Testimony of

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Commissioner
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THE BENEFITS OF A LEGISLATIVE SOLUTION
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Summary

Chairman Leahy, Ranking Member Specter, and Members of the Committee, I am Jon Leibowitz, Commissioner of the Federal Trade Commission. I appreciate the opportunity to appear before you today to testify on behalf of the Commission regarding anticompetitive agreements between branded and generic drug firms.1

Prescription drugs represent a substantial component of health care spending. Protection of competition in the pharmaceutical sector has been and continues to be among the FTC's highest priorities. In that regard, the agency has directed significant efforts at antitrust challenges to what have come to be called "exclusion payment settlements" (or, by some, "reverse payments"), a term used to describe settlements of patent litigation in which the brand-name drug firm pays its potential generic competitor to abandon the patent challenge and delay entering the market. Such settlements restrict competition at the expense of consumers, whose access to lower-priced generic drugs is delayed, sometimes for many years.

Recent court decisions, however, have made it more difficult to bring antitrust cases to stop exclusion payment settlements, and the impact of those court rulings is becoming evident in the marketplace. These developments threaten substantial harm to consumers and others who pay for prescription drugs. For that reason, the Commission supports legislation to prohibit these anticompetitive settlements and strongly supports the intent of the legislation introduced by Senators Kohl, Leahy, Grassley, and Schumer, including the objective to adopt a bright-line approach to addressing exclusion payments.

Generic drugs play a crucial role in containing rising prescription drug costs by offering consumers therapeutically-identical alternatives to brand-name drugs at a significantly reduced cost. To speed market entry of generic drugs, and to ensure that the benefits of pharmaceutical innovation would continue, in 1984 Congress passed the Hatch-Waxman Act.2 Hatch-Waxman established a regulatory framework that sought to balance two fundamental objectives: maintaining incentives for continued innovation by research-based pharmaceutical companies and encouraging market entry by generic drug manufacturers.3 One of the key steps Congress took to promote more rapid introduction of generics was establishing special rules and procedures to encourage firms seeking approval of generic drugs to challenge invalid or narrow patents on branded drugs. The Act likewise encourages brand name drug companies to file infringement suits at an early stage.

Almost six years ago, this Committee held a hearing to examine the implications of some settlements reached under this patent challenge process that Hatch-Waxman established. At that time, the Committee was considering a bill introduced by Senators Leahy and Grassley to facilitate antitrust enforcement by requiring that all such settlements be filed with the FTC and the Department of Justice. Thanks to this filing requirement, which Congress enacted in 2003 as part of a package of reforms to Hatch-Waxman, the FTC staff is able to review all settlements of patent cases brought under the Act.

Despite this important enforcement tool, however, the prospects for effective antitrust enforcement against anticompetitive agreements between branded and generic pharmaceutical manufacturers are substantially less encouraging today than they were in 2001. Two appellate court decisions handed down in 2005 took an extremely lenient view of exclusion payment settlements.

Pharmaceutical companies are responding to this change in the legal landscape. Although settlements with payments to the generic patent challenger had essentially stopped in the wake of antitrust enforcement by the FTC, state attorneys general, and private parties during 2000 to 2004, the recent court decisions have triggered a disturbing new trend. The staff's analysis of settlements filed during the fiscal year ending in September 2006 found that half of all of the final patent settlements (14 of 28) involved compensation to the generic patent challenger and an agreement by the generic firm to refrain from launching its product for some period of time. In the current legal climate, there is every reason to expect the upsurge in such settlements to continue, and early entry of generics under Hatch-Waxman to decline. Why? Because exclusion payment settlements are highly profitable for brand-name and generic firms. If such payments are lawful, companies have compelling incentives to use them.

The implications of these developments for consumers, and for others who pay for prescription drugs, are serious. Although it is well known that the use of generic drugs - which are priced 20 to 80 percent or more below than the price of the branded drug4 - provides substantial savings, what is not so well known is the important role that generic drug firms' patent challenges play in delivering savings to consumers. Generic competition following successful patent challenges involving just four major brand-name drugs is estimated to have saved consumers more than $9 billion.5 The cost savings that result from generic entry after successful patent challenges are lost, however, if branded drug firms are permitted to pay a generic applicant to defer entry.

