers of America. PhRMA members are leading research-based pharmaceutical and biotech companies working to develop new life-saving and life-enhancing treatments.

PhRMA and I appreciate the invitation to participate in today's hearing on important issues concerning pharmaceutical patent settlements. During my own more than 10 years in private practice, I have counseled pharmaceutical companies on the antitrust implications of Hatch-Waxman settlements and represented these companies in antitrust proceedings before the FTC and in various courts.

And, of course, while I was general counsel at PhRMA, I worked on these issues intensively and helped shape PhRMA's advocacy positions on this important topic. I'd like to begin by briefly putting the patent settlements we're discussing today in context.

As Ranking Member Lee noted, it takes, on average, more than $1 billion and 10 to 15 years to bring an innovative medicine to market, and the majority of drug candidates fail during the development process. Innovators need strong patent protections simply to justify making the huge and very risky investments required for drug development.

In contrast, the *Hatch-Waxman Act* allows generic drug companies to use a far less expensive and faster pathway to FDA approval. One expert has pegged the cost of preparing and filing an abbreviated new drug application for a generic at about $1 million.

Based on this and other factors, the *Hatch-Waxman Act* creates significant incentives for drug companies, generic drug companies—to challenge patents, even where the innovator is highly likely to prevail in litigation. According to a recent analysis based on the FTC's own data, a first filing generic challenger often can justify challenging an innovator's patent if it believes it has only a 1.3 percent chance of success of winning that patent challenge in court.

Against this backdrop, it's not surprising that we have seen a proliferation of *Hatch-Waxman Act*'s challenges. it also should not come as a surprise that parties often prefer to minimize costs, minimize litigation risks, and deal with business uncertainty by settling *Hatch-Waxman Act* cases rather than litigating them to final judgment.

In spite of these dynamics, the FTC and others have criticized certain types of patent settlements as pay for delay, but respectfully the very term "pay for delay" is a misnomer in at least two significant respects. First, we can't lose sight of the fact that these settlements, where the innovator gives something of value to the generic, brought generic drugs to market months or years before the patent expiration, before the expiration of presumptively valid patents.

What's more, consideration flowing from the innovator to the alleged infringer is a typical dynamic in settlements. In traditional patent litigation, an alleged infringer brings its product to market, the patent holder files suit, and a settlement often takes the form of a patent holder declining to collect a portion of its damages from the infringer.

Under the *Hatch-Waxman Act*, a generic company can trigger patent litigation without marketing its product so there won't be any damages for the innovator to forgive. In such cases, a separate, pro-competitive transfer of value from the innovator to the generic company can bridge the gap and allow parties to reach a settlement where they could not do so based solely on a generic entry date.

Critics of these types of settlements seem to believe that innovators are willing to settle primarily because the patents in question are weak. But frankly, the data from multiple sources show that innovator companies have prevailed in 50 percent or more of Hatch-Waxman cases litigated to court decisions between 2000 and 2012.

The fact is, we can't simply assume that the innovator's payment or other transfer of value to the generic results in delayed generic entry. Instead, as the Supreme Court told us in the *Actavis* case, we need to look at each settlement on a case-by-case basis in order to determine its net effect on competition.

The Court also explicitly said that these complex settlements should not be subjected to a short-cut presumption of illegality. That is typically reserved for only the most obviously anti-competitive conduct. Applying such a presumption here would be a significant departure from antitrust and patent law principles, it would not necessarily add clarity, and it would significantly undermine the value of patents that are the cornerstone of pharmaceutical innovation.

Thank you again for the chance to speak with you today, and PhRMA looks forward to working with you and all the Members of the Subcommittee and others in Congress on these, and other important issues relating to access to medicines.

[The prepared statement of Diane E. Bieri appears as a submission for the record.]

Senator KLOBUCHAR. Thank you.

Professor Carrier.

STATEMENT OF MICHAEL A. CARRIER, DISTINGUISHED PROFESSOR, RUTGERS UNIVERSITY SCHOOL OF LAW, CAMDEN, NJ

Professor CARRIER. Chairman Klobuchar, Ranking Member Lee, Members of the Subcommittee, thank you for holding this hearing. Reverse payment settlements are one of the most important antitrust issues that we face today. They have a direct effect on the health of millions of Americans and there still is a role for Congress to play even after the *Actavis* decision.

My name is Michael Carrier. I'm a distinguished professor at Rutgers Law School in New Jersey and I have spent my career focused on the intersection of the antitrust and the intellectual property laws. I began at Covington & Burling here in town, focused on these issues, and in my time in academia, I wrote a 400-page book with Oxford press on antitrust and IP and more than 50 articles on antitrust and IP, including a bunch on reverse payment settlements, as well as briefs in appellate courts and one in the Supreme Court on behalf of 118 professors and the American Antitrust Institute that Justice Breyer cited in the *Actavis* decision.

In a nutshell, antitrust alarm bells should be going off when you hear that one company is paying a second company not to enter the market. Market division is per se illegal, and the reason is that there's no competition whatsoever, even worse than price fixing, because the parties do not compete.

Now, here there's a patent, but keep in mind the big picture. The big picture here is that exclusion is not coming from the patent, but it's coming from the payment. So the first problem we have here is that we have significant concerns of market division.

The second problem is that we have the *Hatch-Waxman Act* that has been twisted beyond recognition. Initially there was a 180-day period of exclusivity that was designed to encourage generic entry into the market. The problem is that that period has been twisted so that other generics are not able to enter the market.

The brand company buys off the first generic, and no other generics can enter. So when the first generic says I'm going to enter in 10 years, there's no competition for that period of time. You put together market division, a perversion of the 180-day period, and the fact that this has real consequences for Americans that are not able to take their medications, as we've heard this morning, and we see that there is a real problem.

In the *Actavis* decision, the Supreme Court recognized that reverse payment settlements can be severely anti-competitive, it said that these payments can be unjustified, it said that there could be market power when you see a large payment, and it said that there are ways of settling cases other than with reverse payments.

At the end of the day and despite all that, however, it only applied the Rule of Reason. Under the Rule of Reason, the court said we need to look at various factors, like the size of the payment, the scale in relation to future litigation costs, and independence from other services.

After the decision, the drug companies were not very happy, so PhRMA and the generics association and generic firms like Actavis said this is an uncertain decision, we don't know how to settle

these cases and so we need more clarity, there's something wrong with the decision.

You look at Chief Justice Roberts in dissent in *Actavis* and he said, look, Congress has not acted. There have been 11 times that Congress has considered legislation since 2006, and Congress still has not acted.

S. 214 would be beneficial. The findings section of S. 214 would make clear that the intent of *Hatch-Waxman* has been subverted. The purposes section of S. 214 would make clear that stopping these anti-competitive agreements is a good thing that would help competition. And this would help future courts in trying to figure out how to deal with these complicated agreements.

Most important, as we've heard this morning, S. 214 creates presumptive illegality. We heard from the Chairwoman of the FTC how presumptive illegality will help the FTC in going to court and making clear to courts that this is behavior that generally is illegal, and sure, if you want to come back and show how in a particular case it's not illegal, that's fine, but the default presumption is that this is illegal. S. 214 is also helpful in making clear that just because you have entry before the end of the patent term, that doesn't necessarily mean that it is pro-competitive.

In short, I would say that S. 214 is something that the Subcommittee should look very favorably at: S. 214 would confirm the hazards of reverse payment settlements; S. 214 would provide a framework that would allow the FTC to challenge these settlements in court; and S. 214 would help save consumers money and deal with a pressing problem of public health. Thank you.

[The prepared statement of Michael A. Carrier appears as a submission for the record.]

Senator KLOBUCHAR. Thank you very much. Very good.

Mr. Lee is going to—Senator Lee is going to go out and buy the 400-page book. That's what he was just talking about.

Mr. Orszag.

STATEMENT OF JONATHAN M. ORSZAG, SENIOR MANAGING DIRECTOR, COMPASS LEXECON, LLC, WEST PALM BEACH, FL

Mr. ORSZAG. Thank you, Madam Chair, Ranking Member Lee, Members of this Subcommittee. Good morning.

I have conducted extensive economic research on the effect on consumers of reverse payment patent settlements. The research demonstrates that reverse payment settlements can be good for consumers under certain real-world situations.

One key reason: In those situations, without a payment from the brand to the generic, the parties will be unable to reach an agreement on a settlement even if that settlement were good for consumers. Thus, attempts to ban patent settlements in which some form of consideration is provided to the generic would be misguided public policy because such a ban would make consumers worse off.

One may ask, why would the branded company enter into a, what I'm going to call a pay-for-entry settlement, allowing earlier competition from lower-priced generics? The answer: litigation is expensive. It has a lot of uncertainty associated with it.

If you're the CEO of a drug company, it may be better to have lower profits with certainty than an uncertain world where losing

the litigation means financial harm. Our research shows other real-world situations in which a reverse payment facilitates a settlement that is in the best interests of consumers, that is, a settlement where consumers get lower-priced generics earlier.

The proper economic analysis must also include the important effect of settlements on long-term incentives of branded manufacturers to innovate and the incentives of generic ones to challenge branded patents. Unfortunately, there is very little empirical evidence on this topic. As a first step in filling this gap, we conducted a survey of generic manufacturers. The results of the survey are interesting, and they are included in my written statement.

Now with regard to the Supreme Court decision, the good news is that it got the economics basically right with the Rule of Reason test. It is precisely the Rule of Reason test that sound economics would dictate. The bad news is that the Supreme Court did not delineate precise factors for judges to evaluate whether settlements are pro- or anti-competitive.

Fortunately, economic theory shows circumstances where that is possible. First, is there easily obtained interpreted evidence that the patent is very strong? If the patent is very strong, then whatever the reason is for the settlement, it cannot likely reduce competition. Even the FTC acknowledged the absence of an anti-competitive problem where very strong patents are concerned, and we heard that this morning.

Second, is the reverse payment consistent with the expected litigation costs of the branded manufacturer inclusive of its costs of bearing the litigation risk? The basis for some of the suspicion about the settlement also crumbles if the payment does not exceed the patent holders' expected litigation costs, plus the benefits of reduced uncertainty that the patent holder obtains from settling the litigation.

The Justice Department has stated that a reverse payment is competitively benign when the payment is less than the patent holder's litigation costs. Of course, such safe harbors will not resolve every case. There will inevitably be those cases where the trial court will have to conduct a full-fledged analysis, a full-fledged Rule of Reason analysis.

In such cases, everyone must remember a very basic question: anti-competitive in comparison to what? In other words, what is the alternative to the challenge settlement that the challenging party or parties believe would have been realized but for the settlement?

One final point. The court suggested in its decision that one could examine the size of the reverse payment. However, on closer examination, this may prove less helpful than it seems. Economics shows that the size of the payment may prove to be an unreliably blunt instrument for assessing the competitive effects of settlements.

In conclusion, the Rule of Reason test adopted by the court in *Actavis* is surely the best available posture for guarding the public interest in settlements of pharmaceutical patent disputes involving reverse payments. Finding methods for answering the relevant questions raised under the Rule of Reason test is critical and courts

will be well advised to take a careful and rigorous approach, especially in early cases where the precedents are likely to be set.

Congressional action at this point to upset the process would likely be counterproductive and possibly have very damaging unintended consequences for innovation and competition in the pharmaceutical sector. A ban on settlements would not likely generate the consumer savings that the FTC alleges. If the FTC does its job under the Rule of Reason test, anti-consumer deals will be blocked in the courts and a ban would produce no incremental benefits for consumers.

Thank you again for the opportunity to discuss this issue with the Committee, and I look forward to your questions.

[The prepared statement of Jonathan M. Orszag appears as a submission for the record.]

Senator KLOBUCHAR. Thank you very much.

Mr. Russo.

STATEMENT OF MICHAEL RUSSO, FEDERAL PROGRAM DIRECTOR, U.S. PIRG, WASHINGTON, DC

Mr. RUSSO. Chairman Klobuchar, Ranking Member Lee, thank you very much for this opportunity to testify. My name is Mike Russo, the federal program director with the U.S. Public Interest Research Group, or U.S. PIRG. I think this hearing today is very important to draw attention to this issue of how these deals hurt consumers by inflating drug prices and too often putting critically needed medication out of the hands of patients.

As I mentioned, U.S. PIRG is the federation of State public interest research groups. We're a nonprofit, nonpartisan public interest organization that works to protect consumers, and one of our key concerns as a consumer issue is the high cost of health care because too often consumers and patients pay more than they should.

The issue of pay-for-delay deals, therefore, is one we've paid very close attention to because they are an egregious example of how consumers too often bear much higher costs than they should. Putting an end to these deals would cut a lot of wasteful spending and improve the lives of millions of patients.

Chairman Klobuchar, I appreciate that you mentioned in your opening remarks the story of Karen Winkler, who we've worked with through the course of our campaign, because I think the impact of these deals on everyday consumers is absolutely critical.

We have heard a lot and we'll continue to discuss a lot the impacts of incentives, how court cases would proceed, the decision making of brand-name and generic drug manufacturers, but at the end of the day, the real place where this matters is in the living rooms of consumers across the country, as with Karen Winkler, who is paying hundreds of dollars per month for a medication she needed just to function, and then once the pay-for-delay deal ended was able to get that drug for $16 for a three-months' supply, an incredible difference that she says gave her her life back.

Moving on to what the Supreme Court said in their recent case, it was certainly good news when they ruled that these deals may violate antitrust law and open the door to these kinds of challenges, and it does hold out the hope that antitrust litigation may

lead to the overturning of some of these deals and some compensation for consumers who have suffered as a result of them.

But we don't think it's appropriate to wait for years, if not a decade, for litigation to ultimately converge on a solution to the problem, because consumers need relief right now. We do think that congressional action is urgently needed, and we are happy to support S. 214 by yourself and Senator Grassley, as well as the *Fair Generics Act* by Senators Franken and Vitter.

Also in the wake of the recent Supreme Court ruling, our staff worked together with our partners at Community Catalyst to pull together, again, a real-world example of how these deals are impacting consumers. So earlier this month we did release a report listing 20 drugs known to be impacted by these deals.

We found that these reverse payment settlements have effective drugs used by patients with a wide range of serious and chronic conditions, ranging from cancer and heart disease to depression and bacterial infections. There are a few well-known examples: Tamoxifen, which is used to treat hormone-receptive breast cancer; Cipro, a very important antibiotic; and Profedil, which, as mentioned, helps MS patients and others with fatigue and sleep disorders.

We found that those payoffs in these pay-for-delay deals delayed the entry of those 20 drugs for five years, on average, and the consequences of those delays on patients were significant. On average, the brand-name drug was about 10 times more costly than the eventual generic, in one case about 33 times more costly, and we conservatively estimate that the total amount of sales made by the brand-name company over the course of those delays was $98 billion. Again, that was the total sales, not the net cost to consumers, but it still illustrates the scale of the problem and how much these deals are doing.

Again, without reverse payments we would expect the generic version of these drugs to become available much sooner without the option of making a payment to the generic drug maker. There are several different alternatives, again, which we've heard discussed—other settlements, withdrawing the suit—pretty much all of which would lead to earlier generic entry.

I also wanted to highlight that the Generic Pharmaceutical Association did take issue with our study and also put out their own study that found that there were billions and billions of dollars of savings to consumers as a result of these deals. I think there are a few weaknesses in that study that mean it's not painting an accurate picture of these pay-for-delay settlements.

First, it looked at all settlements, not simply those with consideration, and it also did not assume that a deal could even potentially lead to any cost to consumers even if it was having to do with a patent that would not have been upheld, so we don't think that analysis is the correct one to look at when assessing the cost of these deals to consumers.

Finally, I wanted to thank you for holding this hearing and giving us the opportunity to share our views on this critical issue. Increased attention to the way these deals are impacting consumers comes at a critical time in the wake of the Supreme Court ruling, and while that ruling was a step in the right direction, it really is

up to Congress to put an end to these deals once and for all. We urge all the Members of the Subcommittee, and the Congress at large, to take that action.

Thank you.

[The prepared statement of Michael Russo appears as a submission for the record.]

Senator KLOBUCHAR. Thank you very much, Mr. Russo.

Dr. Addanki.

STATEMENT OF DR. SUMANTH ADDANKI, SENIOR VICE PRESIDENT, NERA ECONOMIC CONSULTING, WHITE PLAINS, NY

Dr. ADDANKI. Chairman Klobuchar, Ranking Member Lee, thank you very much for inviting me here to testify on this important subject.

I have been doing economic research on the pharmaceutical industry for over 30 years, and I've been thinking about these so-called pay-for-delay settlements for about 12 or 13 years. You heard about the Schering-Plough case from Chairwoman Ramirez. I actually served as a trial witness in that case and did a Rule of Reason analysis 12 years before the *Actavis* decision. What is perhaps often forgotten is that the trial judge in that case found that under the Rule of Reason there was no problem with the agreement under consideration.

One of the advantages of going last is that a lot of the things that you were going to say have been said already, so I can make my remarks——

Senator KLOBUCHAR. Well, that never stops any of us from saying it again, so please go ahead.

[Laughter.]

Dr. ADDANKI. I'll make my remarks brief, therefore.

It is, in fact, the case that economics tells us that agreements are not always in possible. A pure term split agreement is not always possible. What that means it that you cannot compare the agreement that you have before you, the settlement agreement you have before you, with some hypothetical settlement that you wish the parties had entered into. You can really only compare it to what would have happened had the parties not settled, which is, of course, litigation.

What that means is that if you are to come to any reasonable conclusion about the actual competitive effect of a settlement you are going to have to think about the patent, the underlying patent. There's no way around it. I think every economist who has written a principal article on the subject has come up with exactly that same conclusion. There are strong patents and there are weak patents.

An agreement involving a weak patent, which involves a payment, may indeed be anti-competitive. An agreement involving a strong patent probably won't be anti-competitive. So this may pose, at first sight, a problem, a conundrum: Why do we want to litigate a patent case that was just settled? And you know, the answer to that apparent conundrum is actually not that difficult.

In almost all of these cases, if you have a settlement you've got a patent suit that's been going for a while, you've got a federal judge sitting there who has learned more than he or she ever want-

ed to know about this patent technology, was probably issued a Markmen ruling, and is certainly, I would think, pretty well qualified at least to make the threshold judgment as to whether this is a strong patent involved in the settlement or a weak patent involved in the settlement.

The other thing that is frequently forgotten, the Rule of Reason, tells us with good reason that the very first step in any such analysis is to ask, is there monopoly power being sought, created, or protected by the agreement at issue? If there isn't, we go home. We don't do anything more. That's an important screen because these analyses, to be sure, are difficult. They're not easy, they're time consuming.

But the question of does the patentee have monopoly power seems to have been completely forgotten in any discussion of these settlements and their analysis and, as we should all know by now, patents confer exclusivity, they don't necessarily confer monopoly power.

So I would say that at least two points are missing from 214 as it currently stands. One, is that you've got to consider the entire settlement in the context of the underlying patent suit, and if you ignore the patent suit you're never going to get to a right answer because you've ignored the most important underlying factor. Second, monopoly power as a screen is an important part of any Rule of Reason analysis and some mention, really, I think, should be of a monopoly power screen.

Finally, presumptions. Presumptions have a way of morphing into per se rules. It would be an odd presumption here to say that an agreement that allows for entry before patent exploration is invalid and illegal and anti-competitive when you've got at the same time, as Senator Lee pointed out, a presumption that a patent is valid. I have certainly seen agreements that, when the FTC has the power to block them, were blocked by the FTC because they appeared to contain—payment terms.

The parties went on to litigate, the patent was upheld, found to be valid and infringed, and the FTC's decision cost consumers three or four years of generic competition. So presumptions, I think, are tricky things. You've got a perfectly good Rule of Reason out there. It seems to me analysis under that Rule of Reason can do the job more than adequately.

Thank you very much.

[The prepared statement of Dr. Sumanth Addanki appears as a submission for the record.]

Senator KLOBUCHAR. Okay. Well, thank you to all our witnesses.

I think I'll start with you, Mr. Romasco, because some of the witnesses, particularly Mr. Orszag, was talking about how, in fact, doing something about this in the Supreme Court's opening the gates, as well as the—most significantly our bill, would somehow be anti-consumer. I find this curious, given that you represent a whole lot of consumers, the seniors of America. And Mr. Russo is over here representing the consumers.

We have AMA supporting this legislation, we have a number of companies that have contacted me, including Wal-Mart, that are looking out for their employees and the cost of health care and they support this legislation. I'm curious how all of these groups could

have gotten this wrong. Could you explain why you think that this is in fact good for the consumer to have our legislation passed and at least have some kind of a presumption that would follow from the Supreme Court's opening the door?

Mr. ROMASCO. Well, we agree with the—we don't think we—we and Wal-Mart and others got it wrong, obviously. The telling issue for us is when you look at patent settlements with and without these agreements, with these agreements, on average, it took 17 months longer to get into the marketplace. That's 17 months where brand—these prices, the generics, weren't allowed to compete, the benefits were kept from consumers, and we had two impacts: Consumers pay more, businesses pay more, and taxpayers pay more.

The other issue is the unintended consequence, or at least not the consequence that people don't talk about, is when people have these prescription drugs they modify their behavior in unhealthy ways. They skip, they don't fulfill, they cut their pills in half. We all bear the cost of poor adherence to prescription drug regimen. The estimate, as I said earlier, is $290 billion a year in incremental health care costs for urgent care inpatient services.

So it's to our benefit to get these drugs as soon as possible at the generic level into the hands of people who can afford it, so that's kind of the model that we look at and the data that encouraged us to support this issue that says at least these agreements bear scrutiny and an intense standard for why they—why they should be allowed to stand. Again, the issue is, they don't all have to be that way, but at least there's a standard and a bright line, as Chairperson Ramirez said.

Senator KLOBUCHAR. Thank you very much.

Professor Carrier, a number of people have talked about the effect of the Supreme Court hearing. I note Mr. Orszag noted that it was bad news that the court didn't delineate precise factors for District Courts to evaluate whether the settlement was competitive, pro-competitive or not.

In fact, after the Supreme Court ruling, an industry analyst said in a CNBC interview that the court created a "holy mess out of this. If I were a patent attorney in the drug world, I would be opening a bottle of champagne right now. It's basically a full employment of patent attorney's decision."

This suggests concern that the decision creates an enormous amount of uncertainty and that it will take years of litigation to determine what *Actavis* means and what types of pay-for-delay deals are illegal. The *Preserve Access to Affordable Generics Act*, which has been referenced many times here today, was originally a per se ban on pay-for-delay settlements.

As part of a compromise, the ban was removed, and it now has a rebuttable presumption of illegality. Would a per se ban be more clear and provide more certainty to the industry and save the inefficiencies associated with years of litigation? Short of a ban, would our bill with its presumption of illegality and delineated factors that a court should consider also help?

Professor CARRIER. A per se ban would be clearer and would leave the lawyers putting the cork back in their champagne because there wouldn't be as much room for negotiation over all of these terms. It's conceivable that if you squint the right way, as

several folks on this panel have said, maybe, in theory, once in a blue moon we see a settlement that can only take place because of a reverse payment, and so if we really want to be as cautious as possible, we would say presumptive illegality is the right approach.

I think as a practical matter that is just hypotheticals. I don't think it's really happened, and so I think per se probably would be fine. But if we really want to be cautious, I think presumptive illegality would be the approach where we see that these agreements are very concerning, they're a form of market division, and the exclusion comes from the payment rather than the patent, but if the settling parties in a particular case want to say our case really is different because there really is no delay in this case, then that can be introduced under presumptive illegality.

Senator KLOBUCHAR. Very good.

According to the FTC, from 2000 to 2004—and most people assume that pay-for-delay agreements were illegal—this is 2000 to 2004—cases settled and none of them involved pay-for-delay. What's different now? Could you answer that, Professor Carrier, and then we'll ask Ms. Bieri.

Professor CARRIER. So between 2000 and 2004, we have a great natural experiment. We always hear the argument that if you get rid of reverse payments then these cases are not going to settle and that has all sorts of bad consequences. But we saw in 2000 that the FTC announced that it was challenging these decisions.

By 2004, the courts had not yet deferred completely to these agreements so we had a period of time in which the settling parties knew that they could settle cases, but it could violate the antitrust laws if they included a payment from the brand to the generic. They still settled cases. Settlements continued, it's just that they took other forms. Those forms are better because they don't involve payments for delayed entry in the market.

