Testimony of

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"Paying Off Generics to Prevent Competition with Brand Name Drugs:
Should It Be Prohibited?"

Introduction

My name is Merril Hirsh. I am a partner in the Washington, D.C. office of the law firm of Ross, Dixon & Bell, LLP and I want to thank the Committee and its staff for affording me the opportunity to comment on the proposed Preserve Access to Affordable Generics Act. Although, on this issue, my law firm has generally represented the interests of companies who pay the costs of drugs through self-insurance, the views I express today are my own and not necessarily those of either my firm or any of its clients. In fact, my firm represents both plaintiffs and defendants in various types oflitigation and I hope that whatever thoughts I can convey to the committee reflect the experience of having been on both sides of litigation.

I believe that a bright line rule preventing reverse payment settlements is the simplest, most efficient and fairest solution to the patent lawsuit issue raised by the Hatch-Waxman Act and promotes the central purposes of the Hatch-Waxman Act to foster both drug innovation and reasonable prices. If reverse payment settlements are permitted, brand and generic drug companies face a powerful- indeed, in some cases, overwhelming - incentive to use the huge monopoly rent earned by the exclusive rights to sell some of the most profitable drugs in history to buy off competition and to avoid challenges to weak patent positions. The proposed legislation would instead create an incentive to achieve a result that fairly reflects the power of the patent position. In fact, there is an irony in this process: the very argument that is most commonly used as a reason to refrain from external antitrust involvement in the marketplace - the fear that the action of the lawmaker, regulator or judge to impose a rule upon a market will, itself, defeat the incentives a free market provides for efficiency - cuts strongly in favor of a bright line rule here, rather than one that relies on case-by-case judgments.

My testimony has three parts. First, although I know that the Committee is familiar with the issue, I will outline briefly the problem of "reverse payments", the situation in which it has commonly arisen and comment on what the issue does not involve. Second, I will discuss the competing arguments often made in favor of either generally permitting reverse payments or some kind of fine analysis on a case-by-case basis. Finally, I will discuss the benefits of a bright line solution to the problem and the draft legislation that is before the Committee. For the

Committee's convenience, I have also attached an article I published with a colleague that discusses these issues in more detail. "I Didn't Say Orphan Often: The Benefits of a Bright Line Rule Barring Brand to Generic Payments in Hatch-Waxman Patent Settlement," ANTITRUST HEALTHCARECHRONICLE,v. 19, NO.2, Summer 2005 (reprinted by permission of the American Bar Association). I

I. THE PROBLEM - WHAT IT IS AND WHAT IT IS NOT

The issue the proposed legislation would address is not whether brand companies can obtain the benefit of patent protection. They can. It is not whether generic companies can challenge patents as being invalid or argue that a generic alternative they would like to sell does not infringe patents. They can do that. It is not about whether the brand companies can bring and pursue non-sham lawsuits to defend their patent position. They can do that. It is not about whether brand and generic companies can settle their disputes over the validity or applicability of patents to potential generic competition. They can do that too. The issue involves whether their settlement can take the form of a payment from the brand company to the generic in exchange for an agreement not to compete. Although sometimes discussion about this issue assumes that situation is really similar to other patent settings, it arises because of the special concerns Congress sought to address in the sale of pharmaceuticals.

No drug company may sell a prescription drug in the United States until it has applied for and received approval from the Food and Drug Administration ("FDA"). To secure FDA approval for a new drug, a drug company must file a New Drug Application ("NDA"), including reports and information that demonstrate the drug is safe and effective for its proposed use(s). New drugs that are approved and marketed through the NDA-approval process are called "pioneer" or "brand-name" drugs. In 1984, concerned that the NDA process was cumbersome and delayed entry of relatively inexpensive generic drugs into the market, Congress enacted the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act.

The Act created incentives for generic companies to bring down prices for blockbuster drugs. The Act established an abbreviated process to obtain FDA approval for generic versions of previously-approved pioneer drugs. Five years after the FDA has approved a new drug, a generic pharmaceutical company may seek approval to market a generic version of the drug by filing an Abbreviated New Drug Application ("ANDA"). To secure FDA approval of an ANDA, the generic company must show only that the proposed drug is bioequivalent to the corresponding brand drug - it need not do all the testing that creates long delays in bringing drugs to market.

But Hatch-Waxman did not just stop with abbreviating the process of FDA approval for generic drugs. It also created a new way of teeing up patent disputes that makes it easier for generic manufacturers to raise genuine challenges. Hatch-Waxman requires the ANDA filer to make one of four certifications concerning patents listed with the FDA for the brand-name drug. In a Paragraph IV Certification (which is the primary one that gives rise to the problem the proposed legislation addresses), the generic manufacturer attests that the listed patent "is invalid ... or will not be infringed" by the generic drug (an "ANDA-IV" certification).

