Testimony of

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Pay to Delay:
Are Patent Settlements That Delay Generic Drug Market Entry Anticompetitive?

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Thank you Chairman Johnson, ranking Member Coble, and members of the Judiciary Subcommittee on Courts and Competition Policy. In particular, thank you Chairman Conyers for inviting us to attend today. My name is Heather Bresch, and I am the Chief Operating Officer of Mylan Inc. For nearly 50 years, Mylan has built a legacy of manufacturing high quality, affordable pharmaceuticals. We are the largest U.S.-based generic pharmaceutical manufacturer and the third largest generics and specialty pharmaceutical company in the world. One out of every 13 prescriptions dispensed in the U.S. – brand name or generic – is a Mylan product. Additionally, Mylan has consistently been recognized by the FDA and by the pharmacy community for excellence in quality and service.

In addition to my 17 years with Mylan, I have served as both Chairman and Vice Chairman of the Generic Pharmaceutical Association (GPhA), and I am currently a member of the association's Executive Committee. GPhA represents more than 100 generic manufacturers and distributors of finished generic products as well as manufacturers and distributors of bulk active pharmaceutical chemicals.

Generic products are now used to fill nearly 70 percent of all prescriptions dispensed across the country but account for only 16 percent of all dollars spent on prescription medicines. A recent study conducted by IMS Health revealed that using generic pharmaceuticals saved the American health care system more than $734 billion in the last decade (1999-2008), with approximately $121 billion in savings in 2008 alone. These savings directly benefit consumers, businesses, and state and federal government agencies.

Mr. Chairman, our country is facing a crisis in rising healthcare costs and the generic pharmaceutical industry represents one of the few proven and successful solutions to contain those costs. President Obama, in his remarks on reforming the health care system stated:

> When it comes to health care spending, we are on an unsustainable course that threatens the financial stability of families, businesses and government itself…
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> Over the last decade, Americans have seen their out-of-pocket expenses soar, while health care premiums doubled at a rate four times faster than wages. Today, half of all personal bankruptcies currently stem from medical expenses.

In 2007, Obama emphasized the importance generics would have in his future administration when he said:

> My administration will look carefully at key industries to ensure that the benefits of competition are fully realized by consumers. Americans, for example, spend billions of dollars each year on drugs. Competition from generic manufacturers has the potential to reduce these costs significantly, or at least prevent these costs from ballooning further.

The generic drug industry plays a key role in reducing health care costs. The entry of safe and effective generic medicines adds competition to the marketplace and reduces the costs of medicines dramatically. In this current economic environment it is therefore even more critical to ensure timely access to generic pharmaceuticals. I am pleased to be here today to discuss critical issues that relate to timely access to affordable generic medicines and how these issues relate to patent settlements.

A BRIEF HISTORY OF HATCH-WAXMAN

By way of background, *Hatch-Waxman* – officially "The Drug Price Competition and Patent Term Restoration Act of 1984" – reflected an attempt by Congress to strike a balance between two policy objectives: to incentivize name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products and to enable competitors to bring lower-cost, bioequivalent and therapeutically equivalent generic versions of those drugs to market. *Hatch-Waxman* is designed to both reward innovation and encourage the development of affordable health care. When the balance is disturbed, the system is jeopardized, and consumers, the government and taxpayers suffer financially.

On the branded pharmaceutical side of the scale, *Hatch-Waxman* protects intellectual property in a variety of ways. It provides the means for innovators to restore up to five years of patent life to compensate for time the product underwent regulatory review at the FDA. Congress has provided branded pharmaceutical companies an additional five years of data exclusivity for new chemical entities; a supplement of three years of data exclusivity for clinical trials; six months marketing exclusivity for pediatric studies; and, an automatic 30-month stay of generic approvals

to resolve patent disputes.

On the generic pharmaceutical side of the scale, *Hatch-Waxman* streamlined the generic drug approval process and provided 180 days of market exclusivity to incentivize generic manufacturers to challenge questionable or frivolous patents held by brand manufacturers that essentially protect monopolies and prevent affordable medications from reaching the market. The marketing exclusivity period allowed generic companies to gain financial resources necessary to reinvest and continue to develop additional affordable and high quality generic products.

In the early 2000s, branded pharmaceutical companies began to exploit certain legislative loopholes in *Hatch-Waxman*. One such loophole was a practice known as 'evergreening,' a tactic which is aptly demonstrated by a brand company's gaming of the system with tactics relating to the depression/anxiety product Paxil®.

The FDA lists drug products approved on the basis of safety and effectiveness in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations," more commonly known as the "Orange Book." If another pharmaceutical company believes a patent listed in the Orange Book is invalid or not infringed by its product, the patent must be challenged by the generic company by filing a Paragraph IV certification. If the brand company sues the generic applicant for infringement, an automatic 30-month preliminary injunction or stay is triggered.