When the brand pays the generic to stay off the market, you have no entry. In contrast, if you have a better settlement when the generic enters the market or you have a patent term split where there are 10 years left and the brand and the generic agree, hey, let's come in in the middle, that is better for competition. So what I think 2000 to 2004 shows is that settlement is completely possible without reverse payments, it's just that it takes forms that are better for competition.

Senator KLOBUCHAR. Uh-huh. And then it wouldn't cost the $4.7 billion per year that was estimated by the CBO, the nonpartisan CBO. Is that correct?'

Professor CARRIER. I think that there would be benefits of billions of dollars from outlawing these reverse payment settlements, and so I don't think we have to worry about there being no settlements whatsoever if S. 214 is enacted.

Senator KLOBUCHAR. Ms. Bieri, how do you respond to the 2000 to 2004 time period, or Mr. Orszag, when they were presumed illegal and we didn't see these kinds of settlements that many of us feel, while settlements may be fine, that these particular type of settlements are delaying entry into the market and hurting consumers and the U.S. Government, which doesn't have a lot of money right now. Ms. Bieri.

Ms. BIERI. Thank you. I think what we know about the time period in 2000 to 2004 is, as Mr.—Professor Carrier said, there was an indication that courts—that the FTC was going to be aggressive in enforcing against these types of settlements and that courts were not sure how to evaluate them, and I think what the lack of so-called reverse payment settlements in that period may show is that companies are very sensitive to enforcement and to uncertainty in the courts and they're trying to follow the rules as the courts and the agencies set them forth. What we don't know about the period from 2000 to 2004 is how many cases would have settled and brought generics onto the market sooner if they could have, in fact, done a pro-competitive settlement with some type of value passing from the innovator to the generic.

So there's an unknown about that period that I—that I think no one can—can speak to at this point. We're all assuming that because there were no reverse payment settlements, that that was a more pro-competitive outcome, and I think that's an assumption that really doesn't have a basis in fact, or at least that we can't prove looking forward.

Senator KLOBUCHAR. Mr. Orszag, did you want to add anything?

Mr. ORSZAG. If I may respond to the 17-month argument, because this has been bantered about a number of times, that the FTC has found that the presence of reverse payment delays entry by a generic by 17 months, on average. There are a few points that are worth noting here.

Number one, in that study the FTC does not control for any differences between patent settlements. They assume that they're all identical for all these different drugs. They don't control for the patent expiry date in any potential differences in the future. They actually assume, with no evidence whatsoever, that these cases could be settled in some other way without a settlement. That is the underlying assumption, is that the——

Senator KLOBUCHAR. I think they assume that because for a number of years they were settled without pay for delay.

Mr. ORSZAG. But not necessarily the ones where there were reverse payments. We don't have access to that data to analyze because it is confidential to the FTC, so it's not been subject to peer review like some of the articles that have analyzed whether reverse payment settlements are pro- or anti-competitive in the real-world situations where those may occur.

So that's an important element to this that that very 17-month assumption is key to the FTC study. It's also key to the CBO study, and CBO has not analyzed the budgetary savings in the presence of the Supreme Court decision where there's a Rule of Reason as the standard that would be used and under the Rule of Reason, presumably as I noted, anti-consumer deals would be blocked by the courts.

Senator KLOBUCHAR. So you disagree with the nonpartisan CBO analysis?

Mr. ORSZAG. I disagree—I believe that a number of the key assumptions in the CBO analysis are misguided. I've written about how they're misguided and I've shared those with Director Elmendorf.

Senator KLOBUCHAR. Thank you.

Senator Lee.

Senator LEE. Thank you, Madam Chair.

I want to start with Dr. Addanki. As you know, our antitrust laws are built upon statutes, statutes that state in pretty simple terms that we need to have pro-competitive policies in place that make sure we don't have a market that's too distorted. We don't want anti-competitive behavior in our marketplace. So the Supreme Court has over time filled in those gaps.

The courts generally, capped by the Supreme Court—courts have had the occasion to consider various formulations, various tests and standards. One of the standards that they've had to consider is how to decide when, whether, to what extent to employ a presumption of illegality.

What the Supreme Court has said in that regard is that a presumption of illegality is proper only when "an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anti-competitive effect on customers and markets" and also added that it's not proper to have such a standard where the agreements "might plausibly be thought to have a net pro-competitive effect or possibly no effect at all on competition." That's from *California Dental Association* v. *FTC*.

Now, you have more than a rudimentary understanding of economics, correct? It's my understanding you've got a Ph.D. in Economics from Harvard.

Dr. ADDANKI. Yes, sir.

Senator LEE. Would you conclude that patent settlements of the sort that we're discussing here, that is, patent settlements involving reverse settlement agreements among pharmaceutical manufacturers, might plausibly be pro-competitive or might, in the words of the Supreme Court, possibly have no effect on competition?

Dr. ADDANKI. Indeed that is the case, Senator. Agreements of this sort can be anti-competitive, can be pro-competitive, can be competitively neutral. It really depends on the facts, and that is why any kind of presumption is an unnecessary thing and one that will surely have unintended consequences, particularly when the Supreme Court has said we analyze these under the Rule of Reason.

If I may just make one more comment on that. People have commented about the lack of guidance. Well, that's not unusual for the Supreme Court, right? When they say you're going to do this under the Rule of Reason, they leave it to the lower courts to develop the jurisprudence that is going to apply because these are all going to be fact-specific investigations, and that is by way of agreeing with Mr. Orszag.

Any assumption that, but for the settlement you would have had this other settlement, that somehow you can characterize enough to say that it had been 15 months, 17 months, or whatever, it is based on all my work in this area, that's absurd. You can't do that because you—every settlement is idiosyncratic and so, but for the settlement what you would have had is really a question that you're going to have to look at on a fact-specific basis in the courts and develop that jurisprudence.

Senator LEE. And it's for that very reason that the Supreme Court has tended, over the course of the last century, to lean more

toward the Rule of Reason and away from per se rules of invalidity and also from presumptions of illegality.

Dr. ADDANKI. Indeed. That is exactly right. For instance, even the long-held view that resale price maintenance was per se has been abandoned.

Senator LEE. Dr. Michaels. Yes. Excellent point. Thank you.

Mr. Orszag, so much of the discussion today, including some of your discussion with Senator Klobuchar, has focused on the potential harm to customers that consumers might incur from reverse settlements among pharmaceutical manufacturers in this type of context we've been discussing today.

Several witnesses have added to this discussion by pointing out that they believe consumers need to be protected because they—from these kinds of settlements because they might cost consumers and taxpayers billions of dollars. But doesn't this overlook part of the equation? I mean, doesn't this overlook the fact that there is a reason why we have patent protection, and the reason why we have patent protection is to spur innovation?

So, you know, we could, for example, save consumers and the government billions of dollars over the next few years, I suppose, if we took the existing patent life and we shortened it, I don't know, by 10 percent, 25 percent, 50 percent, 75 percent, that would save consumers money in the short run, would it not? And if it would, what else would it do that might not be as pleasant?

Mr. ORSZAG. Our patent system, the *Hatch-Waxman Act*, really strikes a balance between the interests in the incentives for manufacturers to innovate and the interests of consumers who benefit from those innovative drugs and benefit also from lower-priced generic alternatives. So there's a balancing act. It provides patent protection but it also facilitates entry by generics under an easier mechanism than the brands have to go through in terms of the testing of the drug, et cetera. So it reflects a balancing act.

When you shift that balance in some ways, for example, taking away an avenue of settlement that may be important for litigation, as I noted, litigation is expensive and it involves a lot of uncertainty, and one avenue of settlement may only occur if you can have a payment of some consideration from the brand to the generic, you shift that balance in some way.

Sitting here today, we don't have strong empirical evidence one way or the other how significant that would be. The survey that we conducted provides a piece of that and it suggests that settlement, the ability to settle, is a factor in generics' decisions to enter markets. That's one piece of empirical evidence that's now been added. I would hope that over time more empirical evidence could be added about this long-term incentive point, which is critically important in this industry and other industries.

Senator LEE. But to the extent that the existence of the patent and the existence of the current patent term as we have it set up, facilitates innovation, leads to innovation. Innovation in this industry presumably extends, improves the quality of, and prolongs life. That, too, could also save money in the long run, could it not?

Mr. ORSZAG. It saves money or improves the quality of people's lives. I think everybody would agree, or I'd be shocked if we didn't all agree, that having a sound patent system produces significant

benefits to consumers because of the innovations that we all benefit, and the drug industry in particular, the types of drugs that are now available help save lives and help save lives in ways that I think many of us could never imagine 10, 20, 30, 40, 50 years ago. So it's because of that patent system that we have those innovations that benefit consumers.

Senator LEE. Okay. Thank you.

My time's expired. Thank you, Madam Chair.

Senator KLOBUCHAR. Thank you very much, Senator Lee.

I understand we're going to have a vote at noon, so we're going to have Senator Franken, then Senator Blumenthal go. I think I will leave briefly and then come back after I've voted, so we may have to recess a little after Senator Blumenthal is done, but it will only be briefly.

Senator Franken.

Senator FRANKEN. Thank you, Madam Chair.

Mr. Romasco, I'd like to thank you and the AARP for its work in this area, and in particular for supporting both my bill and Senator Klobuchar's bill.

I'd like to take a step back for a second and look at the big picture here, which is that pay-for-delay agreements can really hurt our Nation's seniors. I go back to Minnesota nearly every weekend, and I often visit senior centers and also go to nursing homes.

One of the most common concerns I hear from seniors is that prescription drugs cost too much. Now, health reform is doing a lot to change that. Over the next few years, we will completely close the gap, the donut hole, and I think that's a big deal and a big contribution so some of the burden will go to Medicare.

But there's another thing that's costing seniors a lot of money, and that's the lack of availability of generic drugs, and will be costing Medicare. And as we've already heard this morning, this is due, either largely or in some part, to pay-for-delay settlements. Would you say that pay-for-delay settlements impact seniors more than any other group, and can you talk a bit about why AARP has made this issue one of its top priorities?

Mr. ROMASCO. Thank you, Senator. Yes, we believe—first of all, prescription drugs, by definition, are used most heavily by the folks over 65. That's just a fact. As we age, and as the study—CDC study showed, two-thirds of people over 65 use at least three, 40 percent use five. Now, that translates into a nice percentage, but that means tens of millions of people use three or five of these drugs every month.

If you just sort of think through, as John said from Indiana, the difference between $70 for a supply and $15 for a quarter supply, that adds up. If the generics are part of that five drugs, you can do the math and it starts to become hundreds of dollars. When your average Medicare recipient is $20,000 or less or your Social Security—one out of three Social Security recipients are living on $14,000—this is real money to real people.

The other issue that we talked about earlier, and I can't emphasize this enough, the prescription drugs force behavior that says they skip it, they cut the pills in half, and while that saves them a few bucks, it exacerbates the health consequences, so when the—when the—when the lack of avoiding medications because they're

too expensive, then it creates another cost when they go to the emergency room, when they need urgent care. Again, we've documented the fact that that could be as much as $290 billion a year.

So at the kitchen table it's meaningful for millions of retired Americans, particularly those on fixed incomes, and for all of us. We all pay that, consumers, not just seniors, but everyone, and businesses, businesses and taxpayers. So this is a situation that affects everyone, seniors in particular, the people we represent.

Senator FRANKEN. When I was at the State fair in 2009 during the heated debate about the ACA, a woman in her 60s came up to me and she said, at my age everything's pre-existing.

[Laughter.]

Senator FRANKEN. So three to five doesn't surprise me at all, and more.

Professor Carrier, my *Fair Generics Act* would make the exclusivity privilege available to subsequent filers if the first filer bargained the privilege away in a pay-for-delay settlement. Do you agree that this change to the law will reduce patent holders' incentive to enter into these agreements in the first place and would drive down the costs for seniors, and can you explain how this would work in the market?

Professor CARRIER. Yes, I agree that that would reduce the number of these very concerning settlements. The reason why gets to the heart of how the *Hatch-Waxman Act* has been perverted. *Hatch-Waxman* has been beneficial in certain ways. There are a lot more generics on the market today than there were in 1984, but one provision of *Hatch-Waxman* has been twisted beyond recognition.

A 180-day period designed for the first generic to file a validity or infringement challenge against a patent is designed to get the generic onto the market quickly. That is what *Hatch-Waxman* was about. Hey, generic, challenge this patent. We'll give you 180 days on the market to yourself. That 180 days is very powerful.

The problem is that the brand company can now look at that one generic, or if there are a couple on the first day those couple, and say, let me give you money. If I give you money, I get to keep my monopoly, no one is going to challenge it. Those generics get more money, maybe more money than they would get from actually entering the market after winning a patent case, and nobody has an incentive to challenge like those subsequent filers that you're talking about.

So the benefit of opening up that 180-day period is that it gives other generics, who aren't in cahoots with the brand firms, an incentive to actually go to court and win one of these cases knowing that they have a shot at that 180 as well. So I think that would be very helpful legislation.

Senator FRANKEN. It breaks the incentive and the issue of whether it's a weak or strong patent is not really any issue anymore.

Professor CARRIER. I think what it does is——

Senator FRANKEN. Or less an issue.

Professor CARRIER. That's right. It takes the brands and generics and stops them so much from being on the same side, where the brands and the generics benefit from these reverse payment settle-

ments—the consumer, of course, is the one that's hurt—but by opening up the 180 you leave room for other generics to file challenges against validity, which is what *Hatch-Waxman* is supposed to be about.

Senator FRANKEN. Let's take Senator Lee's point in terms of—my understanding is that Senator Klobuchar's bill basically just changed the presumption. What is your experience? I noticed in your—not in your testimony, but in a brief that you filed or that you presented to the Supreme Court, that basically in pharmaceutical the generics prevailed in 73 percent of the challenges. So the presumption—the facts of the matter are, if you reverse the presumption that Senator Klobuchar is talking about, as the Chairwoman is talking about, you're really more reflective of reality. Let me ask you that.

Professor CARRIER. Sure. So in the study that I cited, the FTC found that from 1992 to 2000, generics won 73 percent of these cases against brand firms' patents. And even if you don't take that figure, every study that I've looked at shows that at least 40 percent, and oftentimes more, of patents are invalid or not infringed.

Another point on this presumption is that a procedural presumption is just that. You go into court, one side has to have the initial presumption and their presumption is, Okay, we'll presume the patent is valid. That's the starting point, but that's not the ending point. As a patentee, you have to prove that your patent really is valid and infringed.

One final point on this is that even though there's a procedural presumption of validity, the presumption in terms of infringement is just the opposite. So it is the alleged infringer that has the presumption here. It's the patentee that has to prove to the court that this product really is infringing. So if you're going to make a big deal about this procedural presumption of validity you have to do the same thing and say there's also this procedural presumption of non-infringement.

Senator FRANKEN. Okay. Thank you.

Senator KLOBUCHAR. Thank you very much.

Senator Blumenthal.

Senator BLUMENTHAL. Thank you, Madam Chairman. Thank you all for being here today.

Let me sort of pick up on the point, and I think it's a very important one that Professor Carrier just made, because I think your point, Dr. Addanki, that presumptions morph into per se rules is not really the practical experience of a lot of litigating attorneys. There is a presumption on one side or another. There has to be a presumption because the burden of proof has to exist in any litigation on any question at any time before a case is either resolved or goes to verdict.

So I wonder, Mr. Orszag, your testimony seems to assume that what's proposed here is a ban, and a lot of the testimony seems to assume that there will be in effect a ban on the reverse payments. If you assume that it's a presumption and if you were to tailor that presumption in a way that it could be rebutted by evidence about the benefits of the outcome, would your view be different?

Mr. ORSZAG. My view on this issue is that one should come at this with neutral principles and that you can't, on its face, say

whether these settlements are pro- or anti-competitive with a presumption. It should come at it with a view that one has to look at the facts and circumstances of the individual case. It should be an individualized inquiry without prejudice because, as people have noted, there are some cases that are anti-competitive, there are some cases that are pro-competitive.

That's why I think the Supreme Court—and I noted got the economics basically right because the Rule of Reason test allows for the neutral principles, that you have to come in and you have to show whether the deal is pro-competitive or not or anti-competitive or not, and that's the right way to think about it.

Now, one thing that I benefit from on this panel, is I'm not a lawyer and so presumptions are often more legal terms than they are economic terms. But from an economic perspective, I think the right approach to this is to come at this with neutral principles, the Rule of Reason test, and use the facts of the case to determine whether that individual settlement is pro- or anti-competitive.

Senator BLUMENTHAL. Well, the Rule of Reason case doesn't necessarily bar some presumptions on evidentiary issues, does it?

Mr. ORSZAG. I think when we get into evidentiary issues I'm going to defer to the legal counsel on this issue. As a matter of economics, one should come at this with the view that you have to look at the individual case and while you can have safe harbors, and safe harbors are important, for example, if the clear evidence is that it's a weak patent, that would suggest that any potential—or very weak patent that any potential reverse payment is anti-competitive.

Similarly, the mirror image of that is any very strong patent is likely to be pro-competitive. Those type of safe harbors are important to give businesses certainty, but once you get beyond those types of safe harbors I think one has to have neutral principles on the issue.

Senator BLUMENTHAL. Let me ask the same question of Professor Carrier. Isn't this—the criticism of the presumption at bottom really based on the idea that somehow the door is barred, that there's a per se rule, that the presumption is so strong that it can't be rebutted, whereas if the FTC enforces this law fairly it will look at all of these factors that are raised by Mr. Orszag's survey, by the views of the business community, by the costs in delay in litigation, and by the ultimate benefit to consumers, but just that there is a requirement that somebody come forward with evidence of its pro-consumer effect?

Professor CARRIER. Yes, that's exactly right. No one is saying here that these are per se illegal. So whatever framework we have, if it's Rule of Reason or presumptive illegality, there always will be a chance for the settling parties to say this settlement would not have happened absent the reverse payment and here's why it's good for consumers.

Now, again, it's easy to come up with hypotheticals and have complex models on how this could happen once in a blue moon, when you squint in a certain direction you might actually see it over there, but let's keep common sense in mind here. The reason why presumptive illegality is better than Rule of Reason is because this is not your garden-variety business arrangement.

The Rule of Reason applies when there are anti-competitive effects and pro-competitive effects and having looked at the thousands of Rule of Reason cases and seeing that in nearly all the cases the defendants win, this is the case where generally we're not concerned because there are a lot of good reasons for licensing agreements when the alleged infringer enters the market.

The reason why presumptive illegality is better here is because this stuff doesn't even pass the smell test. Again, you can come up with these complicated formulas, but let's just take a step back. What's going on here is one company is paying another not to enter the market. That is anti-competitive.

And when that payment comes and that payment is leading to the exclusion rather than the patent, that's a real problem.

Again, just to be clear, the FTC has said for a decade that if the two parties can agree on a patent term settlement, so let's say the brand has 10 years left in the patent term and the brand and the generic say it's 50 percent likely, fine, enter in five years, they don't have a problem with that. It's that extra payment. Hey, generic, here is $100 million. Let's forget about year five, why don't you enter in year eight? During those three years, the exclusion comes from the payment and not the patent. That's why presumptive illegality is better than Rule of Reason.

Senator BLUMENTHAL. And to put it in terms that consumers can understand, the payment, in addition to the settlement on time period, probably means that entry is delayed as a consequence of that payment.

Professor CARRIER. That's right. With the payment, the brand firm is getting more delay than it could otherwise get. So let's say it has a weak patent and the generic wants to enter quickly. All of a sudden, the brand says, here's a lot of money, more money than you ever would have gotten from actually winning your patent case and entering the market. We know that there's delay.

Senator BLUMENTHAL. And Mr. Orszag is shaking his head, so I'm going to give him the opportunity in the few moments I have left to offer the other side.

Mr. ORSZAG. Thank you, Senator. The economic models where it results in a payment for entry, that is, the generic enters earlier than expected, are very simple. It's not these—you don't have to twist yourself into a pretzel to do it. You can have a simple situation like this. The brand believes it's going to win with a, say, 80 percent probability. He actually believes it has a strong patent.

If the generic believes that it has a 50 percent chance of winning, so they obviously both can't be right because it should add up to 100 percent, that situation alone can result in a pro-competitive reverse payment settlement. That's all you need. All you need is risk aversion and things like that just——

Senator BLUMENTHAL. Yes. But an equally likely result would be a splitting of the difference in terms of the time of entry if that is the coin of the realm, if that's the currency. If time is the only means of settlement then presumably they would agree in those terms.

Mr. ORSZAG. But in many of these situations when you have, say, the example I just gave, you can actually not reach a cash—a settlement without payment from the brand——

Senator BLUMENTHAL. Why is that?

Mr. ORSZAG. How long do we have?

Senator BLUMENTHAL. Well, let me put it a different way. Why isn't that kind of settlement justifiable in the terms that Chairwoman Ramirez said, the cost of litigation can be considered if a settlement is proposed to the FTC even under this act, this proposed act?

Mr. ORSZAG. So the simplest way to think about this, and it's detailed in relatively simple models with nice pictures in a paper that I have with my former boss, Laurie Tyson, and a colleague of mine. The simplest way to think about this is if the generic believes it has a high probability of winning it doesn't want to settle because it thinks it's going to actually win and get entry sooner.

If the brand thinks it's going to win, it's going to not settle for anything. When you just have the date of entry as the only settlement point, only one avenue of negotiation, we'll believe that the entry date should be much later. They can't come to an agreement on the entry date that is pro-consumer, so you need that payment. It's the only way you can actually get that way.

Senator BLUMENTHAL. You've just described a circumstance where payments are possible——

Mr. ORSZAG. Right.

Senator BLUMENTHAL [continuing]. To delay entry.

Mr. ORSZAG. No. Actually, the payment results in earlier entry than would otherwise occur, because in the real-world situation the brand actually has—understands its probability of winning better than the generic, and so the entry that would occur on an expected value basis in the litigation would be later than the entry date in this when there's a payment.

It's that result where you can't get a settlement otherwise without some form of consideration going from the brand to the generic, which happens all the time. There's a good example here, the example of Plavix.

Senator BLUMENTHAL. Yes. Well, you mention that in your testimony.

Mr. ORSZAG. Yes.

Senator BLUMENTHAL. My time has expired. I am going to turn over to Senator Lee. This is a very interesting and important area. All of these witnesses are experts. I'm going to be reading that paper. Given that I'm a lawyer, not an economist, I'm going to be looking at the pictures as much as the print.

Mr. ORSZAG. It's in a law journal, so that will actually hopefully be helpful.

Senator BLUMENTHAL. Well, then I may be able to understand it. But thank you, each of you, for your expertise and your contribution today. Thank you very much.

Senator LEE. Okay. Running against the shot clock here—it's something we deal with a lot in the Senate—I want to ask a few more questions and then we're going to have to recess briefly before coming back after the vote.

Ms. Bieri, I'd like to ask you a couple of questions. First, could you respond to the point made by Professor Carrier a minute ago about the 73 percent of patents in this area ultimately being found invalid? Do you agree with that statistic?

Ms. BIERI. I think that statistic does come from the FTC study which looked at data from, I believe it was 1993 through 2000. Since then, several other studies have been done that look at more recent data, particularly from the period of 2000. I think one goes 2000 to 2009, another goes 2009 to 2012. So they cover, among two or three different studies, about a 12-year period from 2000 forward.

In those studies, they all trend the same direction, which is that the brand has won in 50 percent or more of the cases that were litigated to final court decision. So I think the FTC study, while it could have represented the data correctly from that time period, I think it's not consistent with what we've seen in later studies that look at litigated cases in later years.

Senator LEE. Okay. In your testimony you note that we have a statutory directive that exists under current law that all patents are to be presumed valid. It would seem that that statutory directive is quite fundamentally at odds with an approach that would place a burden on the patent holder to demonstrate, by clear and convincing evidence no less, that agreements within the scope of their patent are pro-competitive—not just neutral, but pro-competitive.

Do you agree that the presumption of illegality for patent settlements in this context would effectively result in something approaching either a per se rule of illegality or alternatively a presumption of patent invalidity?

Ms. BIERI. Well, I think it certainly would undermine the presumption of validity that we now enjoy with patents. I think from an antitrust perspective you only employ a presumption of illegality where the consequences of the conduct are so obviously anticompetitive that you basically have to abandon the traditional Rule of Reason analysis and say that for the most part these are going to be presumed unlawful, and you're going to put the burden on the parties who engaged in that conduct to prove otherwise.