If the generic company files an ANDA-IV certification, it must provide notice to the patent holder of the certification, including a statement of the factual and legal basis for its opinion that

the patent IS invalid or will not be infringed. The mere filing constitutes a statutory act of infringement, such that the brand company may file an infringement action even though the generic product has not entered the market. If the pioneer (brand) company brings a patent infringement suit against the generic within 45 days of receiving notice of the Paragraph IV Certification, the FDA must delay approving the ANDA until the earlier of (1) 30 months after the brand company's receipt of the notice; or (2) issuance of a court decision relating to the ANDA holding the patent invalid or uninfringed. The effect of this system is that generic drug companies can raise patent challenges without actually going through the cost of marketing the competing drug or bearing the risk of having to disgorge profits in a patent infringement lawsuit.

To provide an even greater incentive for generic companies to create competition for drugs, the Act also provided that the first generic company to file an ANDA enjoys a 180-day exclusivity period. During this period, other generic drug makers are barred from competing in the market for the drug at issue.

Since Congress passed Hatch-Waxman, a major issue running through both the case law and Congress' amendments has been how to make sure that drug companies use its provisions, as Congress intended, to promote competition, rather than to preserve the high prices that come from monopolies. In discussing this issue, I want to make clear: people can properly be concerned about how this process works without criticizing the desire of drug companies to earn profits. In our economy, in general, we expect companies to want to earn profits. And most of the time, that benefits people. The process of fulfilling the vision of Hatch- Waxman has required closing the loopholes that incentivize companies to earn those profits by avoiding competition, rather than engaging in it.

In the Medicare Prescription Drug, Improvement, and Modernization Act (of 2003 the "Medicare Reform Act"), Congress closed some of those loopholes. For example, as originally enacted, Hatch-Waxman allowed the first-filing generic companies to obtain a 180-day exclusivity that ran from the earlier of (I) the first commercial marketing of a generic under the previous ANDA or (2) the date a court hearing the infringement action brought against the previous filer held the patent invalid or uninfringed. The problem was that this created a great incentive for the brand company to settle an infringement action by paying the first generic filer for an agreement never to market a generic product. This was a kind of double-whammy. If the generic company never marketed the product, and a court never reached the question of whether the patent was invalid or uninfringed, the 180-day period would never begin to run and, therefore, never expire. Accordingly, by settling with the first ANnA filer, a brand company could prevent any other generic company from marketing a competing product until the patent expired.

This result obviously defeated the goals of the Hatch-Waxman Act. Congress enacted Hatch-Waxman to encourage generics to compete with brand companies by marketing generic drugs, not to encourage generic companies to sell the right to prevent competition by refusing to market them. And in the Medicare Reform Act, Congress closed this loophole. That Act makes the 180-day exclusivity period contingent on the first ANDA filer marketing its drug by the earlier of 75 days after FDA approval or 30 months after the date of the ANDA filing. See 21 D.S.C. ? 355(j)(5)(D)(i)(I). Accordingly, there is now less incentive for a pioneer to condition settlement with a

first ANDA filer on the generic's agreeing not to waive and/or to defend its 180-day exclusivity period.

In the currently proposed legislation, Congress has the chance to close another loophole that defeats the fundamental purpose of the Hatch-Waxman Act. Even with the Medicare Reform Act, there is still an incentive to use the Hatch-Waxman process to achieve effectively the same result. Unless either Congress, the regulators or the courts stop the practice, a brand company still has a huge incentive to pay the first-filer (and if necessary subsequent filers) to resolve patent disputes not by determining the terms of competition, but by delaying it. To explain the problem, it is important to note three things. First, not all Hatch-Waxman settlements are bad. The concern that this proposed legislation would address involves those settlements that both (1) include a "reverse-payment" (a payment going from the patent holder to the generic company that the patent holder claims will infringe); and (2) obtain an agreement from the generic company not to compete,. These two conditions are important because Hatch-Waxman involves a situation in which the brand company starts out by receiving a monopoly profit. If the brand company can settle its lawsuit by sharing some of that monopoly profit with the generic company, it is incentivized to do that, because effectively consumers then fund the settlement.

If the brand and generic companies are prevented from settling by reverse payment, their negotiation looks a lot different. They need to negotiate not between themselves over how to share the monopoly profit, but at arm's-length over when the generic can enter to market. Put another way - if the brand company cannot pay the generic to stay out, the generic's incentive is generally to come in.