In the case of Paxil, the brand company successfully timed the issuance of multiple patents that resulted in successive 30-month stays that significantly delayed the introduction of a bioequivalent generic version of the product and kept it from reaching patients who suffer from anxiety and/or depression. The first stay of FDA approval expired in November 2000, but the FDA was not able to approve a generic version of Paxil until September 2003 due to four successive and overlapping statutory stays of approval. The brand company had annual sales in excess of $2 billion and these successive and overlapping stays resulted in an almost three-year delay before a more affordable generic product could be offered to consumers.

While Congress put an end to the evergreening practice in 2003 with the passage of the *Medicare Modernization Act* (MMA), brand companies had moved on to new tactics to extend their monopolies. The most notorious of these tactics is the use of so-called authorized generics. The practice has become so prevalent that authorized generics are factored in at every step of a company's decisions regarding each product that could potentially find its way or does find its way into a company's pipeline. Authorized generics affect decision making and the availability of capital needed for research and development and litigation costs required to bring a new generic product to the American market. Since the presence of an authorized generic is assumed on the launch of every product, a company must carefully consider the impact of an authorized generic when it determines what products to develop, how to pursue litigation and when it evaluates a potential litigation settlement.

AUTHORIZED GENERICS

Authorized generics are, in fact, the same exact products as their branded counterparts made on the same production lines with the exact same ingredients, but before packaging, they are given a different label. Same product, same bottle, different label. Brand companies do not release authorized generics until the first true generic begins its 180 days of statutory exclusivity. This practice can all but eliminate the incentive for a generic filer to identify frivolous or invalid patents, invest in the research and development necessary to produce a bioequivalent and affordable generic product and accept the risk of expensive patent litigation. As generic companies, we simply assume that an authorized generic will be launched by the brand company upon release of our true generic, and we assume that our earned 180 days of marketing exclusivity will be significantly diminished.

Let me be very clear: Mylan is not opposed to authorized generics in and of themselves. Our issue lies only in the marketing of authorized generics during the 180 days of exclusivity as provided under *Hatch-Waxman*. Following the 180 days granted to the first generic filer, we recognize and respect the right of any company with an FDA-approved product, including the brand company, to compete in the generic marketplace. The issue is *when* the authorized generic is brought to market.

I might add that it is the timing of the introduction of the authorized generic that has caught the attention of the Federal Trade Commission (FTC) and is being examined in their pending study.

The words of several brand pharmaceutical CEOs best demonstrate their motives.

> In an April 2003 press release, GlaxoSmithKline announced an authorized generic agreement for Paxil®. The agreement prevented the authorized generic from becoming available until "another generic version fully substitutable for Paxil becomes available." In other words, the more affordable authorized generic was prohibited from launching until the product of a generic filer with 180 days of exclusivity was launched.
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> In December 2003 in a Pink Sheet article, Eli Lilly CEO Sidney Laurel was quoted saying that systematically launching authorized generics each time a patent expires would mean the brand industry could "truly eliminate the incentive in the calculation that generic companies would make."
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> In a February 2004 earnings conference call, GlaxoSmithKline CEO J.P. Garner said, *"The idea was somebody has a six-month exclusivity, but we are a king maker; we can make a generic company compete during [the 180-day exclusivity]."*

"King maker" doesn't sound like the competitive balance intended by Congress when it enacted *Hatch-Waxman*.

Professors Aidan Hollis and Bryan Liang prepared a study in 2006 on the effects of authorized generics, "An Assessment of Authorized Generics: Consumer Effects and Policy Issues." [http://www.gphaonline.org/sites/default/files/GPhA_AG_Study.pdf] They assessed claims that authorized generics have positive effects on consumers by allegedly reducing prices on drug products immediately after generic entry during the 180-day exclusivity period. Professors Hollis and Liang found that in fact authorized generics had a negligible effect on prices during

this period. More importantly, they determined that the use of authorized generics diminishes the incentive for generic companies during the 180-day exclusivity period which in turn reduces the incentives generic companies have to challenge invalid patents and develop non-infringing products. They found that authorized generics will lead generic firms to be less aggressive in competing against brand companies and the ultimate losers will be consumers and taxpayers who bear the burden of healthcare costs.

For the past three years, the FTC has been studying the effect of authorized generics in the marketplace. No study has been more anxiously awaited by the generic industry, which has endured enormous detrimental effects from the practice of authorized generics being released during the 180-day exclusivity period. We understand this study will be released in June, and we expect the results to address the immediate negative impact of authorized generics during the 180 days on consumers and the long–term detrimental effects of authorized generics on patent settlements.