In these scenarios, first of all, the Supreme Court has recently said that that's not the case here, that here we have conduct that sometimes could be pro-competitive, sometimes could be anti-competitive, and that should be judged under the traditional Rule of Reason.

I think when you layer on top of that the presumption that patents—the presumption of validity for patents, that's just another reason why one should be very cautious before imposing a presumption of illegality on settlements that I think economists, courts, and agencies throughout the years have noted could be pro-competitive in certain circumstances.

Senator LEE. Right. Right. Whereas, with Rule of Reason analysis they could continue to take into account the presumption of patent validity and that would operate unhindered in that context.

Ms. BIERI. Absolutely. And I think the burden of proof would—you know, to prove a prima facie case at least would be on the government or the private parties challenging these settlements to state their case.

Senator LEE. Okay. By the way, when we're in the context of a patent, isn't there something sort of internally inconsistent or contradictory about a standard that would require the patent holder

in this context to produce clear and convincing evidence to show that the agreement at issue was pro-competitive?

I mean, if the purpose of the agreement is to bolster, shore up, make more certain the interests of the patent holder, and if the whole purpose of our patent law is to limit competition within the scope of the patent life and within the scope of the terms of the patent, don't these two things conflict irreconcilably, almost?

Ms. BIERI. I think potentially there is a tension at least, if not an irreconcilable conflict. I think the other thing that I would note is when you're in a world where these are presumed to be unlawful, these types of settlements, you're really going to have to, as I think Dr. Addanki noted, look at the underlying patent in order to rebut that presumption.

So you are in a position now where the parties to these settlements are going to be, and particularly the innovator obviously, is going to be put in the position where it's going to have to defend its underlying patent. And as you say, that is not necessarily consistent with, or at least intentioned with, the presumption that that patent is valid.

Senator LEE. Okay. Thank you very much. I'm going to have to run to go vote. I'm going to turn into a pumpkin in a few minutes.

Senator Klobuchar will come back in just a few minutes because she's probably voted by now, so depending on the timing of my vote and her return, we will stand in recess for probably just a few minutes. Thank you very much.

[Whereupon, at 12:16 p.m. the hearing was recessed and resumed back on the record at 12:22 p.m.]

Senator KLOBUCHAR. Okay. We're back. The hearing comes to order again. We will have just a few more questions here and then we can conclude. I want to thank you all for staying. It has been a long morning.

I first wanted to talk, I had not asked any questions of you, Mr. Russo. Pay-for-delay settlements are the most egregious form of antitrust violation in my mind and think they have been this kind of agreement between competitors not to compete, to me, is the essence of what we don't want to be doing in a competitive market place.

What is your view of the Supreme Court's decision in *Actavis*? Is it sufficient to protect consumers from harmful play-for-delay deals that limit generic drug competitions?

Mr. RUSSO. I think it is a step in the right direction, as I believe I said in my testimony, but not sufficient, no. And I would certainly agree that this is an egregious example of a violation of what you would think would be common sense antitrust principles.

We are actually doing citizen outreach around this campaign, so we are talking to tens of thousands of Americans to educate them about the problem and get them involved in the campaign. And I think by far the number one response that we get is disbelief, people who just don't think that this could possibly be legal and it could possibly be okay to do this sort of thing. You know, before they know any of the details of the *Hatch-Waxman Act* and exclusivity periods and burdens of proof and presumptions and so on, at just that gut level they think, wait a minute. There has got to be something wrong here.

I think that the Supreme Court case recognized that but was wary of taking the further step which we joined the AARP amicus brief as well, urging them to adopt the presumption. I think there were good reasons, perhaps, why they were hesitant. The institutional competency of the court is not the same as the Congress. So I think what they did was to open a door to allow these arguments to be made to show the potentially anti-competitive impact of some of these deals.

But I think just given the scale of what these deals have potential to do to consumers who rely on this life-setting medications, it is entirely proper to put the burden on the drug companies to demonstrate that actually these have a pro-competitive, not anti-competitive impact. Otherwise, you are just putting too much risk on consumers and potentially forcing them to pay high rates for drugs that they need. And it will take a Congressional action to fix that.

Senator KLOBUCHAR. Thank you. Professor Carrier, Dr. Addanki in his testimony, in discussions with Senator Lee talked about the Rule of Reason analysis and that being sufficient. Could you talk about some of the proof problems in bringing an antitrust cast under Rule of Reason analysis?

Professor CARRIER. The difficulty with the Rule of Reason is that the general presumption is that these agreements are pro-competitive. And so if we don't adopt the two poles of per se legality and per se illegality, the question is what does Rule of Reason do that presumptive illegality does not?

And my sense is that Rule of Reason is completely appropriate for the vast majority of agreements like licensing agreements in which there is market entry and the agreements are pro-competitive. The difficulty here is that you have a payment not to enter the market. That payment is what is driving this exclusion, rather than the patent.

So the problem with the Rule of Reason is there is the potential to throw everything up in the air and say it is the kitchen sink Rule of Reason approach and that puts a lot of thumb on the scale in terms of saying that these agreements are all lawful, when in reality they are payments to delay entry into the market.

Senator KLOBUCHAR. Do you have any comments about also the points Dr. Addanki was making on the patent strength argument?

Professor CARRIER. Sure. So one argument that we have heard this morning and one argument that the pharmaceutical industry always talks about is innovation. Innovation is crucial. The pharmaceutical industry has done a lot for innovation through the years.

But you can't do anything you want and say that will increase your profits and you will plow that back into innovation. If you violate the antitrust laws and take that money and put that in innovation, that is not allowed. The *Hatch-Waxman Act* was a very complicated calibration of how antitrust and patent law should be balanced in the pharmaceutical industry.

And the brand-name drug companies got a lot in *Hatch-Waxman* like patent term extension, non-patent market exclusivity, and a 30-month stay, all very powerful tools. One of the things that generics got was 180 days of exclusivity that was designed to en-

courage market entry, and so that is what we are talking about here in the context of encouraging entry.

My final point on this is that we have heard a lot about weak patents and strong patents. Empirical research has shown that 89 percent of these settlements take place where the patent involved is not on the active ingredient of the drug, but rather on something that is more minor like the formulation or the particle size or the number of times a day you take it. And so when you have so many of these settlements for which the brand company only wins 32 percent that are not on the active ingredient itself, but rather on something that is a lot more minor in nature, that shows additional reason for concern with these settlements.

Senator KLOBUCHAR. Very good. Thank you. Ms. Bieri, I am just trying to figure out if a brand company has the opportunity to stall the entry of a competitor coming into the market and by paying a generic a fraction of the profits, why wouldn't the brand company do it? What incentive do they have not to do it?

Ms. BIERI. Well, I think if you put it starkly in those terms, then the incentive is that it might violate the antitrust laws. I think in these kinds of situations, the companies are trying to resolve a patent dispute. That is kind of first and foremost what they are trying to do.

And in a scenario as Mr. Orszag described where the brand feels that its patent is very strong, they think they have a great chance of winning in patent litigation, but for various reasons, business reasons, risk management reasons and so forth, they would prefer to settle. They are looking to reach an agreement with a generic.

And in situations where the generic is equally certain that it has a strong case and that it would prevail under litigation, the two parties just are not likely to be able to come to an agreement if all they are negotiating about is the split of when the patent would come onto market. So it is in those circumstances where the companies look to do some other type of transaction that will bridge the gap. And if that transaction is lawful, if it is pro-competitive and on its face for fair market value or within the scope of the patent exclusivity that the brand company possesses, then I think they should be looking at those settlements in order to enforce their patents.

Senator KLOBUCHAR. Mr. Orszag, I guess same question, is the same true for a generic company? If a generic company is presented with a settlement agreement where a brand name company would pay it more money to delay entry into the market than it would have been paid if it entered, how could the generic company turn that down?

Mr. ORSZAG. In such circumstance, it would not. I think the simplest way to characterize all of this is—in my perspective—if the deal is truly a pay-for-delay deal, a pay-for-delay relative to what would have occurred otherwise, it is likely to be anti-competitive. But not all reverse payment deals, not all deals involving payments of consideration from the brand to the generic involve a pay-for-delay. Many of them are payments for entry because of the factors that I have discussed, litigation is expensive, the uncertainty involving litigation and the desire of a business to have certainty instead of uncertainty.

And so those are pay-for-entry. So to presume just because there is some consideration paid that it is either a payment-for-delay or payment-for-entry is taking sides in many respects. I think the right way to think about this is come at it with neutral principles, look at each case on their own and determine based on the facts and circumstances of that settlement, because each settlement is different, involving different drugs, different companies, different expectations, whether that settlement relative to what would have occurred otherwise is pro-competitive or not.

Senator KLOBUCHAR. Yes. I just am looking at reality here. You have an FTC which probably does not have the resources to match yours and the pharmaceutical industry, to go up on these cases with Mr. Russo at their side. You have a situation where five Supreme Court justices have said that strong evidence that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market is happening.

You have got the CBO analyses, which I believe. You have got a number of people that are hurt by this that are—I am remembering my college political science class—that are very diffuse, they don't really have the ability to all come together and fight this where the benefits are very focused.

So that is why we were coming up, Senator Grassley and I, with a way to sort of even the playing field in terms of making this simply presumptively illegal, allowing you to still litigate on the margins here when there are exceptions and things where you find that you can show that the benefits outweigh the costs. So that is where we came down in terms of why we did this.

I don't know if you want to comment, Professor Carrier, about those incentives or questions I just asked Ms. Bieri and Mr. Orszag.

Professor CARRIER. Basically, when the cat is away, the mice will play. There is no reason why a brand company or the first filing generic will not enter into those agreements. And so your question was, why would the brand company not do this? And the answer is, there is no reason, absent antitrust law, that the brand would not do this.

The brand often is not sure that the patent is valid. When it is not on the active ingredient, there is a significant likelihood that it is invalid. Rather than taking that chance of having this stream of profits cut off immediately overnight, it pays money to make sure that that never happens.

And we hear a lot about risk uncertainty, risk aversion and all of that. In many cases, that just means that competition is being blocked because they have the certainty of preventing patent challenges. Again, if you are a shareholder in a pharmaceutical company, that is good. If you are a CEO of a pharmaceutical company, that is good. If you are the American consumer, that is bad.

The same goes for the generic firm. If the generic firm makes more money by receiving payment to sit on its hands and not enter the market than it does even if it were to win the patent litigation and enter the market, that tells you that something is wrong.

And one final point is that we hear sometimes that this is entry before the end of the patent term, so therefore, it is good. Some-

thing to keep in mind here is that it is not like just one patent covers every one of these drugs. There are multiple patents covering drugs. It is possible to switch the number of patents to say, OK, we are entering before the last patent, but all of the active ingredient patents have already expired.

There is also—as my final point—the interplay between the settlement by which the brand firm knows that no one is going to challenge and the pharmaceutical industry and product hopping, switching the market to the next product.

So for example, in Provigil, that happened, switching to the new product knowing with the certainty of settlement that it will never be challenged. So in short, there is no reason for a brand company or the first filing generic not to enter into these agreements. That is why antitrust has a crucial role to play here.

Senator KLOBUCHAR. Okay. Mr. Russo, and then I can see you want to say something, Dr. Addanki, and we will get to you in a minute.

Generic and brand name, our witnesses here argue that pay-for-delay deals can be pro-competitive because the settlement may allow for entry for one to two years before the patent expires, and if the case was litigated to completion and the generic company lost, it would be five to 10 years until the patent expires. What is your response to this criticism?

Mr. RUSSO. I think that if that is the case, what is the problem with proving it? I mean, obviously there is process cost, there is litigation cost and so on, but if there are cases where it is clear that it is pro-competitive, we will get a generic on the market sooner as a result of one of these deals, then that would rebut the presumption.

However, there do seem to be very strong indications that that is not the ordinary course of business when you look at these settlements. You know there is the fact that there is the 73 percent rate that was found in 1992 to 2000 before there was this huge increase in the rate of these settlements, the fact that it then goes down to about 50 percent once you start looking in the period where there were many more of these pay-for-delay settlements suggests that there may be displacing cases where the patent was weak and it would have been overturned if it went to trial.

And similarly, the impact on consumers, the bigger the impact on consumers, the bigger potential profits and therefore, the bigger carrot that can be dangled in front of the generic drug maker in order to make a deal happen. When you add that all up, it makes you think that this is dividing the market, that it is about giving up monopolistic profits, and that consumers are the ones who are losing out.

If in a particular case there are enough facts and circumstances to rebut that and say, no, actually there is legitimate uncertainty and we are going to be able to get a generic to market sooner than otherwise, I mean, fine. That is what the bill allows the company to do and they should be allowed to do that. But again, it doesn't seem like that is the ordinary course of business here, and that is why the presumption is so important to establish.

Senator KLOBUCHAR. Thank you. Dr. Addanki, do you want to respond?

Dr. ADDANKI. Thank you. I would like to be very clear that it certainly has never been my position that agreements are presumptively legal. I am certainly not taking the position and I have never taken the position that the Eleventh Circuit got it right. Patents are, indeed, probabilistic rights and when the validity and infringement of potential—the exclusionary part of a patent is being litigated, then it is right to treat it as a probabilistic right.

What I am a little bemused by, I think is the right word, is that the same evidence is being interpreted in any number of different ways by the same people. The reason I said that a presumption will probably operate more like a per se rule, is just looking at the evidence that was adduced earlier today that in the period where this—before the Eleventh Circuit set out its scope of the patent standard, I think we heard from the FTC and from Professor Carrier and a bunch of other people that there were no agreements with a pay-for-delay provision.

Now that the Supreme Court has said it is a Rule of Reason analysis, essentially undoing the Eleventh Circuit's scope of the patent test, why would the very same data not tell us that the incidence of pay-for-delay deals would drop sharply. Now if you go beyond that and say, I am going to move it away from where presumably it was before 2000, 2004 and say, I am going to create a presumption, it seems to me it is going to have—it is going to overreach in the other direction and have the effect of saying don't ever do these.

That was my point. It seems to me the evidence suggests that just putting it back to rule of reason should have—should do the trick based on the evidence that is being adduced by my colleagues on the panel.

Senator KLOBUCHAR. What do you think of that, Professor Carrier?

Professor CARRIER. So we have to keep in mind that in that initial period for part of it it was per se illegal, at least under the Cardizem case in the Sixth Circuit, for a brand to pay the generic to stay out of the market. And so——

Senator KLOBUCHAR Than what we have now, after the Supreme Court decision.

Professor CARRIER. [continuing]. So right now we have Rule of Reason, which is tons better than the scope of the patent test, which is basically pure deference and every agreement in the world is fine, basically. When we go to Rule of Reason, that is a lot better than the scope of the patent test, but presumptive illegality maybe gets us a little closer to the Cardizem, per se, approach.

And if for practical reasons we are not willing to go that far, at least presumptive illegality pushes us in that direction where we will see other types of settlements that are good for consumers, rather than brands paying generics to delay entering the market.

Senator KLOBUCHAR. Okay. I know, Mr. Orszag, you question the CBO numbers, and I just wanted to ask you about your study, the Generic Pharmaceuticals Association study which claimed that drug settlements have saved consumers $25.5 billion. Is it true that this number doesn't say how many of the settlements involved pay-for-delay? I point this out because I don't think anyone here would say that settlements of drug patent litigation are necessarily bad.

It is the pay-for-delay settlement that we have concerns about, Senator Grassley and I, Senator Vitter and Senator Franken and many of the Senators on this Committee, as well as many out there that have been mentioned today, the AMA, WalMart, a number of other companies, the AARP, the consumer groups.

And in fact, many more cases settle without pay-for-delay than with pay-for-delay. In FY 2012 the FTC found, as we have all noted, that 40 pay-for-delay settlements—and 100 of the drug settlements did not involve pay-for-delay, while 40 did. Can the report accurately be used to defend pay-for-delay settlements as saving consumers 25 billion when, in fact, most of them appear not to be pay-for-delay settlements?

Mr. ORSZAG. I can make this very easy. I had no involvement in the study.

(Laughter.)

Mr. ORSZAG. It was, I believe, done by IMS, which is a health care consulting firm. So I have no view on it because I was not involved in it.

If I may have one second? There was a comment made earlier that there has been an increase in the number of cases at the same time that there has been a decrease in the generics winning percentage in many respects. We know that the early evidence from the FTC suggests, I think it was 73 percent of generics won, when they went to the full litigation, to judgment between 1992 and 2000. More recently that number is much lower.

I don't think one can take those pieces of evidence, put them together, and say that somehow it is telling us something about the strength of the patent because of the differences in the cases, but if anything it would suggest because the generic win rate is much lower now, that the cases that go to litigation or the cases that are brought tend to be situations where the brand has a stronger patent. But I wouldn't go to the step of making that full inference given that there are differences in the types of settlements that are out there and types of cases that have been brought. And so I worry about inferring too much from that piece of empirical evidence.

Senator KLOBUCHAR. Okay. All right. You want to respond, Professor Carrier?

Professor CARRIER. For the IMS study, I completely agree. When you take off the table all of the generics that have not entered the market because of delayed entry, that is not an accurate report. And then finally, we will never agree on a single figure for the percentage of patents that are invalid or the number of times the generics are successful challenging patents.

But what is clear is that that number is non-trivial, and addressing that is what *Hatch-Waxman* is supposed to be about. *Hatch-Waxman* is supposed to be about—at least paragraph 4 certifications—challenging invalid or not infringed patents. So even if the number is not 73 percent, let's say it is only 40 percent or 50 percent, those are 40 or 50 percent of the cases in which consumers are paying more money and splitting pills more than they have to because of an invalid or not infringed patent. So even if that number is less than 73 percent, the point of *Hatch-Waxman* and what

Congress can do is to make clear that that sort of delayed entry is not allowed.

Senator KLOBUCHAR. Okay. Very good. Well, I wanted to thank all of you for coming. I also wanted to thank Caroline Holland, my Staff Director here, for the Antitrust Subcommittee, who has done a great job getting ready for this. She also worked on this issue, as you all know, for Senator Kohl, who is now happily retired and engaged in his own competitive endeavor with the Milwaukee Bucks. We prefer the Timberwolves.

I want to thank her as well as Craig Colcutt, my counsel, and Maria Lavidering, everyone who worked on this. I want to also thank Senator Lee's staff, who are also very pleasant to work with.

We have done a number of hearings with, again, I mentioned one on patent issue coming up next week—and also Senator Grassley's staff for their long-term leadership on this issue and work on this issue.

We will leave the record open for two weeks. I want to thank all of you for coming and your well-thought-out testimony. I am hopeful we are going to be able to get this done. I think the door was opened, and we have come up with what I consider a reasonable compromise in this bill, and we hope to move forward with this legislation.

Thank you very much. The hearing is adjourned.

[Whereupon, at 12:44 p.m., the Subcommittee was adjourned.]

APPENDIX

Additional Material Submitted for the Record

Witness List

Hearing before the
Senate Committee on the Judiciary
Subcommittee on Antitrust, Competition Policy and Consumer Rights

On

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

Tuesday, July 23, 2013
Dirksen Senate Office Building, Room 226
10:00 a.m.

Panel I

The Honorable Edith Ramirez
Chairwoman
Federal Trade Commission
Washington, DC

Panel II

Robert G. Romasco
President
AARP
Washington, DC

Diane E. Bieri
Partner
Arnold & Porter LLP
Washington, DC

Michael A. Carrier
Distinguished Professor
Rutgers University School of Law
Camden, NJ

Jonathan M. Orszag
Senior Managing Director
Compass Lexecon, LLC
West Palm Beach, FL

Michael Russo
Federal Program Director
U.S. PIRG

Washington, DC

Dr. Sumanth Addanki
Senior Vice President
NERA Economic Consulting
White Plains, NY

PREPARED STATEMENT OF SUBCOMMITTEE RANKING MEMBER

SENATOR GRASSLEY'S STATEMENT FOR SENATE JUDICIARY ANTITRUST SUBCOMMITTEE HEARING, "PAY FOR DELAY DEALS: LIMITING COMPETITION AND COSTING CONSUMERS" (JULY 23, 2013)

I'm pleased that we're having this hearing today to learn more about how pay for delay agreements harm drug competition. I've been working on this pay for delay problem for a long time, and I'm pleased that Senator Klobuchar has teamed up with me to put a stop to these abusive deals. We should be doing all we can to see that the American consumer has access to lower priced drugs as soon as possible.

The reality is these deals between brand name and generic pharmaceutical manufacturers delay the entry of generic medicines in the marketplace. I don't see how these agreements are competitive or how they benefit consumers. In my opinion, they only end up keeping drug costs artificially high for consumers and

the taxpaying public. Further, these agreements threaten the long term sustainability of federal healthcare programs, such as Medicare and Medicaid.

So I commend the Federal Trade Commission for being vigilant in this area. I urge the Commission to continue protecting the American consumer by continuing to take action against drug companies engaged in these anti-competitive agreements.

PREPARED STATEMENT OF HON. EDITH RAMIREZ

Prepared Statement of
the Federal Trade Commission

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.

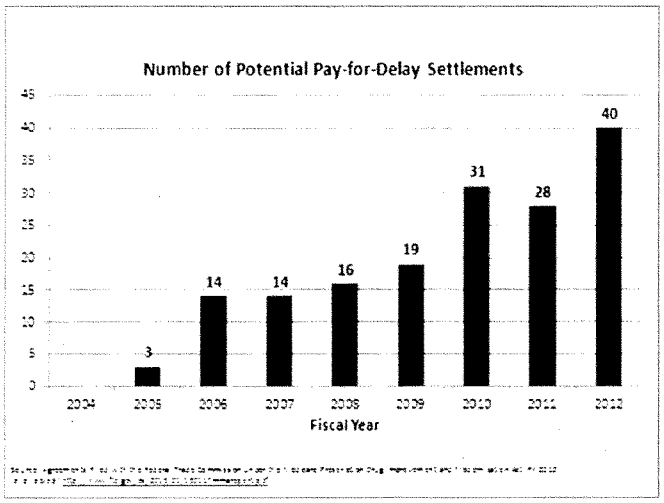

Chart 1

[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.

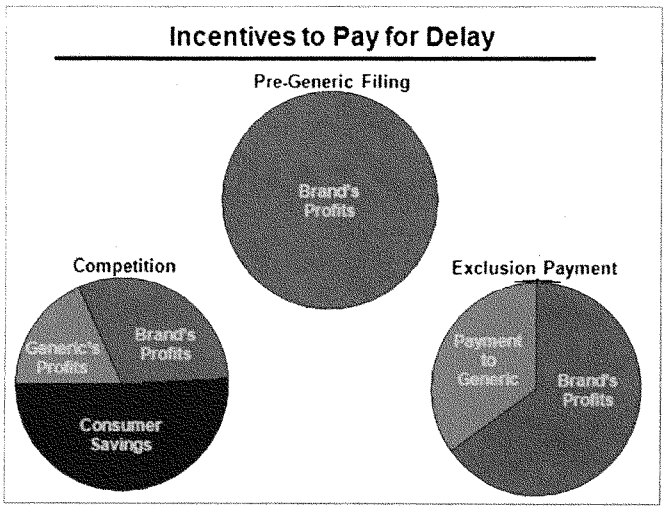

Figure 1

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.

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[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).

PREPARED STATEMENT OF ROBERT G. ROMASCO

TESTIMONY BEFORE THE SENATE COMMITTEE ON THE JUDICIARY, SUBCOMMITTEE ON ANTITRUST, COMPETITION POLICY AND CONSUMER RIGHTS

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

By Robert G. Romasco
AARP President

July 23, 2013

Room 226
Dirksen Senate Office Building
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Chairman Klobuchar, Ranking Member Lee, distinguished members of the Committee, on behalf of AARP's more than 37 million members, we thank you for holding this hearing on "pay-for-delay" agreements – reverse settlements that delay the availability of generic prescription drugs – and their impact on consumers' prescription drug costs. My name is Rob Romasco. I'm a member of AARP's all-volunteer board of directors, and I proudly serve as AARP President.