Advances in the pharmaceutical industry bring enormous benefits to Americans. Because of pharmaceutical innovations, a growing number of medical conditions often can be treated more effectively with drugs than with alternative means, such as surgery. The development of new drugs is risky and costly, and preserving incentives to undertake this task is critically important. Due regard for patent rights is thus a fundamental premise of the Hatch-Waxman framework. But the court decisions allowing exclusion payments grant holders of drug patents the ability to buy more protection from competition than congressionally-granted patent rights afford. These rulings disrupt the careful balance between patent protections and encouraging generic entry that Congress sought to achieve in the Hatch-Waxman Act.

The increased costs resulting from anticompetitive agreements that delay generic competition harm all those who pay for prescription drugs: individual consumers; the federal government, which spends substantial sums under the new Medicare Part D program; state governments trying to provide access to health care with limited public funds; and American businesses striving to compete in a global economy.

The Commission's perspective on the important issue highlighted by this hearing is informed by extensive experience in examining competition in the pharmaceutical industry. The agency has undertaken numerous investigations and antitrust enforcement actions affecting both brand-name and generic drug manufacturers,6 empirical studies and economic analyses of the pharmaceutical industry,7 assessments of competitive issues in matters before the United States Food and Drug Administration ("FDA") regarding Hatch-Waxman implementation,8 testimony before Congress, 9 and amicus briefs in the courts.10 The Commission's 2002 report entitled "Generic Drug Entry Prior to Patent Expiration" ("Generic Drug Study") was based on a detailed examination of experience under the Hatch-Waxman Act and recommended a number of the reforms that Congress adopted in 2003.11 The FTC staff's ongoing review of drug company patent settlements and other agreements filed pursuant to the mandate in the 2003 reforms has enabled the Commission to provide Congress and the public with annual reports on the types of patent settlements being undertaken.12

Today's testimony reviews the role of generic drugs in the pharmaceutical industry and the regulatory framework that governs their introduction, and then discusses the economics of exclusion payment settlements and their impact on consumers, the court rulings and industry response, and some issues relating to a legislative remedy to the exclusion payment problem. The testimony also briefly describes how brand-name drug firms can effectively block generic entry by settling with the first generic applicant and declining to sue subsequent applicants.

I. The Benefits of Generic Competition

Studies of the pharmaceutical industry indicate that the first generic competitor typically enters the market at a price that is 70 to 80 percent of the brand-name counterpart, and gains substantial share from the brand-name product in a short period of time.13 Subsequent generic entrants may enter at even lower prices - discounted as much as 80 percent or more off the price of the brand name drug - and prompt the earlier generic entrants to reduce their prices. As a result of price competition, as well as the policies of public and private health plans and state laws that encourage the use of generic drugs, generic sellers typically capture anywhere from 44 to 80

percent of branded sales within the first full year after launch of a lower-priced generic product.14

A. Statutory Background

Congress intended that the Hatch-Waxman Act would "make available more low cost generic drugs," while fully protecting legitimate patent claims.15 The Act allows for accelerated FDA approval of a drug through an Abbreviated New Drug Application ("ANDA"), upon showing, among other things, that the new drug is "bioequivalent" to an approved drug.16

A brand-name drug manufacturer seeking to market a new drug product must first obtain FDA approval by filing a New Drug Application ("NDA") that, among other things, demonstrates the drug product's safety and efficacy. At the time the NDA is filed, the NDA filer also must provide the FDA with certain categories of information regarding patents that cover the drug that is the subject of its NDA.17 Upon receipt of the patent information, the FDA is required to list it in an agency publication entitled "Approved Drug Products with Therapeutic Equivalence," commonly known as the "Orange Book."18

The Hatch-Waxman Act establishes certain rights and procedures in situations where a company seeks FDA approval to market a generic product prior to the expiration of a patent or patents relating to a brand name drug upon which the generic is based. In such cases, the applicant must: (1) certify to the FDA that the patent in question is invalid or is not infringed by the generic product (known as a "Paragraph IV certification");19 and (2) notify the patent holder of the filing of the certification. If the holder of patent rights files a patent infringement suit within 45 days, FDA approval to market the generic drug is automatically stayed for 30 months, unless before that time the patent expires or is judicially determined to be invalid or not infringed.