Second, Hatch-Waxman settlements generally arise when a lot of money is at stake. Hatch-Waxman has its greatest relevance when we are talking about blockbuster drugs involving hundreds of millions or even more than a billion dollars of annual sales. In 2000, generic companies used Hatch-Waxman to challenge nine of the ten best-selling drugs of 2000, prior to the expiration of their patent. See C. Scott Hemphill Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem, 81 N.Y.U. t. Rev. 1553, 1567 n.52 (2006) ("Paying for Delay") (citing other sources). Those drugs were household names: Celebrex, Claritin, Lipitor, Paxil, Prevacid, Prilosec, Prozac, Zocor and Zoloft. Id.

Not only are generic companies most likely to challenge blockbuster drugs, it is those drugs that are most likely to lead to reverse payment settlements. The more money there is to preserve, the more incentive there is find a way to preserve it.

Third, the numbers are so large that even a little delay matters. In rough numbers, just to illustrate the order of magnitude, if a drug promotes revenue of $1 billion a year, and full generic competition would reduce that price by 50 percent (most estimates place it at more than that), delaying full competition by a mere six months could convert to revenue of$250 million ($1 billion/year x 1/2 year x 50 percent). (The market for these types of drugs tends to be inelastic companies do not generally increase sales for blockbuster drugs by lowering prices).

With numbers like this, it is easy to see why the Medicare Reform Act only solves part of the problem. True, under the law as it now stands, a brand company cannot exclude all the generics by paying money to the first-filing generic. But if allowed to settle the patent dispute by paying

the generic not to compete, the brand company can (1) eliminate from competition the only generic company that has the incentive of a I80-day period of exclusivity; (2) delay competition for additional months, or years, in a situation where even short periods of time matter; and (3) if necessary, reserve the right to enter into similar (probably smaller) settlements with other generics if they, subsequently, mount a patent challenge.

A good example of this comes from the words of the CEO of Cephalon. This CEO was interviewed after his company settled patent challenges by paying reverse payment settlements to each of several generic companies. By settling, Cephalon avoided a ruling on the generic companies' argument that Cephalon's patent for Provigil, a drug for sleep disorders, was invalid, and that their generic substitutes did not infringe the patent in any event. As the CEO explained:

A lot of [Wall Street's enthusiasm for Cephalon's stock] is a result of patent litigation getting resolved for Provigil. We were able to get six more years of patent protection. That's $4 billion in sales that no one expected.
Philadelphia Business Joumal, March 20, 2006 (emphasis added).

This process of paying to avoid patent challenges leads to two results that defeat the fundamental purpose of the Hatch-Waxman Act of encouraging generic competition where that competition is possible. First, instead of encouraging generics to make ANDA-IV certifications when they have good patent challenges, it encourages generics to challenge patents almost regardless of their strength. The more sales a drug has, the better the chance that a brand company will pay off the generic to drop its lawsuit.

Second and worse, the incentive to settle cases with reverse payments means that the weakness of the brand company's patent position translates into a better split for the generic company, instead a/lower prices for consumers. Going back to the example of the brand company with the $1 billion drug facing a 50 percent price reduction if there is full competition, the brand and generic companies essentially have two choices - they can litigate to the end, and, through competition, divide up a pie that much smaller. Or they agree not to compete and instead divide up the extra money the consumers are paying. If that agreement is legal, the incentive to take the money rather than to compete is obvious and, in certain circumstances, overwhelming.

Outlawing the reverse-payment settlement creates incentives that are more consistent with the goals the Hatch-Waxman Act was designed to foster. Barred from bringing lawsuits in the hope of generating a payoff, the proposed legislation would incentivize generic companies to use the Hatch-Waxman process to challenge patents only when the generic companies believe those patents are weak and the companies truly plan to compete in the event they win. Barred from settling by sharing the monopoly profits paid by consumers, brand and generic companies are forced to negotiate at arm's-length over when a generic company can enter the market, with the generic company incentivized by its own business interest to benefit consumers by having the competition start as soon as possible.

Moreover, it is only a bright-line rule that clearly obtains these benefits. If reverse payment settlements might or might not be legal depending upon circumstances, brand and generic companies have an incentive - if only because of the delay it occasions - to attempt to use money between them to by delay in competition for blockbuster drugs.

II. WHAT ABOUT THE ARGUMENTS ON THE OTHER SIDE?

Those who have defended reverse payment settlements in court, and those courts that have upheld those settlements against antitrust challenge, have made a number of arguments. I believe these arguments are unpersuasive and will explain why. But even if these arguments were more persuasive than they are, there is a difference between the arguments a court might consider persuasive in deciding whether existing antitrust law bars certain conduct and the arguments this Committee and Congress must consider in deciding how to fulfill the goals of Hatch- Waxman.