AARP is pleased that this Committee is examining how pay-for-delay agreements drive up consumers' prescription drug costs by delaying access to less expensive generic drugs. Older Americans use prescription drugs more than any other segment of the U.S. population. Two thirds of persons age 65 and older report using three or more prescription drugs within the past month, and forty percent used five or more.[1] Unfortunately, as evidenced by the AARP Public Policy Institute's Rx Price Watch reports[2], retail prices for brand name drugs are continuing to rise at rates that are several times higher than inflation, causing a strain on the budgets of individuals, federal and state governments, and other health care payers. In contrast, generic prescription drugs are considerably less expensive than brand name prescription drugs and, more importantly, their retail prices are actually *decreasing.*

Generic drugs have proven to be one of the safest and most effective ways for consumers to lower their prescription drug costs, and the use of generic drugs has been steadily increasing. In 1984, generic drugs accounted for 18.6 percent of all retail prescription drugs dispensed in the United States.[3] Now, generic prescription drugs account for 84 percent of all prescriptions dispensed in the United States[4] and 75 percent of prescriptions in the Medicare prescription drug benefit program.[5] However, while generic prescription drugs have been essential to the recent slowdown in health care spending, AARP believes that additional savings can be found by eliminating pay-for-delay agreements.

Pay-for-Delay Agreements and the Hatch-Waxman Act

Pay-for-delay agreements are a consequence of the Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act. Hatch-Waxman gives generic drug manufacturers an incentive to challenge brand-name drug patents because the first generic drug manufacturer to receive Food and Drug Administration (FDA) approval to launch a generic copy of a brand name drug can receive a 180-day marketing exclusivity period for its product. The FDA cannot approve any other generic applications for the same drug until the first-to-file generic manufacturer has sold its product for 180 days or has forfeited its exclusivity period.

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[1] Centers for Disease Control and Prevention, Health, United States, 2012, Table 91 (May 2012), http://www.cdc.gov/nchs/data/hus/hus12.pdf
[2] Reports available at http://www.aarp.org/rxpricewatch
[3] Generic Drugs Research Report, AARP Public Policy Institute, publication IB61, May 2003.
[4] IMS Institute for Healthcare Informatics, *Declining Medicine Use and Costs: For Better or Worse? A Review of the Use of Medicines in the United States in 2012*, May 2013.
[5] Cynthia Tudor, "State of Part D: 2006-2012," 2012 Medicare Prescription Drug Benefit Symposium, March 20, 2012.

However, brand-name drug manufacturers often challenge generic drug manufacturers who try to launch their product prior to patent expiration, which results in litigation to determine whether the generic manufacturer is infringing on the brand-name manufacturer's patents. Rather than face the costs and uncertainty associated with patent litigation, some brand-name and generic drug manufacturers choose to settle before a final court decision. A growing number of these settlements also pay the generic drug manufacturer for agreeing to delay the launch of its competing product, which is what attracted the attention of the Federal Trade Commission (FTC). Such agreements can be particularly problematic when they involve the first-to-file generic manufacturer, because no other generic manufacturers can enter the market until the first-to-file manufacturer has marketed its product for 180 days.

These pay-for-delay agreements provide financial benefits to both parties at the expense of consumers: the brand-name manufacturer can continue to charge monopoly prices, and the generic company is compensated for its inaction. The FTC estimates that pay-for-delay agreements cost American consumers $3.5 billion per year – and if nothing changes, will cost consumers $35 billion over the next ten years.[6]

Pay-for-Delay Agreements are Counter to Congressional Intent

The Hatch-Waxman Act provides a means for the approval of generic drugs, but also allows for brand manufacturers to challenge the generic pharmaceutical company's entry prior to coming to market through patent infringement suits. Since the passage of Hatch-Waxman, there have been several well documented instances in which the brand manufacturers abused the legal system to block generic competition. In 2003, Congress took steps to address this in the Medicare Modernization Act, requiring that the FTC be notified of any settlements of patent cases involving prescription drugs.[7] Further, Senator Hatch, one of the original co-authors of the Hatch-Waxman Act has stated that "I find these types of reverse payment collusive agreements appalling. I must concede, as a drafter of the law, that we came up short in our draftsmanship. We did not wish to encourage situations where payments were made to generic firms not to sell generic drugs ..."[8]

Cost to Consumers and Health Care Programs

The FTC has found that pay-for-delay agreements prohibit generic entry for an average of nearly 17 months longer than patent settlement agreements without such payments. In the meantime, consumers must continue paying brand name drug prices, which are typically 80 to 85 percent higher than generic drug prices.[9] Any delay in generic entry results in a longer period of purchases at the full brand price and correspondingly fewer

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[6] Pay-for-Delay: How Drug Company Pay-offs Cost Consumers Billions, An FTC Staff Study, January 2010, http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf
[7] Pharmaceutical Agreement Filing Requirements available at http://www.ftc.gov/os/2004/01/04106pharmrules.pdf.
[8] Senator Hatch Congressional Record at S7567 (June 20, 2002).
[9] http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/ucm167991.htm

purchases at less expensive generic prices.[10] This negatively impacts both consumers and other payers, including taxpayer-funded health programs such as Medicare and Medicaid.

Pay-for-delay agreements can also impact patient health: researchers have found that cost is one of the primary reasons why older adults do not fill prescriptions, skip doses, or take smaller doses.[11] High cost sharing, typically associated with brand-name prescription drugs, has also been found to delay the initiation of drug therapy for patients newly diagnosed with chronic disease.[12] These behaviors can lead to negative health outcomes and also increase health care costs: patients who do not adhere to their prescription drug regimens use more urgent care and inpatient hospital services.[13] The annual excess health care costs due to medication non-adherence in the United States have been estimated to be as much as $290 billion.[14]

Growth in the Number of Pay-for-Delay Agreements

Unfortunately, the number of pay-for-delay agreements has been increasing. According to the FTC, the number of potentially anticompetitive patent settlements between brand name and generic drug companies increased from 28 in FY 2011 to 40 in FY 2012.[15] At the same time, there are numerous opportunities for pay-for-delay agreements as the pharmaceutical industry faces an unprecedented number of patent expirations. In 2011 and 2012, six of the ten top-selling prescription drug products on the United States market faced their first generic competition, and many more drug products are expected to go off patent over the next several years.[16]

The Case of Lipitor

A recent Rx Price Watch report released by the AARP Public Policy Institute examined events that took place as the popular anti-cholesterol drug Lipitor first faced generic competition, including a reported pay-for-delay agreement. Generic drug manufacturer Ranbaxy Laboratories was the first manufacturer to file for FDA approval of its generic version of Lipitor, submitting its application in 2003.[17] In 2008, Pfizer and Ranbaxy

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[10] Federal Trade Commission, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions, January 2010.
[11] K. Zivin et al., "Factors Influencing Cost-Related Nonadherence to Medication in Older Adults: A Conceptually Based Approach," Value in Health, Vol 13(4): 338-345.
[12] M. D. Solomon et al., "Cost Sharing and the Initiation of Drug Therapy for the Chronically Ill," Archives of Internal Medicine, Vol 169(8):740-748.
[13] M.C. Roebuck et al., "Medication Adherence Leads To Lower Health Care Use And Costs Despite Increased Drug Spending," Health Affairs, Vol 30(1):91-99.
[14] New England Healthcare Institute, Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Medication Adherence for Chronic Disease, August 2009.
[15] 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, http://www.ftc.gov/opa/2013/01/mmarpt.shtm
[16] IMS Health, "IMS Forecasts Global Pharmaceutical Market Growth of 5-8% Annually through 2014; Maintains Expectations of 4-6% Growth in 2010," April 20, 2010, http://www.imshealth.com/portal/site/ims/menuitem.d248e29c86589c9c30e81c033208c22a/?vgnextoid=4b8c410b6c718210VgnVCM100000ed152ca2RCRD
[17] K. Eban, "The War Over Lipitor—Full Version," CNNMoney, May 6, 2011.

reportedly entered into an agreement that Pfizer would stop trying to block Ranbaxy's efforts to launch its product if Ranbaxy delayed introduction until November 2011.[18] Several major U.S. retailers have since filed lawsuits that accuse Pfizer and Ranbaxy of violating antitrust laws.[19,20]

Equally notable is the Rx Price Watch report's finding that the retail price of Lipitor increased by 17.5 percent in 2011. Lipitor's manufacturer was also raising its price while the alleged pay-for-delay agreement was in place. This resulted in the average annual retail price of Lipitor increasing by roughly $300 between the end of 2010 and the end of 2011.

Recent Studies on Pay-for-Delay

AARP is aware that recent studies have presented conflicting views of the impact of pay-for-delay agreements. While AARP is appreciative of the fact that some patent settlements may result in generic prescription drugs being launched prior to their brand name counterparts' patent expiration, the fact remains that objective government entities—including the Congressional Budget Office (CBO) and FTC—have concluded that pay-for-delay agreements result in costs to the government and consumers.

Some in the drug industry contend that pay-for-delay agreements are necessary to save the cost of patent litigation and that to prohibit such payments would chill patent settlements. However, while we recognize that patent litigation can be lengthy and expensive, it is AARP's contention that settlement agreements can be reached without negatively impacting consumers; and any potential litigation costs are dwarfed by the potential savings associated with timely access to generic drugs.

The Supreme Court Decision in *FTC v. Actavis*

The Justice Department has challenged pay-for-delay agreements as anti-competitive and the Supreme Court issued its ruling last month in *FTC v. Actavis*. AARP filed a friend-of-the court brief in support of the FTC's argument that pay-for-delay agreements are anticompetitive.[21] In a 5-3 opinion, the Court held that pay-for-delay deals should be subject to the "rule of reason" to determine if they violate antitrust law.[22] Under this doctrine, the Court said the circumstances of an agreement must be considered. The ruling overturns a lower court decision based on the "scope of patent" doctrine that pay-for-delay agreements are with few exceptions per se lawful.

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[18] Pfizer received a six-month patent extension in the European Union (EU) after developing a pediatric version for children with high cholesterol, allowing Lipitor to maintain exclusivity in most EU countries until May 2012. It has been estimated that this extension will bring in an additional $770 million to the company (A. Rappaport, "Pfizer Profits Surge on International Demand," Financial Times, November 1, 2011).
[19] D. Ingram, "Retailers press for damages in 'pay-for-delay' drug cases," Thomson Reuters News & Insight, March 6, 2013.
[20] Walgreen Co. v. Pfizer Inc., No. 3:12-cv-04115-PGS-DEA, at 67 (D.N.J. filed July 5, 2012).
[21] http://www.ama-assn.org/resources/doc/legal-issues/2013-01-29-amicus-brief-ftc-vs-watson-pharmaceuticals.pdf
[22] *FTC v. Watson Pharm.*, 677 F.3d 1298, 1309, 1312 (2012)

Although, the Supreme Court did not agree with the FTC's argument that these arrangements are presumptively illegal, the decision represents a major step forward in eliminating pay-for-delay agreements. It is now expected that more antitrust claims against pay-for-delay agreements will go to court and receive the closer scrutiny they deserve.[23] However, experts generally believe that pay-for-delay agreements, while now more legally risky, will still continue absent additional intervention from Congress.[24]

Need for Congress to Act

In light of the Supreme Court's decision and its expected impact, AARP believes a legislative solution is needed to finally eliminate pay-for-delay agreements and obtain cost savings for both consumers and taxpayers.

AARP urges Congress to take action on S. 214, the Preserve Access to Affordable Generics Act, sponsored by Senators Klobuchar and Grassley. This bipartisan bill would make it presumptively illegal for brand-name drug manufacturers to use pay-for-delay agreements to keep less expensive generic equivalents off the market. It would also establish relevant factors that would allow manufacturers to overcome this presumption by demonstrating that the procompetitive benefits of the settlement outweigh its anticompetitive effects. The CBO expects that enacting this legislation would accelerate the availability of lower-priced generic drugs and generate over $4.7 billion in savings between fiscal years 2012 and 2021.[25]

AARP is also a strong supporter of S. 504, the Fair and Immediate Release of Generics Act (FAIR GENERxICS Act), sponsored by Senators Franken and Vitter. This bipartisan bill would address a provision in the Hatch-Waxman Act that allows first-to-file generic manufacturers to "park" their 180-day period of marketing exclusivity as part of a patent settlement agreement, delaying market entry and effectively blocking other generic manufacturers from entering the market. The legislation would instead grant shared exclusivity rights to any subsequent generic manufacturer that wins its patent case or is not sued for patent infringement by the brand pharmaceutical company. It would also create more certainty around litigation for brand name and generic companies by prohibiting brand name manufacturers from suing generic challengers for patent infringement outside the 45-day window provided under Hatch-Waxman. According to estimates from the CBO, this legislation would generate $3.8 billion in savings between fiscal years 2013 and 2022.

AARP is committed to working to further lower the cost of prescription drugs through the enactment of responsible changes that improve access and reduce costs both for consumers and in the Medicare and Medicaid programs. We look forward to working with members of Congress from both sides of the aisle to address pay-for-delay agreements as we seek to ensure that all older Americans have access to affordable prescription drugs.

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[23] DataMonitor Healthcare, "Reverse payments: What next for generic market entry?," www.datamonitorhealthcare.com

[24] R. Bligh, "FTC v. Actavis: After the Verdict," DataMonitor Healthcare White Paper, June 2013.

[25] Klobuchar: New Report Underscores Need for Legislation to Crack Down on Anti-Competitive Pay-for-Delay Deals, July 11, 2013, http://www.klobuchar.senate.gov/newsreleases_detail.cfm?id=345314&

PREPARED STATEMENT OF DIANE E. BIERI

Prepared Statement of Diane E. Bieri
Partner, Arnold & Porter LLP
On behalf of the Pharmaceutical Research and Manufacturers of America

Hearing: "Pay for Delay Deals: Limiting Competition and Costing Consumers"

Before the Senate Judiciary Subcommittee on Antitrust, Competition Policy, and Consumer Rights

July 23, 2013

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Chairman Klobuchar, Ranking Member Lee, and Members of the Subcommittee:

Good morning. My name is Diane Bieri, and I am a partner in the law firm of Arnold & Porter LLP, appearing today on behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA is a non-profit association whose members are the leading research-based pharmaceutical and biotechnology companies. PhRMA's mission is to advocate in support of public policies that encourage the discovery and development of life-saving and life-enhancing medicines. In 2012 alone, PhRMA's members invested an estimated $48.5 billion in discovering and developing new medicines, and they have invested more than $500 billion since 2000.[1] PhRMA member companies also provide significant support to the economy. The U.S. biopharmaceutical sector employs more than 810,000 workers, supports a total of 3.4 million jobs across the country, and contributes more than $789 billion in economic output, when direct, indirect and induced effects are considered.[2] PhRMA appreciates the invitation to participate in today's hearing on pharmaceutical companies' settlements of patent disputes.

This testimony first describes the larger context that gives rise to decisions by innovator and generic companies to settle some patent disputes by reaching agreements that provide for generic product entry prior to patent expiration and consideration flowing from the innovator to the generic company. We explain the importance of patent protection to pharmaceutical innovation, the incentives established by Congress for generics to challenge innovators' patents, and the reality that innovators must retain the ability to settle patent litigation in order to realize the full value of their patents. We then discuss the recent Supreme Court decision in *Federal Trade Commission v. Actavis*[3], which resolved the important threshold question of the appropriate legal lens through which to evaluate these patent settlement agreements. Finally, we address the legislation that would impose a presumption of illegality on all such agreements. We respectfully submit that there is no reason to depart from basic antitrust principles in order to apply such a presumption to these settlements, particularly where the Supreme Court so recently rejected the idea and confirmed that the traditional antitrust rule of reason analysis should apply.

I. Patent Settlements Between Innovator and Generic Pharmaceutical Companies in the Hatch-Waxman Context Can Promote Innovation and Generate Significant Savings for Consumers

[1] PhRMA, *Pharmaceutical Industry 2013 Profile* 30, 31 fig. 10 (2013), *available at* http://phrma.org/sites/default/files/pdf/PhRMA%20Profile%202013.pdf (hereinafter *2013 Profile*).

[2] Battelle Technology Partnership Practice, *The Economic Impact of the Biopharmaceutical Industry* (July 2013).

[3] *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

A. Patent Protection Is An Essential Building Block for Pharmaceutical Innovation

In terms of their impact on personal and public health, pharmaceutical innovations surely stand among the most important advances in recent history. According to two University of Chicago economists, "[o]ver the last half century, improvements in health have been as valuable as all other sources of economic growth combined."[4] New medications have played a significant role in those societal gains. However, the innovative treatments that PhRMA member companies bring to health care providers and patients do not come easily or cheaply.

A research-based company seeking to bring a new drug product to market goes through a time-consuming and expensive process to secure FDA approval of a New Drug Application, or "NDA." It requires, on average, more than $1 billion and 10 to 15 years to bring a single new medicine from laboratory through FDA approval to the marketplace.[5] For every 5,000 to 10,000 compounds that enter the pipeline, only one receives approval, and even medicines that reach clinical trials have only a 16% chance of being approved.[6]

Innovator companies are able to undertake this costly, time-consuming research despite the relatively low chance of success only because patent protection offers at least the possibility of recovering their investment during the period of patent exclusivity. One economist has noted that "[w]ithout a well-structured system of patent protection, neither the research pharmaceutical industry nor the generic industry would be able to grow and prosper, as the rate of new product introductions and patent expirations would decline significantly."[7] Indeed, without patent protection, an estimated 65 percent of pharmaceutical products would never have been brought to market.[8]

B. The Hatch-Waxman Act Creates Incentives That Fuel Patent Challenges On Most Innovator Drugs, With Very Little Regard for the Generic's Chances of Success in Patent Litigation

Patents provide incentives for investment because, traditionally, they have been given due respect in the law. By Congressional enactment, an issued patent is afforded the presumption of validity.[9] In the antitrust context, courts have held that antitrust laws

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[4] Kevin Murphy & Robert Topel, *Measuring the Gains from Medical Research: An Economic Approach*, 4 (2003).

[5] *2013 Profile*, *supra* note 1, at 32, 38 fig. 10.

[6] *Id.* at 32.

[7] Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 J. INT'L ECON. L. 849, 853 (2002).

[8] Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 MGMT. SCI., 173, 175 (1986).

[9] 35 U.S.C. § 282.

should be interpreted not to supplant legitimate patent rights.[10] Consistent with the antitrust laws, a patent holder may exclude others from producing a patented article, or may grant limited licenses, within the defined scope and term of the patent.[11]

Even as we recognize the critical role that patents and other intellectual property protections play in incentivizing pharmaceutical innovation, we should also acknowledge that generic medicines play an important part in our healthcare system. The Drug Price Competition and Patent Term Restoration Act of 1984 (better known as "the Hatch-Waxman Act") was designed to balance the interests of innovative and generic companies; it granted certain IP protections to innovators to preserve incentives for innovation, and at the same time, created a pathway for and incentives to bring generic drugs to market. The Act allows generic drug makers to obtain regulatory approval to market generic drugs using a radically less expensive and faster process, the Abbreviated New Drug Application, or "ANDA," essentially piggy-backing on the innovator's NDA. In contrast to the huge sums spent on bringing an innovator drug to market, the cost of preparing and filing an ANDA is about $1 million.[12] Firms pursuing this approach must show only that their generic product has the same active ingredients and is bioequivalent to a reference drug that previously has been approved. Further, a company can seek approval from the FDA to market the generic drug before the expiration of a patent relating to the innovator drug by certifying that the patent in question is invalid or not infringed by the generic product (a "Paragraph IV certification").[13]

From the standpoint of the generic company, one of the most attractive features of the Hatch-Waxman Act is the ability to initiate a challenge to the patent without incurring any liability in doing so. The Act includes a provision that allows companies to develop information to submit to FDA without these activities constituting patent infringement.[14] Filing a Paragraph IV certification, in and of itself, constitutes an act of patent infringement that enables the innovator to bring a patent infringement suit.[15] The generic challenger is not required to bring products to market as a prerequisite to the challenge, and therefore, the patent holder does not sustain any damages.[16] Normally,

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[10] *See Simpson v. Union Oil Co.*, 377 U.S. 13, 24 (1964) ("[T]he patent laws . . . are *in pari materia* with the antitrust laws and modify them *pro tanto*.").

[11] *See, e.g.*, *Ethyl Gasoline Corp. v. United States*, 309 U.S. 436, 456 (1940).

[12] Emily Morris, *The Myth of Generic Pharmaceutical Competition Under the Hatch-Waxman Act*, 22 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 245, 262 (2012).

[13] 21 U.S.C. § 355(j)(2)(vii).

[14] 35 U.S.C. § 271(e)(1).

[15] *Id.* § 271(e)(2)(A).

[16] *See* Gerald Sobel, *Consideration of Patent Validity in Antitrust Cases Challenging Hatch-Waxman Act Settlements*, 20 FED. CIR. B.J. 47, 51 (2010) ("Unlike the usual patent case, there are ordinarily no damages claims against the generic because Hatch-Waxman forces the litigation to occur in the period prior to marketing by the generic. As a result, no sales or profits

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the generic drug company's chief risk in challenging a patent is that it will spend money on legal fees and FDA filings that it may not recover (or may recover only after patent expiration) if it loses the litigation. Further, the Hatch-Waxman Act grants 180 days of marketing exclusivity to the first generic company (or companies) to challenge an innovator's patents and gain FDA approval for its product.[17]

Ultimately, this combination of factors in the Hatch-Waxman Act creates significant incentives for generic drug companies to challenge patents even where the patent holder is highly likely to prevail in court. The result of these skewed incentives under the Hatch-Waxman framework is stunning. In its study of authorized generic drugs, the Federal Trade Commission stated that "for a drug with [annual] brand sales of $130 million, a generic that does not anticipate [authorized generic] competition will expect a patent challenge to be profitable if it has at least a 4 percent chance of winning . . . ."[18] But even this statistic vastly understates the magnitude of generic drug companies' skewed incentives. Most innovator drugs have annual sales well over $130 million. According to a recent analysis, for almost 90% of innovator drug sales (measured in dollars), a first-filing generic challenger balancing upside gain under Hatch-Waxman against downside risk limited to litigation costs can justify filing a Paragraph IV certification if it believes it has a *1.3% chance of success* in a patent case.[19]

When a drug with significant sales is involved, it is economically rational for a generic company to challenge the patent even if there is virtually no reason to think that the patent is infirm.[20] Statistics regarding the number of Paragraph IV certifications prove this point. According to research by Duke University economist Henry Grabowski, 75% of innovative medicines faced a Paragraph IV patent challenge in 2008, up from just 17% in 1995.[21] Moreover, given the incentives to challenge patents, it is not unusual for drugs to attract multiple generic challengers.[22]

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are lost by the patentee to the generic. While patent infringement suits are often settled by compromise of a damages claim, that vehicle is typically not available in Hatch-Waxman cases.").

[17] 21 U.S.C. § 355(j)(5)(B)(iv).

[18] Fed. Trade Comm'n, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* at iii n.7 (2011), *available at* http://1.usa.gov/0GSilg.

[19] Kelly Smith & Jonathan Gleklen, *Generic Drugmakers Will Challenge Patents Even When They Have a 97% Chance of Losing: The FTC Report that K-Dur Ignored*, CPI ANTITRUST CHRONICLE 2 (2012), *available at* http://bit.ly/VMMTTS.

[20] *See* Morris, *supra* note 12, at 262 ("In effect, the Hatch-Waxman Act actually makes pharmaceutical patents weaker than any other type of patent by making challenges to pharmaceutical patents easier and more attractive than for any other type of patent.").

[21] H.G. Grabowski et al., *Evolving Brand-name and Generic Drug Competition May Warrant a Revision of the Hatch-Waxman Act*, 30 HEALTH AFFAIRS 2157, 2157-66 (2011).

[22] *See* Christopher M. Holman, *Do Reverse Payment Settlements Violate the Antitrust Laws?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 489, 520-21, n.177 (2007)("Highly profitable

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C. The Ability To Settle Patent Litigation On Terms Acceptable To Both Parties Is A Crucial Component of Patent Enforcement

Pharmaceutical companies, like all patent owners, are entitled to assert their patents in court. Nevertheless, Hatch-Waxman litigation imposes significant burdens on innovator companies. First and foremost, it puts at risk the billion-dollar-plus investment that an innovator company has made in bringing a new medicine to market, as well as the company's ability to fund new technological breakthroughs. In addition, the innovator must incur the many direct and indirect costs of litigation. Such costs include the non-negligible amount of time spent by firm employees preparing the case, producing documents, working with lawyers on litigation strategy, being deposed, traveling for lawsuit-related events, testifying at trial, and observing legal proceedings.[23] Discovery also imposes risks, including loss of control of sensitive competitive information and harm to business relationships.[24] An ongoing litigation may tax an innovator's resources in more subtle ways as well. For example, "[t]he length of patent litigation may mak[e] marketing, research and development, and other business planning difficult while the outcome of the case remains uncertain."[25]

Because of the considerable costs and risks of litigation, the law strongly favors resolution of litigation through compromise.[26] In addition to the costs to the parties, litigation entails social costs in the expenditure of judicial resources overseeing litigation that can take up to a decade, through trial and eventual appeal.[27] Settlements resolve disputes with far less risk, time and expense than litigation. They ease the burden on the already taxed court system. And they provide certainty for all parties, allowing companies to focus on running their business rather than litigating disputes.

