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