In fact, Members of Congress have recognized the detrimental effects of authorized generics during the 180-day exclusivity period and in January House Representative Emerson (R-MO) together with Representatives Berry (D-AR), Moore (D-KS), and Wamp (R-TN) reintroduced bipartisan legislation to prohibit the marketing of authorized generics (H.R. 573). A similar bill has been introduced in the Senate (S. 501) by Senator Rockefeller (D-WV) along with Senators Brown (D-OH), Inouye (D-HI), Kohl (D-WI), Leahy (D-VT), Schumer (D-NY), Shaheen (D-NH) and Stabenow (D-MI). Mylan applauds these Members for recognizing that prohibiting authorized generics is an important part of the solution to the problem of rising health care costs in America.

When crafted, *Hatch-Waxman* offered a careful and thoughtful balance. It promoted innovation and provided an incentive to companies that expend significant resources to bring generic drugs to market, ensuring that Americans have timely access to affordable medicines. When a brand company exploits a loophole in *Hatch-Waxman*, as they certainly do with authorized generics, they artificially extend a patented monopoly. Everyone suffers and the carefully crafted balance disintegrates. Had authorized generics been addressed by Congress in MMA in 2003, it is

unlikely we would be here today discussing patent settlements.

PATENT SETTLEMENTS

Drug patent settlements have recently come under increased scrutiny by the FTC and Congress. The FTC appears to be concerned with settlements that involve a payment of money in exchange for a generic company accepting a fixed date of entry to the market. However, it is important to remember that patent settlements, in and of themselves, do not have a negative impact on competition. In fact, a settlement involving the breast cancer treatment Tamoxifen® allowed a generic version to enter the market nine years before the date the relevant patent expired.

In almost every other type of litigation, settlement is encouraged. It is an efficient way to resolve disputes and not impact court resources. The settlement option is particularly important to generic companies attempting to challenge brand patents. The development of a product including the submission of an abbreviated new drug application is expensive. Patent litigation results in additional costs, which can escalate depending on the complexity of the product and patents at issue. Since these challenges are extremely costly and the outcomes of even the best cases are uncertain, companies need the ability to settle cases.

The process for bringing a generic product to market is not as simple as some may think. In fact, the process starts many years before the affordable generic medication becomes available to a patient. There are many market factors that a company considers before deciding to invest in the necessary research and development for a particular product. These factors include the impact of delay tactics and manipulated loopholes that brand companies employ. These tactics are introduced throughout the entire generic development process, including during patent settlement discussions. The fact that a brand company is almost certain to launch an authorized generic, or at the very least threaten to launch one, means that the incentive to continue litigation is significantly weakened for the generic company.

As a result, brand companies have a much stronger bargaining position during patent settlement negotiations. Brand companies use authorized generics as a "trump card" to reduce generic

returns, even if the generic company believes it can invalidate the brand's patents. This leaves the generic company with limited bargaining power and little choice but to settle. This situation takes the power away from the generic company, the party that is best suited to determine how to get a generic product to the market.

In 2008, the FTC found that 78% of the reported patent settlements involved a restriction on the launch of an authorized generic during the period of the generic company's exclusivity. In essence, generic companies must settle in order to safeguard the exclusivity promised by Congress in 1984 by *Hatch-Waxman*.

The FTC has recognized the crucial role authorized generics play in settlement negotiations. FTC Commissioner Jon Leibowitz noted in a 2006 speech that:

> The profits to be made in the 180-day exclusivity period are reduced substantially [by authorized generics], perhaps even cut in half. So the generic firm's calculus in the fight-versus-settle equation may now be more heavily weighted towards settling. Rather than gamble on winning in court, a generic may decide that a fixed entry date and guaranteed revenue stream is a better value than rolling the dice.

Some might suggest that a bright-line ban on patent settlements involving the receipt of anything of value apart from generic entry pre-patent expiry is required to protect consumers. However, this approach would eliminate many pro-competitive settlements and more specifically would make it illegal for a generic to secure what was intended by Congress in *Hatch-Waxman* – 180 days of *exclusive* market presence. Such a result is inconsistent with the purposes and intent of Congress in enacting the *Hatch-Waxman Act* in the first place. We urge Members of Congress to address all the considerations of patent settlements and to support legislation that would eliminate authorized generics during the 180-day exclusivity period.

In summary, we believe that Congress must ensure the timely access of affordable generic medications is offered to patients when patents are either invalid or not infringed. This requires the restoration of the incentive of the 180-day exclusivity period which will enable generic companies to challenge patents and appropriately pursue worthy patent cases. A prohibition on authorized generics during the 180-day exclusivity period will also re-establish a level playing

field for generic companies as they contemplate settlement with a brand company in patent litigation, thereby allowing the generic company to view settlement options without the threat of an authorized generic looming overhead. Taking away the ability for generic companies to settle expensive litigation without also providing a ban on authorized generics will be sure to result in further delays of affordable generic products for Americans.

I want to thank the subcommittee again for its time and interest in making sure all Americans have access to affordable, safe generic pharmaceuticals. As always, Mylan is willing to work with Congress and the FTC on these issues. I am happy to answer any questions you might have.