The benefits offered by settlements certainly extend to patent litigation, which is a notoriously costly and unpredictable process. Regardless of an innovator's own confidence in the strength of a patent, "[n]o one can be certain that he will prevail in a

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drugs with tremendous therapeutic utility should and do generally attract multiple generic challengers."); Bret Dickey et al., *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 ANNALS HEALTH L. 367, 377, n.59 (2010); *see also* Smith & Gleklen, *supra* note 19 (showing FTC data on incentives for generic firms that do not enjoy the benefit of 180-day exclusivity).

[23] Daniel A. Crane, *Ease Over Accuracy in Assessing Patent Settlements*, 88 MINN. L. REV. 698, 703-704 (2004).

[24] *Id.* at 704.

[25] *Id.* at 704.; *see also Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1075-1076 (11th Cir. 2005) (recognizing that "[p]atent litigation breeds a litany of direct and indirect costs").

[26] See, e.g., *McDermott, Inc. v. AmClyde*, 511 U.S. 202, 215 (1994).

[27] *See id.*; *see also D. H. Overmyer Co. v. Loflin*, 440 F.2d 1213, 1215 (5th Cir. 1971).

patent suit."[28] The risk that a judge or jury will not understand the technical complexities of modern patents is inherent in any patent litigation.

Just as the right to litigate is vital to realizing fully a patent's protective purpose, so too is the right to resolve that litigation through a negotiated settlement. Faced with the substantial uncertainty inherent in all patent litigation, many pharmaceutical innovators quite reasonably choose to settle challenges to their patents, just as patent holders do in the vast majority of cases. Indeed, across all patent cases, 95% are resolved by settlement.[29] For innovators, the prospect of being forced to subject their most successful patents to the vagaries of litigation with limited options available for settlement could chill the massive investments they make in developing and marketing life-saving medications. The impact of restrictions on patent settlements could be particularly significant for smaller pharmaceutical companies whose entire market value often rests on protecting the patent rights that support a handful of products. For these companies, "the uncertainty of litigation can be untenable -- even when the company has no doubt about the validity, scope, and term of its patents."[30] The ability to settle Hatch-Waxman litigation is thus essential to preserving the incentives to innovate.

D. Settlements are a Procompetitive Byproduct of the Hatch-Waxman Regulatory Framework

Consideration flowing from the innovator company to the alleged infringer is not a sign of an anticompetitive scheme. To the extent settlements following a Paragraph IV challenge differ from settlements in ordinary infringement litigation, those differences reflect the special features of the Hatch-Waxman Act. Because Hatch-Waxman litigation, by Congress's design, is triggered when the Paragraph IV certification is filed (and deemed an act of infringement) but before any damages would be incurred, the usual form of consideration from the patent holder to the infringer—declining to collect a portion of the damages—does not yet exist.

Antipathy toward Hatch-Waxman settlements appears to be driven by a belief that patent owners are willing to settle litigation primarily because the patents in question are weak. There is virtually no support for that contention. In reality, statistics show that for the 171 Paragraph IV cases litigated to court decisions between 2000 and 2009,

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[28] *Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 993 (N.D. Ill. 2003) (Posner, J.); *see also Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294, 1310 (11th Cir. 2003) ("Given the assymetries of risk and large profits at stake, even a patentee confident in the validity of its patent may pay a potential infringer a substantial sum in settlement.").

[29] Marc G. Schildkraut, *Patent-Splitting Settlements & the Re-verse Payment Fallacy*, 71 ANTITRUST L.J. 1033, 1048 (2004).

[30] CHARLES-ANDRÉ BROUWERS ET AL., BOSTON CONSULTING GROUP, EMERGING BIOPHARMACEUTICAL COMPANIES: ENSURING A FAVORABLE ENVIRONMENT FOR CONTINUED INNOVATION, (2011).

innovator companies prevailed in 52% of them.[31] More recent data on cases decided between 2009 and 2012 support these findings[32], and in 2012 alone, innovator companies won 72% of Hatch-Waxman cases.[33] Faced with the uncertainties inherent in litigation and a roughly 50% probability of winning, it is no surprise that both parties often prefer to settle rather than litigate to final judgment.

The adverse consequences of deterring innovation by declaring all settlements where consideration flows from the innovator to the generic to be presumptively unlawful would be severe. Benefits from innovation are far more valuable to consumers than static price competition.[34] To take just one very specific example, since 1980, life expectancy for cancer patients has increased by about three years, with 83% of the gains attributable to new treatments, including medicines.[35]

In addition to preserving incentives to innovate, Hatch-Waxman settlements, including those with consideration flowing to the alleged infringer, also benefit patients and payers by facilitating entry of generic competitors prior to the expiration of innovators' patents. Of the 22 generic drugs that entered the marketplace in 2011, 17 of the entries resulted from the settlement of patent infringement litigation.[36] One generic manufacturer estimated that the early generic entry permitted by its settlements alone "removed 138 years of monopoly protection" and saved consumers $128 billion.[37] Indeed, despite claims that patent settlements with consideration would cripple the ability of generic drugs to enter the market, the generic industry estimates that the amount of consumer savings due to generic drugs has hit new record highs in each of the past ten years, in substantial part due to the ability of parties to arrive at litigation settlements.[38] Limiting

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[31] Royal Bank of Canada (RBC) Capital Markets Corp. Report, *Industry Comment: Pharmaceuticals: Analyzing Litigation Success Rates* (2010).

[32] Gregory Glass, *Legal Defenses and Outcomes in Paragraph IV Litig.*, 10 J. GENERIC MEDS. 4 (2013) (finding that innovator companies won 54% of Paragraph IV cases litigated to court decisions between 2009 and 2012).

[33] PwC, *2013 Patent Litig. Study: Big Cases Make Headlines While Patent Cases Proliferate* (2013).

[34] See Mark A. Lemley, *A New Balance Between IP & Antitrust*, 13 SW. J. LAW & TRADE AM. 237, 248 (2007).

[35] E. Sun, et al., *The Determinants of Recent Gains in Cancer Survival: An Analysis of the Surveillance, Epidemiology and End Results (SEER) Database*, 26 J. OF CLINICAL ONCOLOGY suppl. 15 (2008).

[36] GPhA, *Savings: 1.1 Trillion over Ten Years: Generic Drug Savings in the U.S.* at 7 (2012), *available at* http://www.gphaonline.org/media//cms/IMSStudyAug2012WEB.pdf.

[37] *See* Teva Pharms. USA, Press Release, *Teva Pharmaceuticals Issues Statement in Response to Federal Trade Commission Claims on Patent Settlements* (June 24, 2009), *available at* http://tinyurl.com/TevaStatement.

[38] Paul Bender, et al., *S. 214's Inappropriate Interference With the Fundamental Right to Settle Litigation*, 9-10 (March 2013), *available at*

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settlement options could result not only in fewer settlements, but ultimately in fewer patent challenges because generics will face greater risks in challenging patents.

II. The Supreme Court's Decision in *FTC v. Actavis* Establishes a Definitive Legal Standard for Evaluating the Potential Antitrust Implications of Certain Types of Patent Settlements

In June, the U.S. Supreme Court issued a decision in *FTC v. Actavis, Inc.*, bringing clarity to the antitrust treatment of Hatch-Waxman settlements involving consideration flowing from innovator companies to generic competitors.[39] Prior to the Court's decision, several circuit courts of appeal had split on the issue of the appropriate lens through which to evaluate these agreements.[40]

Prior to the *Actavis* decision, three courts of appeals--the Eleventh Circuit[41], the Second Circuit[42], and the Federal Circuit[43]--had adopted a "scope of the patent" approach. Under the scope of the patent analysis, a settlement that fell within the exclusionary potential of the patent would essentially be immune from antitrust attack unless the patent was obtained by fraud or the underlying litigation was a sham.[44] This approach focused on the need to give full effect to the exclusionary power of a presumptively valid patent.

In contrast, the Third Circuit had held that settlements containing a transfer of value from the innovator company to the generic were presumptively illegal and that courts reviewing such agreements should proceed under a "quick look approach."[45] The "quick look" approach, which was advocated by the FTC as an amicus in the Third Circuit, effectively mimics a statutory presumption of illegality. It rests on the premise that, barring convincing evidence from defendants of the procompetitive effects of the settlement agreement, all so-called reverse payment settlements should be found to violate the antitrust law.[46]

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http://www.gphaonline.org/media/cms/S._214_Is_Harmful_and_Inappropriate_Legislation_3-22_.pdf

[39] *Actavis,* 133 S. Ct. at 2231, 2237-38.

[40] *Id.* at 2230.

[41] *See FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1312 (11th Cir. 2012).

[42] *See Joblove v. Barr Labs (In re Tamoxifen Citrate Antitrust Litg.)*, 466 F.3d 187, 202 (2d Cir. 2006).

[43] *See Ark. Carpenters Health & Welfare Fund v. Bayer AG (In re Ciprofloxacin Hydrochloride Antitrust Litg.)*, 544 F.3d 1323, 1336 (Fed. Cir. 2008).

[44] *See Actavis*, 133 S. Ct. at 2230 (citing *Watson*, 677 F.3d at 1312 and describing Second Circuit and Federal Circuit approaches as "similar").

[45] *See In re K-Dur Antitrust Litig.*, 688 F.3d 197, 214-218 (3d Cir. 2012).

[46] *See Actavis*, 133 S. Ct. at 2237.

In *Actavis,* the Court rejected both the scope of the patent and the "quick look" approaches and opted instead for the more conventional rule of reason analysis.[47] The rule of reason analysis, the Court explained, strikes the proper balance between the goals of the patent system and those of the antitrust laws.[48] Under the rule of reason approach, courts weigh a multitude of factors including "likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations in the circumstances"[49] as well as specific industry context[50]. The Court stated that under the rule of reason analysis the FTC may be able to prove its prima facie case without litigating the validity of the patent, given that "the size of the unexplained reverse payment can provide a workable surrogate for the patent's weakness."[51] The Court also noted, however, that when evaluating reasonableness, "'the quality of proof required should vary with the circumstances.'"[52] There is nothing in the majority opinion that suggests that the strength of the patent is irrelevant or that prohibits an antitrust defendant from arguing that the payment had not harmed competition because the patent holder would have won the underlying patent litigation, thus preventing generic entry until patent expiration. The rule of reason analysis, the Court concluded, thus allows trial courts to "structure antitrust litigation so as to avoid, on one hand, the use of antitrust theories too abbreviated to permit proper analysis, and on the other, consideration of every possible fact or theory irrespective of the minimal light it may shed . . . ."[53]

Significantly, the Court unanimously rejected the presumption of illegality standard proposed in *Actavis* by the FTC. Writing for the majority, Justice Breyer concluded that so-called reverse payment patent settlements are too complex to meet the criterion for applying a presumptive rule.[54] Thus, the Court held that a presumption of illegality is not appropriate and the FTC must prove its case as in traditional rule of reason cases.[55] The dissenting Justices would have adopted the scope of the patent approach but joined the majority in inexorably, if implicitly, rejecting the FTC's proposed presumption of illegality standard.[56]

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[47] *Id.* at 2231, 2237-38.

[48] *Id.* at 2231 (citing *United States v. Line Material Co.*, 333 U.S. 287, 308 (1948)).

[49] *Id.* at 2231.

[50] *Id.* at 2237.

[51] *Id.* at 2236-37.

[52] *Id.* at 2237-38 (citing *Cal. Dental Ass'n. v. FTC*, 526 U.S. 756, 780 (1999).

[53] *Id.* at 2237-38.

[54] *Id.*

[55] *Id.*

[56] *Id.* at 2243 (Roberts, C.J., dissenting) ("Our cases establish that antitrust law has no business prying into a patent settlement so long as that settlement confers to the patent holder no

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III. Legislation To Establish a Presumption Of Illegality for So-Called Reverse Payment Settlements Is Unnecessary and Inconsistent With Longstanding Principles of Antitrust and Patent Law

A. The Supreme Court Has Confirmed That Patent Settlements Should Be Evaluated On a Case-By-Case Basis

The question of the appropriate legal standard to apply when evaluating settlements where the generic enters before patent expiration and the innovator provides something of value to the generic company has been exhaustively debated in the courts, in both chambers of Congress and among a host of antitrust practitioners and economists for more than a decade. By the time the *Actavis* case reached the Supreme Court, the debate had largely crystallized into a binary dispute, with the FTC and its amici advocating that virtually all such settlements should be presumed unlawful, and the innovator and generic companies and their amici arguing that these settlements should only be considered anticompetitive if their terms exceeded the scope of the innovator's presumptively valid patent. This debate was squarely before the Court -- it was, unquestionably, at the heart of the *Actavis* case.

The Supreme Court accepted briefs, heard oral arguments, considered both sides' views and wrote a comprehensive opinion. It addressed the question of the appropriate legal standard head-on and concluded that neither the presumption of illegality nor the scope of the patent test should apply. Instead, as described above, the Court chose the traditional rule of reason standard. The Court provided some guidance on what the rule of reason analysis ought to involve. But ultimately, by refusing to draw any bright lines in favor of or against these types of settlements, the Court determined that, as with most antitrust cases, lower courts should have the flexibility to review the details and likely consequences of the agreements on a case by case basis.

In light of the Supreme Court's unambiguous holding, we now have, for the first time, a national legal standard that will apply to all so-called reverse payment settlements. While it is not the standard either side advocated in the *Actavis* case, the rule of reason is familiar territory for courts, agencies and litigants alike. Moreover, innovator and generic companies will take this standard into account as they attempt to resolve their patent disputes going forward. Under these circumstances, there is no need for legislation to ensure that courts will apply the same legal standard and analyze the competitive effects of these types of settlement agreements in a comprehensive fashion.

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monopoly power beyond what the patent conferred--unless, of course, the patent was invalid, but that . . . is a question of patent law, not antitrust law.").

Moreover, legislation to reverse the Supreme Court's rejection of a presumption of illegality is not warranted. The Court's decision in this regard is fully consistent with well-established precedent. The rule of reason, after all, is "the prevailing standard of analysis" when evaluating agreements for potential anticompetitive impact.[57] In contrast, as described further below, treating these settlements as presumptively illegal would represent a marked and unjustified departure from both antitrust and patent law principles.

B. There Is No Justification for Applying A Presumption of Illegality To Certain Patent Settlements

The Supreme Court has stated unequivocally that so-called reverse payment settlements should not be presumed to be unlawful.[58] Specifically, the Court followed its previously established principle that conduct may be condemned using a "quick look" presumption of illegality only when "an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets." *Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 770 (1999). In *California Dental*, the Court held that "quick look" treatment was inappropriate because the challenged restrictions "might plausibly be thought to have a net procompetitive effect, or possibly no effect at all on competition." *Id.* at 771.

Likewise, there is no basis to believe that settlements that include consideration flowing from the innovator to the generic company inevitably have an anticompetitive effect. Patent holders often prevail in infringement litigation, and any settlement that allows early entry by an infringer that would otherwise be off the market for the life of the patent has a net *procompetitive* effect regardless of the presence of a transfer of value from the patent holder to the infringer.

This is not a hypothetical argument. The cases reveal concrete examples of pharmaceutical patent owners that settled with some generics with arrangements that have been characterized as reverse payments and early entry and then litigated with other generics and prevailed, keeping these later infringers off the market. For example, after the settlement at issue in the Second Circuit's *Cipro* case, the patent was repeatedly upheld as valid in other Hatch-Waxman litigation, meaning that absent the settlement there likely would have been no early entry by any generic at all. *See In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 519-520 (E.D.N.Y. 2005) (summarizing results of litigation where Bayer defeated two generic companies' validity challenges on summary judgment and overcame another generic's validity challenge after a nine-day bench trial). The same outcome occurred after the

[57] *Continental T.V., Inc. v. GTE Sylvania, Inc.*, 433 U.S. 36, 49 (1977) (citing *Standard Oil Co. v. U.S.*, 221 U.S. 1 (1911)).

[58] *Actavis*, 133 S. Ct. at 2237 (noting that the complexities involved in analyzing the competitive effects of these settlements "lead us to conclude that the FTC must prove its case as in other rule-of-reason cases").

settlements at issue in *In re Tamoxifen Citrate Antitrust Litigation* were reached, 466 F.3d 187 (2d Cir. 2006), where the patent was repeatedly upheld as valid. *See Zeneca Ltd. v. Novapharm Ltd.*, No. 9601364, 1997 WL 168318(Fed. Cir. Apr. 10, 1997); *Zeneca Ltd. v. Pharmachemie B.V.*, No. CIV.A.96-12413-RCL, 2000 WL 34335805 (D. Mass. Sept. 11, 2000). Similarly, after the FTC blocked a so-called "reverse payment" settlement between Bristol-Myers Squibb (BMS) and Apotex involving the drug, Plavix, BMS took the patent case to trial and won. *Sanofi-Synthelabo v. Apotex, Inc.*, 492 F. Supp. 2d 353, 397 (S.D.N.Y. 2007). These examples demonstrate that settlements with consideration flowing from an innovator company to a generic firm can have procompetitive effects by permitting generic entry that would not have occurred in the absence of the settlement.

C. Applying a Presumption of Illegality Would Turn the Well-Established Presumption of Patent Validity On Its Head

Finally, the concept of a presumption of illegality for certain types of patent settlements ignores the statutory directive that all patents "shall be presumed valid."[59] An issued patent is presumed valid until it is adjudicated otherwise. As the Supreme Court recently recognized, in the face of similar arguments in a different context, neither allegations of "bad" or "weak" patents nor purported flaws in the patent system justify adoption of a legal standard that ignores the Congressional intent of the presumption of patent validity.[60]

Quite simply, the Hatch Waxman Act was intended to give generic drug companies the incentive to challenge patents, which it clearly does. The Supreme Court's decision in *Actavis* permits an antitrust review of each and every settlement using the traditional antitrust analysis of the rule of reason announced almost a century ago in *Chicago Board of Trade*.[61] There is no need to replace this approach with an industry-specific presumption of illegality that would further undermine the value of patents.

Thank you again for the chance to speak with you today. We welcome your interest in this issue, and look forward to working with members of the Subcommittee and others in Congress as you address these and other important policy issues relating to innovation and access to medicines.

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[59] 35 U.S.C. § 282.

[60] *See Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2251-52 (2011) (policy arguments concerning "bad" patents cannot override Congress' intent that the presumption of a patent's validity can be overcome only by clear and convincing evidence).

[61] *Chicago Board of Trade v. United States*, 246 U.S. 231 (1918).

PREPARED STATEMENT OF MICHAEL A. CARRIER

Testimony of

Michael A. Carrier

Distinguished Professor
Rutgers Law School

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.

PREPARED STATEMENT OF JONATHAN M. ORSZAG

TESTIMONY OF
JONATHAN M. ORSZAG
BEFORE THE SENATE JUDICIARY SUBCOMMITTEE ON ANTITRUST, COMPETITION POLICY, AND CONSUMER RIGHTS
JULY 23, 2013

Chairman Klobuchar, Ranking Member Lee, and Members of the Subcommittee, good morning.

My name is Jon Orszag and I am a Senior Managing Director and member of the Executive Committee of Compass Lexecon, an economic consulting firm. I am also a Senior Fellow at the Center for American Progress and a Fellow at the University of Southern California's Center for Communication Law & Policy.[1]

In the 1990s, I served on President Bill Clinton's National Economic Council and as the Assistant to the Secretary of Commerce and Director of the Office of Policy and Strategic Planning.

In these capacities, I had to consider the tradeoffs that often occur when making public policy. The patent system affecting the pharmaceutical industry reflects such tradeoffs.

Consumers benefit from the availability of innovative new drugs and from price competition from manufacturers of generic drugs. Competition policy towards the pharmaceutical industry must therefore represent a balance between protecting incentives for manufacturers of branded drugs to innovate and facilitating entry by manufacturers of lower-priced generic drugs.

The current framework for patent litigation between branded and generic pharmaceutical manufacturers, established by the Hatch-Waxman Amendments in 1984, is an important component of this balance. Generic manufacturers must notify branded manufacturers before launching a potentially infringing generic product, providing branded manufacturers an opportunity to sue for patent infringement before the generic enters the market. In many cases, litigation is resolved with a settlement between the parties.

This hearing concerns a subset of these settlements: ones where some form of consideration is conveyed from the branded manufacturer to the generic one. In these settlements, the parties settle the patent litigation and the branded manufacturer (1) allows the generic manufacturer to enter at or after a particular date in the future (prior to the expiration of the patent) and (2) pays some form of compensation to the generic manufacturer. That compensation can be in the form of cash or through some other business transaction (*e.g.*, a cross-licensing agreement), which provides a conduit through which the branded manufacturer might allegedly "overpay" the generic manufacturer.

[1] The views and opinions expressed in this testimony are solely mine and do not necessarily reflect the views and opinions of any of the organizations with which I am affiliated. I have served as an economic consultant to brand and generic manufacturers regarding the competitive effects of patent settlements.

Some analysts contend that such "reverse payments" are on their face evidence that the settlements are nothing more than a payment by the brand manufacturer to delay generic entry. They argue that in what one might think of as the typical patent settlement case, the defendant (an alleged patent infringer) makes a payment to the plaintiff (the holder of the patent). But in reverse payment settlements, they argue that the payment flows the wrong way, from the patent holder (the branded manufacturer and plaintiff) to the defendant (the generic manufacturer and alleged infringer).

"Reverse payment" is a misnomer based on flawed logic. In contrast to a "typical" patent case, where the alleged infringer is already selling a product and the patent holder is suing for damages, in patent suits between branded and generic pharmaceutical manufacturers, the generic has typically not entered the market and the branded manufacturer is suing for a remedy akin to injunctive relief.[2] In this case, there is no *a priori* expectation that a payment should flow from the generic manufacturer to the branded manufacturer.

I have conducted extensive economic research on the effects on consumers of these patent settlements. I co-authored a paper with Dr. Laura Tyson, my former boss on President Clinton's National Economic Council, and Dr. Bret Dickey, a colleague of mine at Compass Lexecon, that presents an economic framework for evaluating such settlements (see attached).[3] Our paper demonstrates that patent settlements between branded and generic manufacturers, even settlements involving reverse payments, can be procompetitive or anticompetitive, depending on certain factors.

Our research shows that, under certain conditions, without a payment from the branded manufacturer to the generic manufacturer, the parties will be unable to reach agreement on a settlement – even if that settlement would benefit consumers. Thus, attempts to ban all patent settlements in which some form of consideration is provided to the generic manufacturer would be misguided, because in some situations an all-out ban would deprive consumers of benefits.[4]

One example of how an outright ban of reverse payment settlements would harm consumers is found in the experience with the drug Plavix. The Federal Trade Commission ("FTC") blocked the reverse payment settlement between the parties and the parties were thus forced to litigate the matter. In the end, with the reverse payment settlement, generic entry would have occurred an estimated 10.5 months *earlier* than actually occurred without the reverse payment settlement. Thus, generic entry was delayed by the FTC's actions seeking to block an apparently procompetitive reverse payment settlement.

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[2] From this perspective, the fact that the settlement payment flows from the branded manufacturer to the generic one is a product of the Hatch-Waxman Act.

[3] Bret Dickey, Jonathan Orszag, and Laura Tyson, "An Economic Assessment of Patent Settlements in the Pharmaceutical Industry," *Annals of Health Law*, Volume 10, Issue 2, Winter 2010.

[4] Litigation imposes substantial costs upon the litigating parties and on society as a whole, costs which can be mitigated through settlement. Settlements also reduce risk associated with litigation. Because settlements can lower costs and uncertainty, economists agree that settlements can be procompetitive.