Even courts that have upheld the use of reverse-payment settlements against antitrust challenge are troubled by the practice. They recognize the risk of a payoff being used to avoid competition. But they are concerned about the proper standard to be used generally, as a matter of antitrust law, to assess the lawfulness of conduct alleged to be anticompetitive.

For example, a significant concern that courts have is that, in general, settlements are considered to be good and continued litigation, bad. In general, this is true. But it is not true about the Hatch-Waxman Act. The Hatch- Waxman Act actually encourages litigation - it sees, in a particular situation, an advantage to having generic companies challenge weak patent positions in the hopes of generating competition of enormous benefit to consumers. Under Hatch-Waxman, it is not better to have cases settle on terms that do not generate the competition Hatch- Waxman was designed to foster than it is to litigate them. See Paying for Delay, 81 N.Y.U. L. Rev. at 1616. Litigating the patent cases to conclusion, or settling them at arm's length by agreeing on when the generic company can enter the market, serves the purposes of the Hatch-Waxman Act. Reverse payment settlements defeat those purposes with no benefit to consumers.

Antitrust law is flexible and largely judge-made. But a judge is still not a policy-maker. A court may decide that a private settlement does a disservice to consumers; even an extreme disservice. But that does not mean that the court feels authorized by existing law to correct the problem. It is Congress that makes our policy judgments.

With that general comment, I would like to address briefly the main arguments made in court cases in defense of reverse-payment settlements:

Reverse payment settlements do not "protect" patent rights or innovation.

It is true that society has an interest in protecting patents. Patent protections spur innovation that, in turn, ultimately benefits competition and consumers. But this interest in protecting patents does not mean that there is an interest in protecting a "right" to avoid patent challenges through reverse payments.

To begin with, society is not as interested in protecting weak patent positions as it is in protecting patents. In fact, "[i]t is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly.'" United States v. Glaxo Group Ltd., 410 U.S. 52, 58 (1973). Suppose a brand company has ten patents, and it believes that each of them has a 60 percent chance of being upheld and enforced. If the brand and generic companies litigate the case to conclusion, the brand company expects that it would face competition for four out of those ten drugs. And that

competition would come at lower prices that could save consumers billions of dollars. If the law permits the brand-name company to settle all ten of these cases by paying the generic company some of its monopoly profit to stave off a patent challenge, there is no competition in any of the ten cases. That is not "good" for society. It thwarts competition and the innovation that it spurs.

Moreover, the connection between the terms under which someone can settle an eventual patent case, and the incentive to develop drugs is incredibly remote. There is no reason to believe that a brand company that is willing to go to all the expense and risk of developing and testing a drug (and then enjoy at least a five to seven-and-a-half year period of monopoly sales before the first generic can hit the market) is not going to do so based upon the fear that if the drug is approved by the FDA, and if the brand-name company obtains a patent, and if it is challenged by a generic company someday, it will, at that point, be unable to settle the litigation by paying off the generic company.

In any event, our desire to protect patent interests is ill-served by a system that encourages parties to pick patent fights in the hopes of being paid off. A system that eliminates the incentive to obtain payoffs limits patent challenges to those that have merit in circumstances where the generic company genuinely expects to compete. This change protects strong patent positions.

A rule against reverse payments does not prevent desirable settlements.

As I discussed above, the fact that settlements, in general, are good things, does not mean that we should permit settlements that defeat the purposes of the statute. Under the Hatch-Waxman Act, bringing serious patent challenges can be a good thing; and settling them without obtaining competition is not.

But even if settlements were always a "good thing," this still would not justify the use of reverse payment settlements. To begin with, eliminating reverse payments does not prevent brand and generic companies from settling. They can settle. They just have to negotiate over when the generic company comes into the market, instead of how to divide a monopoly profit.

There is theoretical discussion about circumstances in which it might be conceivable that a brand and generic company cannot come to terms without having the brand company make a payment to the generic. As the attached article explains in more detail, there are a number of responses to this argument, but the most basic response is that this discussion really is theoretical. When the FTC initially took the position that settlements involving substantial reverse payments were presumptively anticompetitive, and the Sixth Circuit in the Cardizem case rejected one such settlement, brand and generic companies settled cases without reverse payments. An FTC Report published in early 2005 concluded that "[s]ettlements after 1999 do not appear to include a payment from the brand-name company to the generic manufacturer in exchange for the generic's agreement not to market its product." See Bureau of Competition, FTC, Agreements filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of2003: Summary of Agreements filed in FY 2004 (2005) (available http://www.ftc.gov/osI2005/0l/050107medicareactrpt.pdf).