To encourage generic drug manufacturers to challenge questionable patents, the Hatch-Waxman Act provides that the first generic manufacturer to file an ANDA containing a Paragraph IV certification is awarded 180 days of marketing exclusivity, during which the FDA may not approve a potential competitor's ANDA.20 Although a first-filer can forfeit its exclusivity under certain conditions,21 ordinarily it will be entitled to 180 days of exclusivity beginning on the date of the first commercial marketing of the generic drug product.22 Even if the first filer substantially delays marketing its product, under the prevailing interpretation of the Hatch-Waxman Act, a later ANDA filer may not enter the market until the first filer's 180-day period of marketing exclusivity has expired.23

B. Consumer Savings from Challenges to Drug Patents

Experience has borne out the efficacy of the Hatch-Waxman process and the correctness of its premises: that many patents, if challenged, will not stand in the way of generic entry, and that successful challenges can yield enormous benefits to consumers. The Commission studied all patent litigation initiated between 1992 and 2000 between brand-name drug manufacturers and Paragraph IV generic challengers, and found that the generics prevailed in cases involving 73 percent of the challenged drug products.24 Many of these successes involved blockbuster drugs and allowed generic competition years before patent expiration (see chart).25

II. The Economics of Exclusion Payment Settlements and the Role of Antitrust Enforcement

Although patent challenges have the potential for substantial consumer savings, the competitive dynamic between brand-name drugs and their generic equivalents creates an incentive for brand and generic manufacturers to conspire to avoid competition and share the resulting profits. The reason is simple: In nearly any case in which generic entry is contemplated, the profit that the generic anticipates will be much less than the amount of profit the brand-name drug company stands to lose from the same sales. This is because the generic firm sells at a significant discount off the price of the brand name product; the difference between the brand's loss and the generic's gain is the money consumers save.

Consequently, it will typically be more profitable for both parties if the brand-name manufacturer pays the generic manufacturer to settle the patent dispute and agree to defer entry. As is illustrated below, by eliminating the potential for competition, the parties can share the consumer savings that would result if they were to compete.

Although both the brand-name companies and generic firms are better off with such settlements, consumers lose the possibility of earlier generic entry, which may occur either because the generic company would have prevailed in the lawsuit (as noted, the FTC's Generic Drug Study found generic challengers enjoyed a success rate in excess of 70 percent), or because the parties would have negotiated a settlement with an earlier entry date absent the payment. Instead, consumers pay higher prices because such early generic entry is delayed.

Several years ago, this Committee recognized the threat that such agreements pose, and, to promote effective antitrust enforcement, Congress amended the Hatch-Waxman Act in 2003 to require brand-name companies and generic applicants to file patent settlement agreements with the Commission and the Department of Justice. As the Senate Report explained, those amendments sought in part to stamp out the "abuse" of Hatch-Waxman law resulting from "pacts between big pharmaceutical firms and makers of generic versions of brand name drugs, that are intended to keep lower cost drugs off the market."26

The Commission has challenged patent settlements in which brand-name and generic companies have eliminated the potential competition between them and shared the resulting profits.27 All settlements include some form of consideration flowing between the parties; it is the type of consideration that matters in the antitrust analysis. Some types of consideration, such as an early entry date, a royalty to the patent-holder, or compromising on a damage claim, do not generally involve sharing the benefits that come from eliminating potential competition. But the sharing of profits achieved by eliminating competition is at the core of what Section 1 of the Sherman Act proscribes.

