ConsumersUnion
POLICY & ACTION FROM CONSUMER REPORTS

STATEMENT FOR THE RECORD

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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

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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.