One may ask: Why would the branded company settle to allow for earlier competition from a low-priced generic? The answer: Litigation is expensive and uncertain. For the CEO of a branded drug company, settling a patent litigation with a generic may be the difference between financial disaster and survival. Not only does settling directly reduce legal costs, which can be substantial, but it can also allow a branded manufacturer to move forward with investments in research and development for new drugs that represent the future of pharmaceutical businesses. In other words, it may be better to have lower profits with certainty than an uncertain world where losing the litigation means financial doom. It is precisely in these situations that a payment from the branded drug company to the generic company may facilitate a settlement that is in the best interests of consumers.[5]

Ultimately, the competitive effects of a particular settlement will depend importantly upon the underlying strength of the patent. If the patent is strong, and likely to be found valid and potentially infringed, then even a settlement with an agreed-upon entry date well into the future, but before patent expiration may bring generic drugs to market sooner than continued litigation, and generate lower prices for consumers. If, despite the strength of the patent, the branded manufacturer wants to avoid the cost and uncertainty of litigation and pays the generic as part of a settlement, the net result of the reverse payment settlements could easily be called "pay-for-entry" settlements (such as the Plavix experience).

In contrast, if the patent is weak, and likely to be found invalid and/or non-infringed, then even a settlement with an entry date not far in the future may delay generic entry and harm consumers.

The proper economic analysis is even more complex than the discussion above, however, raising further doubts about an all-out ban on reverse payment settlements. In particular, competition policy towards patent settlements can have important effects both on the *long-term* incentives of branded manufacturers to innovate and on the incentives of generic manufacturers to challenge branded patents. For consumer welfare, these long-term incentives can be far more important than short-term economic effects. For example, Frank Easterbrook, the Chief Judge for the US Court of Appeals for the Seventh Circuit, has said, "An antitrust policy that reduces prices by 5 percent today at the expense of reducing by 1 percent the annual rate at which innovations lower the costs of patent introduction would be a calamity. In the long run a continuous rate of change, compounded, swamps static losses."[6]

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[5] My research shows other real-world factors will affect whether a settlement is procompetitive, including (1) information asymmetries, that is, information that is available to one of the parties but not to the other; (2) differences in expectations, such as the parties' beliefs about their chances of winning the patent litigation, and (3) differences in discount rates, that is, differences over the value of future income relative to present income. *See, also,* John P. Bigelow and Robert D. Willig, "Antitrust Policy Towards Agreements that Settle Patent Litigation," *The Antitrust Bulletin,* Fall 2004, pp. 655-698. ("Bigelow and Willig")

[6] Frank H. Easterbrook, Ignorance and Antitrust, in Antitrust, Innovation and Competitiveness 119, 122-23 (Thomas M. Jorde & David J. Teece eds. 1992).

A broad ban on "reverse payment" settlements would narrow the patent protection provided to branded manufacturers and, on the margin, reduce incentives to invest in new medicines in the future. Importantly, such a ban would also reduce the ability of generic manufacturers to settle such cases and increase the cost and risk of litigation – and therefore the cost and risk of bringing a generic drug to market prior to patent expiration. On the margin, this will also reduce the incentives of generic pharmaceutical manufacturers to challenge branded patents in the first place. Even if the effect on a particular generic manufacturer's decision is relatively small, the collective impact on future generic competition could be substantial.[7]

Unfortunately, there is very little empirical evidence on the *dynamic, long-term* incentives of drug manufacturers. As a first step in filling this research gap, Dr. Dickey and I conducted a survey of the manufacturer members of the Generic Pharmaceutical Association ("GPhA") on their generic investment decisions and patent litigation experience. The generic manufacturers who responded to our survey account for nearly $1 billion in annual research and development spending. The results of our survey show:

- Consistent with previous evidence, bringing a generic drug to market can be an expensive process.
- Settlement is an important option for resolving patent litigation. On average, respondents reported settling 64 percent (165 of 256) of resolved patent suits.
- When patent litigation went to judgment, the generic respondent lost two out of every three times. Such evidence may suggest that branded patents were relatively strong, and where patents are strong, settlements with consideration are more likely to benefit consumers.
- A variety of factors are important in the decisions of a generic to enter a particular market. Such factors include the first-filer opportunity granted under the Hatch-Waxman Act; the number of generic competitors; the market size; and the perception of the generic manufacturer of the strength of the brand's patent. The ability to settle patent litigation was also recognized as an important factor in determining in which generic drugs to invest.

Thus, from an economic perspective, the research shows clearly that reverse payment settlements can be pro- or anticompetitive and should continue to be closely scrutinized on an individualized basis, without prejudice, by the antitrust authorities and the courts.

The FTC has strongly disagreed with this economic perspective. The FTC has argued that such settlements should be treated as presumptively anticompetitive and has even published a study claiming that such a ban would save consumers significant sums of money. But the FTC study and the follow-on Congressional Budget Office ("CBO") study estimating the budget savings from implementing such a ban are deeply flawed as a matter of economics.[8]

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[7] Bret Dickey and Daniel L. Rubinfeld, "Would the Per Se Illegal Treatment of Reverse Payments Settlements Inhibit Generic Drug Investment," *Journal of Competition Law & Economics*, 8(3), 615-625.

[8] For a more complete discussion of the flaws in the FTC and CBO studies, see Bret Dickey, Robert Willig, and Jonathan Orszag, "A Preliminary Economic Analysis of the Budgetary Effects of the Proposed

First, the FTC claims that reverse payment settlements delay generic entry by 17 months on average, but the FTC neither controls for differences across settlement agreements nor differences in the patent expiry date. The FTC prejudicially assumes with no evidence that these cases would have been settled in some other way, even if reverse payments could not be made for legal reasons. (I should note that the FTC refuses to make its data available to researchers to test its assumptions.)

Second, the FTC ignores social benefits from settlements and the dynamic, long-run innovation effects. (CBO at least acknowledges that a ban would restrict generic entry, in some cases, leading to higher prices for those products.)

Third, and crucially, the FTC and CBO studies assume that anticompetitive agreements go unchallenged in the current regulatory structure, which is clearly false given current antitrust reviews of such agreements. If the FTC is doing its job, anticompetitive agreements should be blocked and thus banning reverse payments should not produce *any* savings for consumers.

Earlier this month, Community Catalyst and U.S. PIRG put out a similar study claiming that generic entry has been delayed by, on average, five years and that branded manufacturers have made an "estimated $98 billion in total sales of these drugs while the generic versions were delayed."[9] This study is fatally flawed. It effectively assumes that there is no patent protection for the branded manufacturer and that the generic manufacturer can enter the market whenever it believes that the brand's patent has expired or is invalid or non-infringed by the generic product. In other words, Community Catalyst and U.S. PIRG effectively assume that key patent protections afforded branded manufacturers in the Hatch-Waxman Act do not exist. Such an assumption is not the reality of the Hatch-Waxman Act, and if it were, it would dramatically destroy the careful balance in the Hatch-Waxman Act between incentives for branded manufacturers to develop new innovative drugs and the ability of generic manufacturers to enter markets to sell lower-priced drugs.

In *FTC v. Actavis*, the Supreme Court of the United States had to evaluate two competing perspectives on reverse payment patent settlements. As noted above, the FTC advocated its view that reverse payment settlements should be presumptively anticompetitive. The drug manufacturers advocated a view that "absent sham 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."[10] This was the so-called scope of patent test.

Restrictions on 'Reverse Payment' Settlements," August 10, 2010, and Robert Willig and Jonathan Orszag, "A Preliminary Economic Analysis of FTC Chairman Leibowitz's June 23rd Speech," June 24, 2009.

[9] Community Catalyst and U.S. PIRG, "Top Twenty Pay-for-Delay Drugs: How Drug Industry Payoffs Delay Generics, Inflate Prices and Hurt Consumers," July 2013.

[10] In The United States Court Of Appeals For The Eleventh Circuit, *Federal Trade Commission, vs Watson Pharmaceuticals, Inc., Solvay Pharmaceuticals, Inc.*, No. 10-12729, April 25, 2012, p. 30. ("Watson")

The Supreme Court rejected both views and adopted a "rule of reason" test – that is, that each settlement would have to be evaluated on its own merits based on the facts and circumstances of each individual settlement.[11] The good news is that the Court got the economics basically right. As Dr. Tyson, Dr. Dickey, and I showed in our research paper, reverse payment settlements can be pro- or anticompetitive, depending upon specific, individualized factors.[12]

The bad news is that the Supreme Court did not delineate precise factors for district court judges to evaluate whether settlements are pro- or anticompetitive. Therefore, I will spend the rest of my testimony explaining my views about how such settlements should be analyzed.

Given the complexity of these settlements, it is appropriate to look for conditions under which the need for a full-blown analysis of all the possible complications could be obviated. Fortunately, there are some circumstances where that is possible.

The case against reverse payment settlements arises, after all, from a very simple perspective on the settlement, namely that the brand manufacturer's willingness to pay a would-be generic entrant must be in exchange for increased time as a "monopolist" of a particular drug and that the brand would only be willing to pay for such time if the patent were too weak to withstand a patent challenge. If that basis for suspicion could be eliminated, then – whatever the complex reasons for reaching the settlement may be – the case against it as an act of anticompetitive behavior could be dismissed.

It would, therefore, make economic sense to encourage courts hearing these cases to make an initial inquiry into two fundamental questions:

First, is there easily obtained and interpreted evidence that the patent is very strong?

Second, is the reverse payment consistent with the expected litigation costs of the branded manufacturer, inclusive of its costs of bearing the litigation risk (*i.e.*, the benefits of reduced uncertainty that the branded manufacturer obtains from settling)?

If the patent is very strong, then whatever the reason is for the settlement, it cannot likely reduce competition. Here is a simple example: The brand's patent expires in 2018. If that patent is very likely to hold up to challenge, the brand will have the exclusive right to sell the relevant product until 2018. Any settlement that allows generic entry before that date is likely procompetitive, since it results in generic entry earlier than the patent expiration date. (Similarly, if the patent is very weak, the reverse payment settlement is likely to reduce competition.)

The basis for suspicion about the settlement also crumbles if the payment does not exceed the patent holder's expected litigation costs plus the benefits of reduced uncertainty that

[11] Supreme Court of the Unites States, *Federal Trade Commission v. Actavis, Ind. et. al.*, June 17, 2013. ("Actavis")
[12] *See, also,* Bigelow and Willig.

the patent holder obtains from settling the litigation. If the brand manufacturer gets out of the litigation for a cost that is less than the cost of conducting the litigation (including the value of increased certainty), the settlement is economically efficient and does not come at the expense of consumers. When the payment is less than the economic costs of litigation, there are sound reasons besides increased market power for the parties to agree to the settlement. Then there would be no basis for inferring that such a settlement would be anticompetitive.

These considerations suggest that antitrust analysis of reverse payment settlements should include two "safe harbors." If the parties to the settlement can show that the patent is sufficiently strong or if the size of the reverse payment is less than the brand manufacturer's expected litigation costs (including the value of increased certainty), then there should be the presumption that the settlement is not anticompetitive.

These two safe harbor provisions should be uncontroversial. Even the FTC in its brief to the Supreme Court acknowledged the absence of an anticompetitive problem where strong patents are concerned. The FTC stated specifically, "When the brand-name manufacturer holds a strong patent, it is likely to prevail in litigation and to prevent or significantly delay generic entry—*as it should, in order to preserve the incentives to innovate that benefit consumers in the long run.*"[13]

Similarly, the proposition that even a reverse payment settlement is benign when the payment is less than the patent holder's litigation costs was embraced by the Department of Justice ("DOJ") in its brief to the Third Circuit in the case involving the drug K-Dur. Speaking of the proposed presumption against reverse payment settlements, the DOJ conceded that the presumption could be rebutted under just these circumstances by stating that, "The defendants clearly rebut the presumption if they show the payment was no more than an amount commensurate with the patent holder's avoided litigation costs. A payment up to the amount saved by avoiding litigation does not suggest the settlement departs from the expected outcome of litigation."[14]

To be clear, litigation costs are more than just the out-of-pocket litigation costs for lawyers, expert witnesses, document production and review, and other expenses. Businesses benefit significantly from the increased certainty associated with settling intrinsically risky litigation. From an economic perspective, risk bearing is costly, and it is a truism to observe that one of the functions of capital markets is to put a price on risk bearing. That price is rarely zero.

A brand manufacturer who initiates and persists in patent litigation faces the chance that its patent will be ruled invalid or not infringed or that its protections may be weakened. Any of these outcomes would reduce the firm's profit – and it is the chance of those reductions that make the litigation risky. The brand manufacturer, therefore, incurs a cost of risk bearing by participating in the litigation. This cost of risk is thus one of the costs

[13] FTC Brief, p. 45 (emphasis added).

[14] In the United States Court of Appeals for the Third Circuit, *In Re: K-Dur Antitrust Litigation,* Brief for the United States as Amicus Curiae, May 18, 2011, p. 29. ("DOJ K-Dur Brief")

of litigation. Therefore, a proper assessment of a safe harbor based on the cost of litigation would include this risk cost. The cost of risk bearing is generally recognized by economists to increase with the amount of uncertainty (or variance) in the uncertain outcomes in question. That variance will be at its greatest in litigation over patents whose strength or weakness is most uncertain. Therefore, these will prove to be greatest in cases where – controlling for other factors – the size of the safe harbor is largest.

If this seems a little abstract, it is worth considering some of the practical consequences of the presence or absence of a safe harbor related to risk bearing. Imagine the kind of pharmaceutical firm that conducts an active research program and brings new and innovative drugs to market. Such a firm is very likely to have better information about the prospects of its pipeline drugs than would the capital markets at large. Therefore, there would be a substantial efficiency advantage to such a firm using internally generated funds – such as the profits from existing drugs – to finance research and development of new drugs. The kind of safe harbor about which I am speaking here offers such a firm a degree of certainty that makes the use of internal funds easier. If the firm faces the risk of substantial variance in its fortunes resulting from uncertain litigation, the availability of internal funds will be attenuated.

Of course, safe harbors will not resolve every case. There will inevitably be those cases where, as per the Supreme Court's decision in *Actavis*, the trial court will have to conduct a full-fledged rule of reason analysis of the alleged anticompetitive effects of a reverse payment settlement.

In any such analysis, those alleging that the settlement is anticompetitive should have an answer to the basic question, "Anticompetitive in comparison to what?" In other words, what is the alternative to the challenged settlement that the challenging party or parties believe would have been realized but for the settlement? Is the alternative that the litigation would have continued to its completion?

If so, it is hard to know how the trial court could avoid the "turducken task"[15] of assessing the likely outcome of the patent litigation – or at least conducting a rigorous analysis of the strength of the patent.

The Court expressed confidence that requiring the FTC to prove its case "is not to require the courts to insist, contrary to what we have said, that the Commission need litigate the patent's validity," and that "trial courts can structure antitrust litigation so as to avoid, on the one hand, the use of antitrust theories too abbreviated to permit proper analysis, and, on the other, consideration of every possible fact or theory irrespective of the minimal light it may shed on the basic question—that of the presence of significant unjustified anticompetitive consequences."[16] If the case against a settlement is that it is anticompetitive relative to the likely outcome of the underlying litigation, then an

[15] Referring to the task of deciding the merits of the underlying patent case in litigation over a reverse payment settlement the 11th Circuit wrote, "If we did that we would be deciding a patent case within an antitrust case about the settlement of the patent case, a turducken task." (Watson, p. 39)
[16] Actavis, p. 21.

analysis of the outcome of that litigation could hardly be said to shed "minimal light" on the "basic question." However, if the case against a settlement is that it is anticompetitive relative to a different settlement without a reverse payment, then under the rule of reason there must be a proof that such a settlement would have been reasonably feasible, and that is an issue that can be subjected to analysis and factual discovery.

It might be tempting to avoid looking at the strength of the underlying patent case by examining proxies, but this should be approached with the caution and burden of proof that are characteristic of the rule of reason test. For example, the Court suggested in its *Actavis* decision that one could examine the size of the reverse payment.[17] However, on closer examination this may prove less helpful than it seems. As I explained above, taking account of the costs of risk bearing, a patent suit can be very costly indeed to a patent holder, which leads to the conclusion that – just for risk bearing reasons alone – a benign reverse payment might, in fact, be large. Moreover, there is nothing in the economic theory of reverse payments that are essential to procompetitive settlements to suggest that payments in those settlements are small. Therefore, the size of the payment may prove to be an unreliably blunt instrument for assessing the competitive effects of the settlement.

In conclusion, the rule of reason test adopted by the Court in the *Actavis* decision is surely the best available posture for guarding the public interest in settlements of pharmaceutical patent disputes involving reverse payments, particularly in comparison with other approaches that would either make them essestially *per se* illegal or *per se* immune to challenge. Finding methods for answering the relevant questions raised under the rule of reason test is critical and courts would be well advised to take a careful and rigorous approach – especially in early cases – where the precedents are likely to be set. Congressional action at this point to upset the process would likely be counterproductive and possibly have very damaging unintended consequences for innovation and competition in the pharmaceutical sector.

Thank you again for the opportunity to discuss this issue with the Subcommittee.

[17] "In a word, the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself." Actavis, p. 19.

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TESTIMONY OF

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Before the

UNITED STATES SENATE
JUDICIARY COMMITTEE

SUBCOMMITEE ON ANTITRUST, COMPETITION POLICY AND CONSUMER RIGHTS

On

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

July 23, 2013

I. Introduction

Chairman Klobuchar, Ranking Member Lee, and members of the Subcommittee, I am Mike Russo, Federal Program Director for the U.S. Public Interest Research Group (U.S. PIRG) Thank you for the opportunity to testify on the issue of pay for delay settlements, and how they hurt consumers by inflating drug prices – too often, putting needed medication out of reach for patients.

U.S. PIRG is the federation of state Public Interest Research Groups. As a non-profit, non-partisan public interest organization, we work to advance solutions that protect consumers; encourage a fair, sustainable economy; and foster responsive, democratic government. One of our key concerns as a consumer group is the fact that health care costs more than it should. Health care costs burden state and federal budgets, and high insurance premiums and out-of pocket costs squeeze family budgets across our country. Given that, this issue of pay for delay settlements is one we've paid close attention to. It is an egregious example of how consumers and taxpayers are bearing higher costs than they should. Putting an end to it would cut wasteful spending and improve the lives of millions of patients.

In addition to our research on the issue, we are conducting a public education campaign on the problem of pay for delay. Since the details of these settlements rarely become public, consumers have been largely kept in the dark about the problem and how it affects them. We are working to change that by reaching out to consumers in communities across America. Due to that effort, our staff are hearing first-hand about how the high cost of prescription drugs affects people and how pay for delay makes it harder for patients to access the medication they need.

II. How Pay for Delay Hurts Consumers

I wanted to start my testimony by sharing the story of someone who found out about this practice the hard way – Karen Winkler, a wife and mother of three who lives in Michigan. She has Multiple Sclerosis, and suffers from chronic fatigue caused by that disease. Her doctor prescribed Provigil, and without that medication, she found she could barely function. The drug made a big difference – but it cost her $500 a month out of pocket, even with insurance. For years, the high price forced her to skip pills or split doses just to get by – she eventually had to stop taking the medicine for a time.

Fortunately, a generic version of Provigil went on the market last year. Karen now is able to get the medication she needs with a $16 co-pay for a three-month supply. She's back to living her life. Karen's story eventually had a happy ending. But the truth is, that happy ending was put off due to a pay-for delay-deal struck by Cephalon, the maker of Provigil. In late 2005, Cephalon paid over $200 million in a series of settlements that kept the generic off the market for six years[1] – six years during which Karen was stuck paying $500 a month instead of $16 every three. Even Cephalon's CEO admitted the harm – he explained that by settling with the generics, "we were able to get six more years of patent protection. That's $4 billion in sales no one expected."[2]

Karen's story isn't an isolated one. We are concerned that these pay-for-delay deals are becoming a routinely-used tool to keep generic versions of drugs off of the market.

III. Why Congress Must Act to End Pay for Delay

It was good news when the Supreme Court ruled last month that these deals may violate antitrust law, and opened drug makers to lawsuits over these payoffs. It holds out the hope that

antitrust litigation may lead to some consumers being compensated for the harm they've suffered because of inflated drug prices. But we can't wait for years – perhaps decades – of litigation to solve this problem. Consumers need relief now.

That's why we believe Congressional action is urgently needed, and why we think it is so important that Senator Klobuchar and Senator Grassley have introduced S. 214, the Preserve Access to Affordable Generics Act. We are pleased to be supporting this bill, as well as the other bi-partisan bill in the Senate, which Senator Franken and Senator Vitter have brought forward, S. 504, the FAIR Generics Act.[3]

IV. Recent Research

In the wake of the recent Supreme Court ruling, our staff worked together with researchers at Community Catalyst to pull together examples of how pay for delay affects consumers. Earlier this month, we released a report listing 20 drugs known to be impacted by pay-for-delay deals.[4] We found that reverse payment settlements have affected drugs used by patients with a wide range of serious or chronic conditions, ranging from cancer and heart disease to depression and bacterial infection. A few examples: Tamoxifen – a widely used treatment for hormone-receptive breast cancer; Cipro – a key antibiotic and anti-anthrax treatment; and Provigil – needed by MS patients and others with fatigue and sleep disorders, and which costs as much as $1,200 a month for the brand-name version.

We found the payoffs delayed these 20 drugs for five years on average, and as long as nine years. And the consequences for patients were significant – on average, the brand name drug was 10 times more costly than the eventual generic. In one instance, the brand name was 33

times more expensive. We conservatively estimated the total sales made by brand-name drug companies while the generic alternatives were delayed at $98 billion.

Without reverse payments, we would expect the generic versions of these drugs to have become available much sooner. Without the option to pay off the generic drug maker, there are several alternatives all of which would lead to earlier generic entry.

First, it the brand name firm could withdraw its patent infringement lawsuit against the generic company, allowing the generic to enter the market immediately. It is worth noting that these settlements often are used to protect the weakest patent claims. Second, the firms could agree to a settlement without payment. In that situation the generic firm would bargain hard for the earliest possible entry date, since it could no longer accept payment in compensation for a later date. And third, the brand-name company could try to take the case to trial.

For the 20 drugs on our list, this last option appears to be the least attractive option, given the fact that the brand-name drug company apparently preferred paying off a would-be competitor over the option of having to prove that the generic actually would infringe on the patent. As the Supreme Court noted in their recent ruling, the very existence of a large payoff suggests the brand-name company doubts that it would succeed in its lawsuit against the generic, and the purpose of such a payoff is to maintain high brand-name drug prices rather than face what might have been a competitive market. There is therefore good reason to believe that if the makers of these 20 drugs went to trial, they would fare even worse than brand-name drug companies do on average in such lawsuits – failing against a generic challenger between 48 and 73% of the time, according to a range of studies.[5]

The Generic Pharmaceutical Association recently released a study that attempts to rebut these arguments and claims that pay for delay settlements actually save consumers money.[6] But

to reach this counterintuitive conclusion, they included all settlements between brand name and generic companies – not just those involving a reverse payment. In addition, they counted "savings" even when a settlement caused a generic to come to market after the expiration of the active ingredient patent, and assumed that there's no cost to consumers from settlements even if the patent at issue would not have been upheld. In this case, the counterintuitive conclusion is just wrong.

When a brand-name company pays off a would-be competitor, one can be sure it's not to bring generic competition to market earlier than it otherwise would. These payoffs delay generics, and without competition, brand-name drug companies can keep prices high. Pay for delay is a win-win for brand-name and generic drug makers. But it is lose-lose for the rest of us, who face delayed access to lower-cost generics, and inflated brand-name prices.

V. Conclusion

Thank you for holding this hearing, and for giving us the opportunity to share our views on the issue. Increased attention to the way these deals are harming consumers comes at a critical time, and we urge all the members of this committee to support legislation to address this problem. The Supreme Court's decision was a step in the right direction, but it's up to Congress to finish the job and pass legislation that would finally put a stop to this anticompetitive practice that harms consumers.

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[1] Multiple pay-for-delay settlements starting in December 2005 allowed for generic entry in April 2012, causing a delay in generic access from Jan. 2006 to at least March 2012. Scott Hemphill, *An Aggregate Approach to Antitrust Using New Data and Rulemaking to Preserve Drug Competition*, Columbia Law Review, Jan. 2009, at 11, Table 2: Settlements with Monetary Payment; and Adam Greene, *Analyzing Litigation Success Rates*, RBC Capital Markets Industry Comment, Jan. 15, 2010, at Appendix C.