Initially, the Commission's enforcement efforts in this area appeared be a significant deterrent to anticompetitive behavior. In the late 1990s, the Commission learned of exclusion payments arising in Hatch-Waxman patent litigation and began to investigate.28 Public reports of those investigations began to appear in 1999, and the Commission brought a number of enforcement actions beginning in 2000. For several years, such agreements essentially stopped. The Commission is not aware of any pharmaceutical settlement between a brand-name manufacturer

and a generic filer that included both a payment to the generic company and an agreement by the generic company to defer marketing its product between 2000 and the end of 2004.

During the same period, however, patent settlements did not disappear. To the contrary, in less than five years, there were at least as many settlements as there were in the seven years in which pharmaceutical companies were settling litigation with payments and restrictions on generic entry.29 Parties simply found different ways to resolve their disputes, presumably on the basis of the relative strength of their cases.

III. The Current Threat to Consumers from Exclusion Payment Settlements

In 2005, two appellate courts adopted a permissive - and, respectfully, in our view, incorrect - position on exclusion payment settlements.30 After years of active antitrust enforcement, including the Sixth Circuit's decision in the Cardizem case holding a challenged exclusion payment arrangement unlawful,31 these two rulings have prompted a resurgence of settlements in which the parties settle with a payment to the generic company and an agreement by the generic company not to market its product.

In the Schering case,32 the Eleventh Circuit vacated a decision in which the Commission found two patent settlements violated the FTC Act. Schering-Plough Corporation ("Schering"), the manufacturer of a brand-name drug called "K-Dur 20," settled patent litigation with two manufacturers of generic counterparts, Upsher-Smith Laboratories, Inc. ("Upsher") and American Home Products Corporation ("AHP"). The two generic manufacturers agreed to forbear marketing their generic drugs until specified dates in exchange for guaranteed cash payments totaling $60 million to Upsher and $15 million to AHP. A full trial was held before an administrative law judge, and the Commission reviewed the entire record de novo. The Commission concluded that in each settlement, Schering had paid its generic competitors to accept the settlement and that the settlements provided Schering with more protection from competition than a settlement without a payment or simply proceeding with litigation. As a result of these agreements, Schering continued to enjoy supracompetitive profits from K-Dur 20 for several more years, at the expense of consumers.

The court of appeals set aside the Commission's decision.33 The court purported to assess whether the agreement exceeded the exclusionary potential of Schering's patent. In so doing, the court relied on the incorrect supposition that the patent provided Schering with "the legal right to exclude Upsher and [AHP] from the market until they proved either that the . . . patent was invalid or that their products . . . did not infringe Schering's patent,"34 and noted that there was no allegation that the patent claim was a "sham."35 In particular, the court ruled that a payment by the patent holder, accompanied by an agreement by the challenger to defer entry, could not support an inference that the challenger agreed to a later entry date in return for such payment, even if there was no other plausible explanation for the payment.36 The Commission sought Supreme Court review. Thirty-six states, AARP, and a patent policy think tank supported the Commission's petition. The Solicitor General filed a brief in opposition, acknowledging the importance of the issues presented, but arguing that the case was not the right vehicle for the Court to address them. In June 2006, the Supreme Court declined to review the Eleventh Circuit's ruling. The impact of the Eleventh Circuit's decision - in the courts and in the pharmaceutical industry - has been evident. Other courts have understood that decision to require

only an inquiry into the nominal reach of the patent, and not (as some have suggested) a direct assessment of the likelihood that the patent holder could successfully effect exclusion through patent litigation.37 A divided panel of the Second Circuit, ruling on an antitrust challenge to a patent settlement involving the anti-cancer drug Tamoxifen, followed the Eleventh Circuit's holding.38 The plaintiffs in the Tamoxifen case have asked the Supreme Court to review the Second Circuit's ruling, and their petition for certiorari is pending.