Then, in 2005 and 2006, coinciding with the decision against the FTC's position by the Eleventh Circuit in Schering-Plough, and what was then the lower court decision upholding a reverse-

payment settlement in Tamoxifen, brand and generic companies reversed course and entered into a number of new reverse payment settlements. See Bureau of Competition, FTC, Agreements filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of2003: Summary of Agreements filed in FY 2005 (2006) (available http://www.ftc.gov/osI2006/04/fy2005drugsettlementsrept.pdf); Paying for Delay, 81 N.Y.U. L. Rev. at 1571, n.71 (citing other sources).

If several years of cases can be resolved without reverse payments only to have reverse payment settlements return after the legal winds change, reverse payments must not be "essential." Brand and generic companies will enter them if they can. As history has demonstrated, if they cannot, they will resolve their disputes in a different way. Moreover, much as it may be good to settle some cases, it is better for the brand company, for the generic company and the courts not to have weak cases brought in the first place. To tout the benefits of settlement misses the genuine cost of leaving in place a system that encourages generic companies to file ANDAs in the hopes of receiving a reverse payment sett1ement from the brand company in the resulting litigation. Fewer lawsuits is better than more settlements.

Preventing reverse payment settlements in Hatch-Waxman cases does not create a slippery slope.

Another group of arguments maintain that the word "reverse payment" is a misnomer. These arguments assert that all that is happening is that the unusual structure of Hatch-Waxman (in permitting patent suits before there is any actual infringement giving rise to damages) merely makes apparent a trade-off that occurs in all patent litigation. The theory is that every time a patent holder settles a case with an alleged infringer and, in the process accepts less than 100 percent of its potential damages in settlement it is in effect making a reverse payment equal to the difference between its settlement and its highest hopes. Then, the argument goes on to assert, establishing a rule that bars reverse payments in the unusual Hatch-Waxman setting, will, like falling down a slippery slope, lead to a bar on all settlements.

As the attached article explains this comparison is not really apt for a number of reasons. Patent settlements do not all involve agreements by the defendant not to compete. And, even if they did, there is a significant difference between having parties compromise off their highest hopes in litigation, and the Hatch-Waxman settlement in which money changes hands in order to settle a dispute in which both parties' expectation is that they will receive $0 - win or lose.

But even if the comparison were apt, the slippery slope argument would not be. Congress passed Hatch-Waxman because it recognized that the drug approval process created unique competitive issues that necessitated a unique system for encouraging and resolving patent disputes. It does not have to legislate all cases when it legislates pharmaceutical cases.

Reverse-Payment settlements are an inefficient way to fund competition.

Finally, some argue that reverse-payment settlements are competitive because they provide money that generic companies can then use to fund other competition. But the truth is that if generics require funding they can obtain it through the ways other companies obtain funding - take out loans, find venture capital, issue bonds, sell stock. There is no reason why we should

want to encourage generics to pick patent fights in order to pursue the sales of drugs that they cannot afford to market and/or cannot demonstrate are worth funding.

III. WHY DO WE NEED A BRIGHT LINE?

Usually, when lawyers make arguments against bright-line tests in antitrust litigation, the most common argument involves a fear of false positives. The theory goes that antitrust law is based in a paradox: the premise of antitrust law is that fair competition and the market will lead to the best result; but enforcing fair competition requires judges or regulators or lawmakers to impose rules that are not decided by the market.

Whether this theory is correct or not, in the case of reverse-payment settlements under the Hatch-Waxman Act, the theory cuts dramatically in the opposite direction. A case-by-case resolution of the viability of reverse-payment settlements is certainly better than a result that routinely approves them regardless of how anticompetitive they are. But it is a remedy devised by judges or regulators or lawmakers, not by the market.

As I have tried to explain, the issue of reverse-payment settlements is one of incentives. If we create an overwhelming incentive for brand companies to payoff generics who challenge patents, we can expect to produce litigation and payoffs, but not competition. If we create an incentive for generic companies to negotiate the earliest time to begin competition, we harness the market remedy of arm's-length negotiation to achieve a result where generic companies bring fewer lawsuits; bring better lawsuits; and resolve them in ways that reflect a market judgment about the strength of the patent in litigation. This result does not, by itself, overcome all the obstacles to fulfilling the laudable purpose of the Hatch-Waxman Act. But it is a large step forward. I strongly urge passage of the proposed legislation.

1. This article footnotes references for a number of the points I make here. Accordingly, I will not burden this
testimony with additiOnal footnotes, and add only those references that post-date the article.