[2] John George, *Hurdles Ahead for Cephalon*, Philadelphia Business Journal (Mar. 20, 2006), http://www.bizjournals.com/philadelphia/stories/2006/03/20/story1.html.

[3] On May 8, 2012, the U.S. Public Interest Research Group jointed Community Catalyst, the Consumer Federation of America, Consumers Union, Families USA, Health Care for America Now, and the National Legislative

Association on Prescription Drug Prices on a letter to Senator Tom Harkin and Senator Mike Enzi supporting legislation to put an end to pay for delay.

[4] *Top Twenty Pay-for-Delay Drugs: How Drug Industry Payoffs Delay Generics, Inflate Prices and Hurt Consumers*, U.S. PIRG and Community Catalyst, 2013. See http://uspirg.org/reports/usp/top-twenty-pay-delay-drugs

[5] The 48 percent figure is from the RBC study that included cases from 2000-2009, the period of time when the number of pay-for-delay deals grew. See Adam Greene, *Analyzing Litigation Success Rates*, RBC Capital Markets Industry Comment, Jan. 15, 2010. An earlier FTC study of cases from 1992-2002, before deals became prevalent, found that generic companies won 73 percent of the time. See *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, July 2002.

[6] IMS Institute for Healthcare Informatics, for the Generic Pharmaceutical Association, *Impact of Patent Settlements on Drug Costs: Estimation of Savings*, June 2013. See http://www.gphaonline.org/media/cms/Impact_of_Patent_Settlements_on_Drug_Costs_Estimation_of_Savings_070813_FINAL_81.pdf.

PREPARED STATEMENT OF DR. SUMANTH ADDANKI

Statement of

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

Hearing Entitled
"Pay-for-Delay Deals: Limiting Competition and Costing Consumers"

Presented on

July 23, 2013

Chairman Klobuchar, Ranking Member Lee, and distinguished members of the Subcommittee, thank you for inviting me to appear before you today to testify regarding so-called Pay-for-Delay deals in general and, more particularly, in the context of proposed legislation S214.

I have been researching, writing about, lecturing about and testifying about such settlements for over 12 years, starting with my work on behalf of Schering Plough in the FTC action against Schering and others in 2001 and extending through articles recently published and pending publication. Based on my work, I would like to draw your attention to a few important points that seem to have been overlooked in the public debate and, indeed, in the draft legislation S214 as it stands. I will make these points in very summary form, but I urge that you consider, too, the more complete discussion of these points in some of my articles on the subject, which I have attached to my written testimony.

Settlement of patent litigation, including Hatch-Waxman cases between brand and generic manufacturers, can provide significant benefits to consumers. Any settlement that allows for entry prior to patent expiration has at least the potential to benefit consumers who might otherwise have had to wait until patent expiration to see such competition.

Unfortunately, a pure "term-split" settlement, i.e., one where the only terms of the settlement are that the alleged infringer will enter at some point before patent expiration, is

often simply not feasible, for a number of reasons which have been discussed in the literature. Diverging views about the strength of the patent, about the likely future of the market, asymmetric information, and other factors, can make such a pure settlement impossible.

What this in turn means is that any evaluation of the likely competitive effects of a settlement agreement needs to be carried out in comparison not to a hypothetical agreement that might never have been possible at all; rather, it has to be carried out in comparison to the likely or expected outcome of litigation. If the parties had not settled, but had litigated instead, would consumers have been better off or worse off than they are under the settlement before us?

That, of course, depends on the strength of the underlying patent. If the patent is very strong and was likely to have been adjudicated to be valid and infringed by the would-be entrant—the generic in the Hatch-Waxman case—a settlement that provides for entry before patent expiration may well be beneficial to consumers. On the other hand, if the underlying patent is weak—likely to be judged invalid or not infringed or both—a settlement that does not permit immediate or near-immediate entry may well be bad for consumers relative to the alternative of litigation.

I should stress that the fact of a so-called reverse payment does not convey much information about whether a given settlement is actually better for consumers than the alternative of litigating the patent. For reasons thoroughly discussed in the economic literature, a patentee may well make a "reverse payment" and still agree to an entry date that is better for consumers because it is earlier than the expected outcome under the litigation alternative: risk aversion, divergent views about the strength of the patent or future market developments or the time value of money are some of the factors that can engender this outcome.

The implication is obvious: rather than focusing on bright-line questions like "does the settlement contain a reverse payment," we need to consider the settlement in its entirety—including whatever payment terms it might contain—and then evaluate its effect on consumers relative to the likely outcome of patent litigation. Necessarily, this involves at least some consideration of the merits of the underlying patent case and of the likely strength of the patent.

Such analysis is not as onerous as some, including the Federal Trade Commission, have suggested. For every patent settlement that we actually have to deal with, there is a federal judge who has acquired considerable knowledge of the merits of the underlying patent case and, more often than not, has construed the claims of the patent in a *Markman* ruling. It seems entirely likely that a judge in that position has more than enough information about the underlying patent suit to have an informed judgment of the strength of the patent,

certainly enough to be able to judge—aided by expert analysis if necessary—whether a given settlement of that suit is likely to benefit consumers.

To be sure, the analysis that I describe is neither easy nor swift. And that brings me to my final point, one that seems curiously to have been lost in the debate. When analyzing settlements like this under the rule of reason—which is what the Supreme Court has said we must do—the very first step can be called a "gating" step. Does the patentee possess monopoly power? If not, *the inquiry ends*. There is *no need* to undertake the potentially difficult and time consuming tasks of ascertaining whether or not a reverse payment even exists (by no means self-evident in a complex agreement) and, should it exist, of evaluating the settlement's outcome against the outcome of litigation. And, as we should all know by now, a patent may confer exclusivity, but it by no means necessarily confers monopoly power. If there is no monopoly power present, there is no basis on which to condemn these settlements or, indeed, to analyze them in detail.

In light of the foregoing points, I respectfully suggest that S214 in its current form needs to be modified in three respects if it is to lead to the right economic outcomes. First, a reverse payment does not necessarily imply any anticompetitive effect, so the presumption of anticompetitive effects should be dropped. Second, the relevance of the underlying patent suit to any competitive analysis of a given settlement of that suit needs to be recognized explicitly and given due weight in the analysis prescribed by the bill. Finally, and perhaps most important, the bill needs to acknowledge the importance of the monopoly power screen and give due weight to that screen in the analysis of any settlement.

Thank you for your consideration. I have attached two articles that discuss these issues further and may be of use to you.

References (attached)

Sumanth Addanki and Alan J. Daskin, "Patent Settlement Agreements," Chapter 85, Volume 3, in *Issues in Competition Law and Policy*, published by American Bar Association, Section of Antitrust Law, August, 2008.

Sumanth Addanki, "*Schering-Plough* and the Antitrust Analysis of Patent Settlement Agreements in Pharmaceutical Markets," *Antitrust Insights*, National Economic Research Associates, Inc., 2005.

MISCELLANEOUS SUBMISSIONS FOR THE RECORD

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.

####

Prepared Statement of Senator David Vitter of Louisiana
Senate Committee on the Judiciary
Subcommittee on Antitrust, Competition Policy and Consumer Rights
Hearing on the Pay-for-Delay Deals: Limiting Competition and Costing Consumers
Tuesday, July 23, 2013

Vitter Statement at Pay-for-Delay Hearing

Thank you Madame Chair for holding this important hearing on anti-competitive pay-for-delay deals.

Over the last several years, we have seen a huge increase in anti-competitive pay-for-delay deals. Brand-name drugmakers are paying off, or "settling," with a first-to-file generic drugmaker, often restricting generic market entry for years in the future. Simply put, this is delaying significant health care savings to consumers. As prescription drug prices have exploded and put real pressure and a real burden on many Americans' budgets, particularly senior citizens, these deals are counterproductive in making medications more affordable and are clearly hurting consumers by delaying cheaper generic drugs to market. This business practice is unfortunately increasingly becoming a prevailing model that is a win-win for brand-name and generic manufacturers at the expense of patients and taxpayers. Additionally, pay-for-delay patent settlements are delaying timely public access to generic drugs, which costs consumers and taxpayers billions of dollars annually.

The Federal Trade Commission (FTC) compiled data revealing "the continued trends of record numbers of brands and generics resolving patent litigation prior to a final court decision" and "significant numbers of such settlements potentially involving pay-for-delay." In 2004, the FTC identified zero potential pay-for-delay deals. In 2006, they identified 14 potential deals, and in 2011 they identified 28 -- doubling in just five years. That is "28 final settlements (that) contain both compensation to the generic manufacturer and a restriction on the generic manufacturer's ability to market its product." The FTC noted that of these 28 potential pay-for-delay settlements, 25 of them involve branded pharmaceuticals with combined annual U.S. sales of $9 billion.

The pay-for-delay issue is a problem than must be solved due to its significant impact on the rising cost of health care. Congress must focus on reforming the underlying regulatory problems that stifle competition and unnecessarily raise the costs of health care for consumers. The time is right for Congress to act to root out other anticompetitive practices and enact legislation to solve the pay-for-delay problem once and for all. I would like to thank Senators Grassley and Franken for joining me this year by cosponsoring my amendment to the budget to address this problem. I look forward to continuing to work with my colleagues to finding solutions to lower prescription drug prices for Americans.

James L. Madara, MD
Executive Vice President, CEO

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July 23, 2013

The Honorable Amy Klobuchar
United States Senate
302 Hart Senate Office Building
Washington, DC 20510

Dear Senator Klobuchar:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to express support for S. 214, the "Preserve Access to Affordable Generics Act." The AMA has policy, passed by physicians in our House of Delegates representing all states and national medical specialties, supporting the Federal Trade Commission (FTC) in its efforts to stop "pay-for-delay" arrangements by pharmaceutical companies. We appreciate your efforts to clarify and strengthen the FTC's authority to bring an end to tactics that delay the entry of generics into clinical practice.

The cost to the health care system and individual patients of anti-competitive settlement agreements between brand and generic manufacturers is substantial. Brand-name firms have used exclusion agreements to delay the entry of generics by an average of seventeen months and to terminate patent challenges that could otherwise generate billions of dollars in patient savings. The lack of low cost treatment options reverberates throughout the entire health care system and can exact a heavy toll on the uninsured. Even for those patients who are insured, but who are on fixed or limited incomes, having a generic option is often the difference between having access to a health care treatment or not having any treatment at all. Due to the foregoing, the AMA has supported the FTC's efforts to bring an end to pay-for delay arrangements by most recently joining with other organizations in filing a friend-of-the court brief in the U.S. Supreme Court. While the Court held that such agreements are illegal, the decision placed a very high burden on the FTC in challenging such agreements. S. 214 would unambiguously restore the congressionally intended balance between the Hatch-Waxman Act's provisions to spur innovation while also fostering competition through the development of generic drugs.

Sincerely,

James L. Madara, MD

March 12, 2013

The Honorable Amy Klobuchar
302 Hart Senate Office Building
Washington, DC 20515

Dear Senator Klobuchar:

The Academy of Managed Care Pharmacy (AMCP) is pleased that you have introduced S. 214, the "Preserve Access to Affordable Generics Act," which would prohibit brand-name and generic drug manufacturers from entering into generic exclusion agreements. AMCP believes that such agreements deny patients access to affordable generic drugs, unnecessarily raising prescription drug costs for patients, employers, health plans and taxpayers.

AMCP is a national professional association of pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to improve health care for all. The Academy's almost 7,000 members develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit.

While AMCP realizes that appropriate incentives must be retained in order for brand-name manufacturers to recoup their investment in research and development of brand-name drugs, the use of strategies that can unnecessarily delay the entry of generic drugs into the marketplace must be prohibited. If there was concern regarding either the safety or efficacy of a generic drug, a delay would be warranted. However, it appears that most frequently, brand-name manufacturers and generic manufacturers come to legal agreements that delay the entry of generic competitors for reasons other than safety and efficacy. AMCP believes these agreements must be addressed in order to streamline the generic approval process and allow patients greater access to generic drugs.

AMCP's staff would be pleased to work with you and your staff to support passage of this legislation. Please do not hesitate to contact me or AMCP's Vice President of Government Affairs, Lauren Fuller, at 703-683-8416, or by email at lfuller@amcp.org, whenever we may be of assistance. Thank you again for your efforts to ensure access to safe and affordable prescription medications.

Sincerely,

Edith A. Rosato, R.Ph., IOM
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NERA
Economic Consulting

A NERA Perspective

Antitrust Insights

Spring 2005

A NERA Economic Consulting Publication

From the Editor:

In the US, the growth in spending on prescription drugs has exceeded that of any other single category of health care spending. This is due, in large part, to increases in pharmaceutical research and development spending, which has led to new and sometimes more expensive medicines, as well as broader insurance coverage for prescription drugs, which is one of the main drivers of demand. To spur competition at the retail level without compromising manufacturers' incentives to innovate, the US Congress passed the Hatch-Waxman Act in 1984, which was designed to encourage the entry of generic drugs. Since the Act was passed, generic entry has played an increasingly important role in keeping drugs affordable.

In this issue of Antitrust Insights, *Sumanth Addanki, a Senior Vice President in NERA's White Plains office, tackles one of the most important economic, legal, and public policy issues surrounding competition in this industry—the rationale and competitive effects of an agreement between a generic and branded drug manufacturer to settle a patent dispute, where the settlement involves a payment from the patent holder (i.e., the branded manufacturer) to the alleged infringer (i.e., the generic manufacturer). The Federal Trade Commission (FTC) has challenged these types of agreements, claiming that these so-called "reverse payments" necessarily serve to delay generic entry. Sumanth explains why the FTC's "bright line" rule about such agreements is not appropriate, as it is based on a fundamentally invalid assumption, one that ignores the risks of litigation and the parties' desire to avoid or reduce these risks. Therefore, as Sumanth points out, the FTC's rule could invalidate procompetitive agreements as well as anticompetitive ones. The FTC's test, he argues, is no substitute for case-by-case analysis.*

Sumanth specializes in antitrust, intellectual property and the evaluation of commercial damages. He has analyzed the competitive consequences of numerous mergers and has frequently presented the results of his analyses to the US antitrust agencies and courts. Many of Sumanth's antitrust inquiries have focused specifically on intellectual property and its unique role in the analysis of market power and competitive effects.

I hope you enjoy this issue.

—Lawrence Wu, Editor

Schering-Plough and the Antitrust Analysis of Patent Settlement Agreements in Pharmaceutical Markets

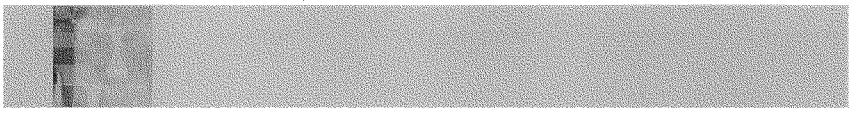
By Sumanth Addanki [1]

The Court of Appeals for the Eleventh Circuit dealt the Federal Trade Commission (FTC) a blow in March 2005, when it resoundingly rejected the Commission's conclusions in *In the Matter of Schering-Plough Corporation.*[2] The Commission's Opinion had concluded that agreements entered into by the Schering-Plough Corporation (Schering) in settlement of patent litigation against Upsher Smith and ESI Lederle violated the antitrust laws. Those conclusions, in turn, rejected the earlier findings of the Administrative Law Judge (ALJ) who, after a nine-week trial, had concluded that the agreements were *not*, in fact, anticompetitive. In reversing the FTC Opinion, the Eleventh Circuit reinstated the ALJ's findings for the most part. And, in the most recent twist in this convoluted controversy, the FTC has moved (in April 2005) for *en banc* reconsideration of the Eleventh Circuit's ruling.

The ultimate outcome of the FTC's unremitting efforts is yet to be determined, but the agency's reverses stem in large part from fundamental flaws in its analytic approach to the matter. Although the shortcomings in the FTC's approach were pointed out at the trial of the matter before

[1] The author served as an economic expert witness for Schering-Plough in the FTC's administrative proceeding against Schering-Plough and Upsher Smith. The opinions expressed here are based on the Expert Report that he filed in 2001 and expert testimony that he delivered at the hearing in 2002. Needless to say, they do not necessarily reflect the opinions of any other economists at NERA. Some of these ideas have been discussed in Schildkraut, Mark, "Patent-Splitting Settlements and the Reverse Payment Fallacy," *Antitrust Law Journal*, 71, 2004; and Willig, J. and Bigelow, J, "Antitrust Policy Toward Agreements that Settle Patent Litigation," *Antitrust Bulletin*, Fall 2004.

[2] FTC vs. Schering-Plough et al., US Court of Appeals for the Eleventh Circuit, March 8, 2005.



"The FTC argued that the appropriate measure of any 'anticompetitive effect' of a given settlement agreement is the amount of time by which it delays entry relative to alternative settlements or litigation."

the ALJ, the FTC did not respond to the substance of these criticisms during the trial. Curiously, the Commission's subsequent Opinion overturning the ALJ also failed entirely to address these shortcomings. Perhaps the most important of these—and the one that is discussed here—is that the FTC's analytic framework—and, more important, the simple "bright line" test that the FTC urges for future analyses of such agreements—are neither usable nor defensible.

Background

Schering held a patent on a micro-encapsulated extended-release potassium chloride supplement which it marketed in the US as K-Dur 20. In late 1995, Upsher Smith, a generic drug manufacturer, applied for Food and Drug Administration (FDA) approval to market a generic version of the product. Schering sued for patent infringement and, after protracted litigation, the parties agreed to a settlement in June 1997. Under the settlement, Upsher was permitted to enter the market no earlier than September 2001 (the patent will expire in 2006) and Schering licensed several other Upsher products in development (products unrelated to potassium chloride), for which it agreed to pay $60 million.

The FTC declared that the licenses to other Upsher products were a sham and that the $60 million payment was nothing more than a bribe that Schering paid Upsher to delay its entry into the marketplace, to the detriment of consumers. The FTC further proposed a "bright line" litmus test under which any settlement which incorporates a so-called "reverse payment," i.e., a payment by the patentee to the alleged infringer, would be regarded as anticompetitive on its face.

The FTC's Three-Part Test for Anticompetitive Settlements

Through the testimony of its economic expert, the FTC claimed that a simple three-step test is sufficient to determine whether an agreement that settles a patent infringement case is anticompetitive: (i) does the patent holder (plaintiff) have monopoly power? (ii) is there a threat to that monopoly power? and (iii) is there a payment to the potential entrant (defendant) to delay market entry by the defendant? If the answer to all these questions is affirmative, the FTC asserted that the agreement must be anticompetitive, and that it would necessarily make consumers worse off than they could have expected to be had the matter been resolved through litigation.

The following economists contributed to this edition of *Antitrust Insights*:
:: ***Lawrence Wu, Vice President/Editor (San Francisco, +1 415 291 1007, and White Plains, +1 914 448 4054)***
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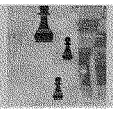
:: ***G. Steven Olley, Senior Consultant (White Plains, +1 914 448 4139)***



The proposed test was defended as follows. To begin with, the FTC argued that the appropriate measure of any "anticompetitive effect" of a given settlement agreement is the amount of time by which it delays entry relative to alternative settlements or litigation; according to the FTC, this measure is reasonable because consumers are better off the sooner the generic entrant enters the market. The FTC then argued that settlements that involve payments from patentee to infringer are necessarily anticompetitive: on the one hand, if the parties could reach a settlement without a side payment, the settlements reached with side payments are "more anticompetitive," i.e., result in later generic entry, than the settlement that those same parties would have reached otherwise. On the other hand, when payments are necessary for settlement even to be feasible, such payments in the "wrong" direction, from incumbent to entrant, lead to outcomes "more anticompetitive"—i.e., later entry dates—than either party expects under litigation.

The Proposed Test is Useless as a Means of Identifying Anticompetitive Settlements

The FTC's Reasoning

The fatal flaw in the foregoing reasoning lies in the argument that settlements that involve payments to the generic entrant will necessarily result in entry dates later than might be expected under litigation. In essence, the FTC argues as follows. Suppose for simplicity that the litigation has reached a stage where discovery is complete, so that the parties have learned all that they could expect to learn prior to trial about their odds of winning at trial; suppose further that both parties agree that each one's chances of prevailing in the litigation are roughly 50 percent. Then, each party expects that, if they continued to litigate, the probability of the defendant prevailing and entry occurring virtually immediately is 50 percent, while the probability of the patentee prevailing and of entry being delayed until expiration of the patent is, also, 50 percent.[3] Therefore, the FTC argues, the "expected" time to entry under

> *"The FTC argued that settlements reached with side payments are 'more anticompetitive,' i.e., result in later generic entry, than the settlement that those same parties would have reached otherwise."*

[3] I will assume, following the FTC and its economic expert, and only for purposes of the present discussion, that the outcome of the trial will be made known relatively quickly, so that, should the generic manufacturer prevail, its entry would not be subject to any additional delay. In fact, of course, this assumption is frequently unrealistic, and it appears unrealistic in the instant case, as discussed more fully below.

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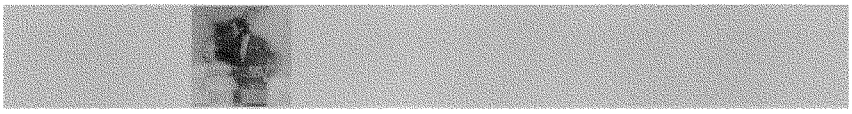

> *"Economists have long understood that most individuals are 'risk averse' in that they value outcomes that are inherently uncertain less than outcomes that can be known with certainty."*

litigation (i.e., the probability-weighted average of the two entry dates under the two alternative outcomes) is approximately one-half of the term remaining on the patent.[4] Any settlement that results in an entry date *later* than this benchmark would, then, be deemed anticompetitive.

The FTC further argues that if the parties agreed that their respective chances of prevailing were 50 percent each, they would not agree, absent side payments, to any settlement that specified an entry date different from this benchmark date; the patentee, according to this view, would accept no date earlier than the benchmark, whereas the entrant would accept no date later than the benchmark, each party reasoning that it could expect to do at least as well should it pursue the litigation to its conclusion. Therefore, the FTC concludes, any payment from patentee to entrant must necessarily be a "bribe" to persuade the entrant to delay its entry.

The Role of Risk and Risk Aversion

A crucial flaw in this chain of reasoning lies in the assertion that the patentee would not settle for an entry date earlier than the benchmark (i.e., the expected, or probability-weighted average, date of entry under litigation). The implicit assumption here is that the patentee would view a *date certain* entry of, say, four years in the future as exactly equivalent to engaging in litigation whose *expected* entry date is also four years in the future (because, say, it offers equal odds of entry today or entry eight years hence).

The problem with this assumption is that it is frequently violated in practice. There are many sound (and commonly occurring) economic reasons why a patentee may be willing to settle for an entry date earlier than that expected under litigation. Among these is risk and people's attitudes toward risk. Economists have long understood that most individuals are "risk averse" in that they value outcomes that are inherently uncertain less than outcomes that can be known with certainty. Our everyday experience is replete with examples of this. Companies whose fortunes are more volatile (i.e., risky) have to offer higher *expected returns* to their investors than do companies that are less risky. The interest rates on corporate bonds reflect the same reality: companies whose prospects are regarded as more risky (and whose ratings by bond rating services like Moody's reflect that assessment) have to offer higher interest rates in order to attract investors than do companies that are regarded as less risky.

[4] For instance, if the patent at issue has eight years to run, the probability of instantaneous entry is 50 percent—reflecting the likelihood that the infringer prevails in the lawsuit. However, because there is also a 50 percent chance that the patentee will prevail, the probability that entry would be deferred for eight years is also 50 percent, which means that the expected time to entry under litigation is four years (a 50 percent chance of zero and a 50 percent chance of eight years).

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Paying for Certainty

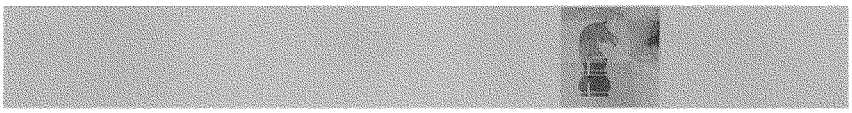
The immediate implication of this, of course, is that an individual who is risk-averse might well be willing to sacrifice some portion of his/her expected return from a venture, if, in exchange, he/she could reduce the uncertainty associated with that venture. A patentee who has built a substantial business around a patent is very likely to be risk-averse in exactly that fashion: when choosing between a settlement and pursuing litigation to its final outcome, the patentee would recognize that the nonzero probability associated with "losing it all" creates very real risk, regardless of the expected value associated with litigation. If, as in our example above, the expected date of entry associated with litigation were four years (because there was equal likelihood of immediate entry or entry after eight years, upon patent expiration), the risk-averse patentee would be willing to sacrifice some of this expected value in exchange for reducing the uncertainty attendant upon litigation. In other words, the risk-averse patentee would be willing to settle for a "date certain" *earlier* than the expected date under litigation so as to avoid the risk associated with the litigation. In effect, the patentee's risk aversion could make the settlement more favorable to consumers than the expected outcome under litigation.

Of course, such a settlement could also be attractive to the entrant, because it would permit entry sooner than might have been expected under litigation. The problem is that the would-be infringer may well also find that its liquidity position does not permit it to "wait out" the period until that entry date.[5] In other words, while attractive, the settlement may not be feasible for the entrant without some sort of cash infusion that would help it to survive until the entry date at issue (even though it is earlier than the expected outcome under litigation). In this situation the only path to a settlement could well be one in which the patentee provides such a cash infusion. Why? Simply because, without the infusion, even though the patentee would be willing to entertain a definite entry date earlier than the expected outcome of litigation, that earlier date would remain infeasible for the entrant. Or, to put it differently, any date that the entrant would regard as feasible (absent the cash infusion) would be too early for the patentee to accept, given its odds of prevailing in the lawsuit (even allowing for risk aversion). Thus, the only alternative to the settlement with a cash payment might, in fact, have been litigation, under these circumstances; a settlement without a cash payment might not be feasible at all.

"When choosing between a settlement and pursuing litigation to its final outcome, the patentee would recognize that the nonzero probability associated with 'losing it all' creates very real risk."

Note that this does *not* mean that the resulting date of entry would be later

[5] Note that the potential entrant may well have the cash resources to wait until the outcome of litigation is known but not enough to survive until the mathematical "expected outcome" of the litigation. For instance, suppose that the patent at issue has 12 years to run, each side has a 50 percent chance of winning, and that the litigation will take 3 years to complete. Under these assumptions, the "expected" entry date is the weighted average of 3 years and 12 years, which is 7 years and-a-half. The entrant may well be able to survive for 3 years but not for 7 years or longer.



"The FTC's proposed test is useless as a litmus or 'bright line' test. Its critical assumption that the patentee would never agree to a settlement that embodied an entry date earlier than the date that might be expected under litigation is fundamentally invalid."

than the expected outcome of the litigation. In fact, the date agreed upon by the parties—even with the cash payment—may well be *earlier* than the date that might be expected under litigation. This, of course, is the crucial question: is the entry date specified in the settlement earlier than or later than the benchmark entry date that might be expected under litigation? In this example, whether or not it is earlier than the benchmark date depends upon the degree of risk aversion of the patentee, the amount of the payment required and the returns that each party expects to earn under the alternatives.

Implications

What this means is that the FTC's proposed test is useless as a litmus or "bright line" test. Its critical assumption that the patentee would never agree to a settlement that embodied an entry date earlier than the date that might be expected under litigation is fundamentally invalid. The invalidity of this underlying assumption, of course, necessarily nullifies the proposed test. Moreover, it is important to note that the risk aversion discussed above represents only one of several possible reasons why the FTC's key assumption could easily be violated. For instance, the patentee might simply be pessimistic about its case; the judge or magistrate may have placed particular pressure on the patentee to settle; litigation costs, including out-of-pocket costs as well as the significant opportunity costs that litigation imposes on senior management time and attention, could be a factor.[6] Therefore, contrary to the FTC's assertion that a payment from patentee to potential entrant is necessarily anticompetitive, agreements that provided for payments from the patentee to the entrant could, in fact, be procompetitive.

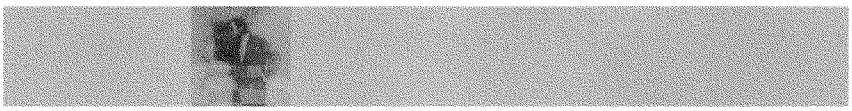
A More Appropriate Test

What, then, is the analyst to do? In many situations, the monopoly power portion of the proposed test—if properly applied—could obviate the need for further inquiry. If there is no monopoly power present, there is no need for any further inquiry; the agreement could not be anticompetitive in its effect.[7] Assume, however, that further analysis establishes that the patentee possesses monopoly power and that, for any of a number of reasons, including those discussed earlier, a settlement without cash payments is not feasible.[8] In that case, as even the FTC's economic expert conceded, the appropriate test is whether or not settlement resulted in an agreed-upon entry date later than what might have been expected under litigation.

[6] There are certainly other reasons why the FTC's assumptions may be violated. Among other things, there might be antitrust counterclaims that would be disposed of concurrently with the patent litigation, which could bear on the parties' incentives to settle.

[7] Because of other fundamental flaws not discussed here, the FTC erroneously concluded that Schering's K-Dur 20 possessed monopoly power. As I showed in my testimony—adopted by the trial court—appropriate application of the monopoly power test indicated clearly that there was no such power in this case.

[8] Even the FTC's economic expert acknowledged that such situations could arise.



It seems eminently reasonable to suppose that, to establish whether or not this occurred, one must evaluate the likely outcomes of the patent case, as well as each party's odds of prevailing in litigation. These facts would help establish what the expected outcome would have been under litigation. However, the FTC explicitly disavowed the need for any such investigation. Rather, the FTC proposed *inferring*—based on economic argument—that the settlement with cash payments *could not* have resulted in an earlier entry date than might be expected under litigation. But, as I have discussed at length above, the fundamental underpinnings of the proposed economic reasoning may not be satisfied, for a number of possible reasons. Therefore, the "inferential" conclusions are unsupportable; some alternative means must be found to evaluate whether or not the settlement is anticompetitive in its effect.

The correct approach to this is, in fact, the obvious one stated above. Any assessment of the likely competitive effects of the settlement—relative to the litigation alternative—should be based squarely on the facts surrounding the underlying patent case itself. Suppose, again, that the expected (or agreed-upon) entry dates offer a reasonable yardstick with which to evaluate the competitive effects of a given settlement. The objective facts elicited in the patent infringement case—presumably including findings regarding patent claim construction and the like—may constitute the best available information regarding the relative odds that each party would have prevailed in the underlying patent suit. Thus, an agreement that, say, splits the remaining patent term in half, could be viewed as relatively procompetitive if the objective facts uncovered in the litigation suggest that the expected time to entry under litigation was longer, i.e., that the patentee had the better of the case. Analogously, if the patentee had monopoly power, such a settlement might be viewed as anticompetitive if the objective facts suggested that the patentee had relatively low odds of prevailing.

"Any assessment of the likely competitive effects of the settlement—relative to the litigation alternative—should be based squarely on the facts surrounding the underlying patent case itself."

In this connection, it is important to recall that the assumption underlying these discussions is that entry would be virtually instantaneous should the entrant prevail in the litigation. In actual fact, even a victory could result in deferred entry, either because

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"In those situations in which a properly applied test indicates that the patentee possesses monopoly power, it is necessary to evaluate whether the settlement agreement at issue, on balance, delayed entry beyond the date that might have been expected under litigation."

of appeals or because the entrant's approvals (or other FDA permissions) were still pending. In that case, the expected time to entry would exceed one-half the time remaining on the patent even if the odds of the entrant prevailing were 50 percent. Therefore, any empirical evaluation of whether or not a given agreement is anticompetitive requires that we inquire not only about the odds of each party prevailing, but also about the likely entry dates under alternative litigation outcomes.

To recapitulate, in those situations in which a properly applied test indicates that the patentee possesses monopoly power, it is necessary to evaluate whether the settlement agreement at issue, on balance, delayed entry beyond the date that might have been expected under litigation; such an evaluation would, necessarily, involve an assessment of the facts surrounding the underlying patent case in order to ascertain the outcomes that the cases could have generated, as well as the relative likelihood of each of those outcomes in litigation. Only then could one establish whether or not the agreement resulted in an entry date that is later than the date that might have been expected under litigation. The FTC's proposed "inferential" approach fails to meet this burden.

In Conclusion: There Are No Shortcuts!

In articulating its attack on Schering's agreement with Upsher, the FTC proposed a seductive-sounding analytic shortcut: the FTC suggested that detailed analysis of the agreement's competitive effects was superfluous because payments from patentee to entrant automatically signal anticompetitive effects. That argument, as we have seen, is unfounded. There are sound economic reasons why parties may find it necessary to include a payment in an agreement whose ultimate effect is, nevertheless, procompetitive. Therefore, this "shortcut" is, in fact, entirely unhelpful. The FTC's proposed approach cannot substitute for a detailed investigation of the facts of the case; only such a detailed investigation can establish whether the settlement agreement at issue was procompetitive or anticompetitive relative to the likely outcome of litigation.

ConsumersUnion
POLICY & ACTION FROM CONSUMER REPORTS

STATEMENT FOR THE RECORD

GEORGE P. SLOVER
CONSUMERS UNION

BEFORE THE

SUBCOMMITTEE ON ANTITRUST,
COMPETITION POLICY, AND CONSUMER RIGHTS
COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE

ON

PAY-FOR-DELAY DEALS: LIMITING COMPETITION
AND COSTING CONSUMERS

JULY 23, 2013

Introduction

Consumers Union, the policy and advocacy arm of Consumer Reports,[1] commends the Subcommittee for holding this important hearing, and we appreciate the opportunity to present our views.

The availability of affordable generic alternatives to patented brand-name pharmaceutical drugs has saved consumers substantial sums over the years, totaling many billions of dollars. Consumers benefit in two ways – they pay less for the generic drug; and because the prices are lower, the drug is affordable and available to more consumers.

Consumer Reports has been very active in informing consumers of the benefits of generic alternatives and how to shop around for the best deals on the medicines they need.

In 2004, Consumer Reports launched a free public education initiative, "Consumer Reports Best Buy Drugs," to provide consumers with reliable, easy-to-understand advice about the safest, most effective, and lowest-cost prescription drugs available. We currently provide information for 26 different classes of medicine, and we will likely add more classes as we go forward. Consumers can use this information to check to see if there is a safe, effective, and low-cost alternative to a medicine they are taking. We encourage consumers to talk to their doctors about this information.

We also publish articles periodically in our magazine explaining the cost-saving benefits of generic alternatives, and alerting readers, with specific examples, of how prices for some common generic drugs can vary widely depending on the retail pharmacy.

The Promise of Hatch-Waxman and the Problem of Pay-For-Delay

We were strong supporters of the abbreviated new drug application process established under the Hatch-Waxman Act in 1984. Experience has borne out our prediction that it would create powerful incentives for brining new generic alternatives to market. These incentives included not only the less costly and more expedited path to FDA approval, but also a special 180-day exclusivity period, under which the first generic alternative to a brand-name drug would have 180 days in the market to itself, as the sole alternative to the brand-name drug, before competing approved generic alternatives would be permitted to enter the market.

During the 180-day period, the generic would sell for less than the brand-name drug did under monopoly conditions, but still for more than under fully competitive conditions. A typical

[1] Consumers Union is the public policy and advocacy division of Consumer Reports. Consumers Union works for telecommunications reform, health reform, food and product safety, financial reform, and other consumer issues. Consumer Reports is the world's largest independent, not-for-profit product-testing organization. Using its more than 50 labs, auto test center, and survey research center, the nonprofit rates thousands of products and services annually. Founded in 1936, Consumer Reports has over 8 million subscribers to its magazine, website, and other publications

price reduction during the 180-day period might be 20 to 30 percent, as compared to a reduction of 80 percent or more under full competition. For a major drug, the additional benefit of this 180-day period to the first generic could be in the hundreds of millions of dollars – a powerful financial incentive to be the first to develop a generic alternative and apply for FDA approval expeditiously, while still shortening the time before the market would be opened to full competition.

But the amount of money at stake for the brand-name drug maker in protecting its monopoly for as long as possible – potentially billions of dollars over the life of its patent – also creates powerful incentives for the brand-name drug manufacturer to find a way to delay competitive entry. And the ways entry has been delayed have not been limited to the time-honored way established under the patent laws, defending its patents vigorously in court, and prevailing against the generic manufacturer for infringement. They have also included the less honorable way, of inducing the generic manufacturer to voluntarily delay introduction of its competing product, thereby prolonging the period during which it can charge monopoly prices to consumers who need the drug and have no alternative.

Because the additional monopoly profits the brand-name drug maker can reap from staving off competition far exceed the profits the generic drug maker could reasonably expect to gain by competing, the brand-name drug maker can pay the generic drug maker more for agreeing not to compete than the generic drug maker can earn by competing, and still come out way ahead. Looked at another way, what the brand-name gives up in monopoly profits if the generic enters the market doesn't all go to the generic. A significant portion of it goes to consumers in cost savings as a result of competition.

And those consumer cost savings can increase even more dramatically once the 180-day exclusivity period ends and full competition arrives. Of course, when that happens, both the brand-name and the first generic have to accept reduced profits.

So putting off the beginning of the 180-day period, and the competitive free-for-all that follows it, for as long as possible is a big win for the companies who enter into this anticompetitive scheme. But it is a big loss for consumers.

And it's not as if pay-for-delay is necessary to enable parties to settle costly patent litigation under Hatch-Waxman. If there is no payoff in exchange for delay, what the generic and the brand-name drug makers are left to negotiate over is when the generic will enter the market. If the generic drug maker is willing to agree to delay entry for X years if it gets a payment of $10 million a month while it waits, it stands to reason that it will not be willing to wait that long if it gets no money while it waits. Whatever period of delay the parties eventually agree to, it will be a shorter period without the payoff, and consumers will begin to benefit from competition sooner. The addition of the pay-off just skews the negotiations in the anticompetitive direction.

And as if those anticompetitive temptations weren't already too powerful, a drafting issue in the Hatch-Waxman Act has perversely made the incentive to agree to a payoff for delaying generic competition even harder to resist. The special 180-day exclusivity period, as interpreted by the courts, is awarded to the first generic drug for which an application is filed with the FDA, regardless of what happens after the filing. This interpretation allows the generic who is first at the filing gate to grab the 180-day exclusivity period, "park" it, take the payoff from the brand-name drug for delaying introduction of its competing alternative drug, sometimes for years, and still get the full benefit of the 180-day exclusivity period down the road.

This interpretation also makes it easier for the generic and brand-name drugmakers to make their pay-for-delay agreement succeed, because it denies the 180-day exclusivity period to other generic drug makers who might come after.

From the beginning, the Federal Trade Commission vigorously challenged pay-for-delay settlements as violating the antitrust laws, and for a number of years, that largely stopped them. But in the 2005 *Schering-Plough* decision and the 2006 *In re Tamoxifen* decision, two circuit courts, dismissed the antitrust challenge, even while readily acknowledging that the pay-for-delay settlement in question was anticompetitive. The courts reasoned that the patent underlying the settlement had to be presumed to be valid and, assuming that it was valid, the pay-for-delay settlement enjoyed the same antitrust immunity as the patent as long as it did not go beyond the scope and life of the patent.

In other words, the courts ruled that patent law principles and legal policies favoring settlements over litigation required them to look the other way, in defiance of common sense.

These court rulings threatened to give free rein to pay for delay, ignoring the obvious question: why would the brand-name drug manufacturer be willing to pay tens or even hundreds of millions of dollars to delay entry of a generic alternative when it really believes it is already protected from entry by a valid, enforceable patent?

As long as these court rulings stood, anticompetitive pay-for-delay settlements were effectively immune from legal challenge. As these settlements came roaring back into vogue, Consumers Union joined with others in calling – including in testimony before this Subcommittee in January 2007 – for a legislative solution addressing both the antitrust immunity and the 180-day exclusivity period.

The Supreme Court's Actavis Decision

We are pleased that the Supreme Court has now ruled, in *Federal Trade Commission v. Activis, Inc.*, that pay-for-delay settlements are subject to the antitrust laws, that they cannot hide behind a smokescreen of dubiously presumed patent validity. The Court's opinion does not go as far as it could have. The Court certainly had reason enough to pronounce these settlements

presumptively unlawful, to be given a "quick-look" analysis that then puts the evidentiary burden on the two drug companies to justify their anticompetitive agreement and explain, if they can, how it is somehow actually precompetitive and pro-consumer. But the opinion nevertheless goes far enough to subject these agreements to meaningful scrutiny under the antitrust laws. That's a great step forward.

And there is plenty in the Supreme Court's opinion to lead the lower courts to find most if not all pay-for-delay agreements to be in violation of the antitrust laws. Even though the Court directs that these agreements be evaluated under the rule of reason, it also notes that rule of reason analysis is not uniformly wide open, that there is a "sliding scale" of how much proof may be required. So if the lower courts follow these aspects of the Supreme Court's opinion, the end result may ultimately not be noticeably different from a quick look.

Under the best scenario, this decision can now open the way for vigorous antitrust enforcement against pay-for-delay agreements, creating a strong deterrent against them and spurring increased competition through properly directed, healthy incentives for robust development and introduction of affordable generic alternative medications.

But questions remain as to how the lower courts will apply the decision. For one thing, now that presumed patent validity is not an absolute bar to antitrust liability, will drug makers defend their pay-for-delay agreement by proving that the patent is valid, and infringed by the generic? The Supreme Court emphasizes that its opinion should not be read "to require the courts to insist, contrary to what we have said, that the Commission need litigate the patent's validity." The lower courts could decide, on that basis, that patent validity is not relevant in a pay-for delay settlement, or that there is a strong legal presumption that the patent is invalid, or not infringed, if the two companies are willing to agree to pay-for-delay. But it is not clear yet how the courts will treat that question.

And that is only one of a number of questions the lower courts will need to address, any of which could help determine how strong a deterrent this decision will ultimately create. And it will be many months, even years, before all those questions are resolved. Rule-of-reason litigation is time-consuming and costly. So while this decision provides an important and welcome opening, it is far from a complete and immediate solution to pay-for-delay.

A Role for Legislation and Continued Oversight

So there is still a beneficial role for legislation. Two bills in particular, sponsored by members of this Subcommittee, are constructive and well-considered and warrant support. They address pay-for-delay from two different angles – one strengthens the enforcement deterrent against it, the other reduces the incentive to engage in it.

The first bill, S. 214, the Preserve Access to Affordable Generics Act, amends the Federal Trade Commission Act to strengthen the antitrust enforcement deterrent against pay for delay. This bill was introduced in February, months before the Supreme Court announced its decision. But it touches on many of the same issues now confronting the lower courts in the wake of that decision.

The bill takes a measured and balanced approach. It does not conclusively deem all pay-for-delay settlements automatically anticompetitive; it makes them presumptively anticompetitive, with the opportunity for the settling parties to show that their agreement is actually pro-competitive on balance. That test is a bit stronger than the rule of reason, closer to the "quick look" advocated by the Federal Trade Commission and the Department of Justice in *Actavis*. But as we note above, in light of the guidance given by the Supreme Court, the two tests may not be very different in practice. And the factors set forth in the bill are consistent with those identified by the Supreme Court as important.

The bill would thus establish a structure for enforcing the antitrust laws against pay-for-delay settlements very close to what the Federal Trade Commission and others have been advocating, and essentially consistent with the Supreme Court's guidance. Furthermore, the Federal Trade Commission has made clear that it intends to continue its vigorous enforcement in this area. But even assuming the lower courts adopt every aspect of the structure set forth in the bill, it will likely take years to get there definitively. So supporting this legislation could hasten the establishment of a clear and strong antitrust deterrent.

The second bill, S. 504, the Fair and Immediate Release of Generic Drugs Act, amends the Hatch-Waxman Act to reduce the incentive to delay for pay. This bill targets the 180-day exclusivity period as it has been interpreted by the courts. Under this bill, the first-to-file generic drug maker would share exclusivity with other generic drug makers who successfully complete the application process and resolve the patent issues in time to enter the market during that period.

Furthermore, under this bill any generic drug maker who agrees to a delayed entry date in exchange for payment or other consideration does so at considerable risk, as it would now be held to that date. It will no longer be able to "accelerate" its entry if another generic drug maker qualifies and prepared to enter the market, as it can under current law; instead, it will now be required to wait until either that agreed-upon delayed entry date, or until after the other qualifying generic has enjoyed its full 180-day exclusivity period, whichever comes first. By then, there could be several competing generics in the market ahead of it.

The combination of these two changes could neutralize the anticompetitive incentive to grab the 180-day exclusivity period and "park" it as part of a pay-for-delay settlement. The exclusivity period would then be able to fulfill its intended purpose, as a true reward for bringing a cost-saving generic alternative *on* the market *sooner*, not a bargaining chip to be used to keep all generic alternatives *off* the market until *later*.

And to the extent these changes could result in more than one generic sharing in the 180-day exclusivity period, that would further hasten the day when consumers benefit from even more competition.

Competitive development of affordable generic alternatives has suffered from too much incentive to stall competition, and from too little countervailing deterrence in the way of antitrust enforcement. Both sides of the problem need to be addressed. Both of these bills would make significant improvements.

It may also be time to revisit other well-intentioned incentives created 30 years ago by the Hatch-Waxman Act, and consider whether they are now creating unintended anticompetitive side effects that outweigh any continued usefulness for innovation. For example, the brand-name drug maker can automatically delay generic entry for 30 months by suing a generic challenger for patent infringement.– even after having previously settled with another generic challenger. These special incentives may well have been useful in an era of fledgling start-up generic pioneers. With today's generic drug industry populated by large, well-established companies, it is time to reconsider whether they still make sense for competition and consumers.

Finally, while there are important generic drugs in the development pipeline, and there will continue to be new drugs for which generic alternatives can be developed, we also need to pay attention to biologic drugs. These drugs, created by biological processes rather than chemical synthesis, are becoming increasingly important for the future. Biologic drugs are not covered by Hatch-Waxman; but Congress established an analogous process for approving alternatives, known as biosimilars, in the Biologics Price Competition and Innovation Act of 2009, also referred to as the Biosimilars Act, which was enacted as part of the Patient Protection and Affordable Care Act. We are concerned that the same kinds of incentives and opportunities for pay-for-delay settlements are present here as with generics, and we urge this Subcommittee to keep a watchful eye in this area as well.

Conclusion

Thank you again for calling this hearing on an issue of great importance to consumers, and for giving us the opportunity to present our views.

Walmart

July 24, 2013

The Honorable Amy Klobuchar
U.S. Senate Committee on Judiciary
Chairwoman, Subcommittee on Antitrust, Competition Policy and Consumer Rights
Washington, D.C. 20510

Dear Chairwoman Klobuchar:

As one of the nation's largest providers of health benefits and a leading provider of affordable prescription drugs, we take seriously our commitment to saving our customers and associates money so that they can live better. As such, Walmart is pleased to support S. 214, The Preserve Access to Affordable Generics Act.

This bipartisan legislation, led by you and Senator Grassley, would establish a presumption that brand name/generic manufacturer patent settlements or "pay for delay" agreements are on their face unlawful if the filer receives anything of value and agrees to limit or forego research, development, manufacturing, marketing, or sales of the generic drug for any period of time.

This language clarifies that payments from brand name to generic manufacturers are anti-competitive, and will help to save consumers billions on future drug costs by assisting the Federal Trade Commission (FTC) as it brings actions in such matters. As you are aware, the FTC has recently stated that it believes these agreements are costing American consumers $3.5 billion annually.

Walmart is committed to reducing the cost of health care for all Americans. As part of our commitment, we launched a $4 generic drug program in 2006 saving our pharmacy customers more than $3.5 billion in the last 7 years. In 2010, we partnered with Humana to provide a new Medicare Part D offering that we estimate is saving seniors hundreds of dollars a year. Yet, roadblocks remain to market entry of generic drugs, reducing our ability to provide affordable medicines to even more of our customers. S. 214 presents an effective solution to the anti-competitive, anti-consumer impacts of pay-for-delay settlements, and would allow us to build on the 300 prescriptions currently covered in Walmart's affordable pharmacy program.

We thank you for your leadership in increasing the affordability of health care for all Americans, and look forward to working with you to ensure the timely passage of The Preserve Access to Affordable Generics Act.

Sincerely,

E. Ivan Zapien
Vice President, Federal Government Relations

Cc: The Honorable Charles Grassley
U.S. Senate
Washington, D.C. 20510

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