The response of pharmaceutical companies to these developments in the courts is reflected in the changing nature of patents settlements since the Schering decision. One investment analyst report described the Eleventh Circuit's Schering decision as having "opened a Pandora's box of settlements."39 After a five-year hiatus in payments to generics following the initiation of Commission enforcement actions aimed at exclusion payment settlements, pharmaceutical companies have once again started entering into settlement agreements that include both compensation in various forms to generic challengers and restrictions on generic market entry.40 By the end of fiscal year 2005, the year of the Eleventh Circuit's decision in Schering, there were three such settlements. In fiscal year 2006 - the Tamoxifen ruling came early that year - there were significantly more:

? Fifty percent (14 of 28) of the 2006 final settlement agreements between brandname and generic companies included both an agreement to defer generic entry and some form of payment from the brand-name firm to the generic challenger.

? The findings concerning settlements with first generic filers - that is, settlements that can serve to block FDA approval of later applicants - are even more striking. More than 80 percent (9 of 11) of the settlements with first generic filers involved a payment to the generic challenger and a restriction on generic entry. One of the two first filer settlements that did not follow the trend involved a case in which the patent was due to expire within the year. In that case, the generic abandoned the patent challenge without compensation. The other settlement is currently being investigated by FTC staff.

? The compensation conveyed to the generic firm under the settlements takes various forms, and frequently includes agreements involving a product other than the one at issue in the patent litigation.

? Notably, so-called "side deals," such as purchasing rights to unrelated products and co-promotion arrangements, were observed in settlements that restrained generic entry, but virtually never in settlements that did not.41 This pattern indicates that such "side agreements" may be serving as a vehicle to compensate a generic challenger for its agreement to a later entry date than the generic firm would otherwise accept.

The economic implications of the courts of appeals' rulings are substantial. Americans spent $200.7 billion on prescription drugs in 2005.42 Many of the top-selling prescription drugs in the U.S. - including such blockbusters as ulcer drug Nexium, the anti-psychotic Seroquel, and cancer treatment Gemzar - are currently the subject of patent challenges by generic firms seeking to enter the market under the provisions of the Hatch-Waxman Act. The prospect of consumer benefit from such challenges is enormous, to the extent that they lead to early, non-infringing generic entry. Indeed, generic competition following successful patent challenges involving just

four major brand-name drugs (Prozac, Zantac, Taxol, and Platinol) is estimated to have saved consumers more than $9 billion.43 Under the courts of appeals' rulings, however, the parties in such cases have the strong economic incentive, discussed above, to enter into anticompetitive settlements that deprive consumers of the benefit of low-cost, non-infringing generic drugs.

Where a patent holder makes a payment to a challenger to induce it to agree to a later entry than it would otherwise agree to, consumers are harmed - either because a settlement with an earlier entry date might have been reached, or because continuation of the litigation without settlement would yield a greater prospect of competition.44 Some who disagree with the Commission's position argue that, rather than treat the outcome of the patent suit as uncertain (as it often is), antitrust analysis must presume the patent is valid and infringed unless patent litigation proves otherwise. This argument, however, ignores both the law and the facts. The antitrust laws prohibit paying a potential competitor to stay out of the market, even if its entry is uncertain. Indeed, the position that antitrust law would bar a brand name drug firm from paying a generic filer to withdraw its application for FDA approval should be uncontroversial, even though the potential generic competitor's application might not be approved. The suggestion that generic entry before the end of a patent term is too uncertain to be of competitive concern is likewise untenable. It is contradicted both by the Hatch-Waxman framework, which encourages patent challenges, and by the empirical evidence that generic applicants have enjoyed a nearly 75 percent success rate in patent litigation initiated under Hatch-Waxman.45 Finally, the argument that prohibiting exclusion payments will prevent legitimate settlements is contradicted by experience during the period from 2000 through 2004. Patent settlements - using means other than exclusion payments - continued to occur. And patent settlements will continue if Congress enacts legislation that prohibits anticompetitive payments in settlements of Hatch-Waxman patent cases.

In sum, the majority opinion in Tamoxifen and the court of appeals ruling in Schering, take an extremely lenient view of exclusion payment settlements. Given that the brand-name and generic company are both better off avoiding the possibility of competition and sharing the resulting profits, there can be little doubt that, should those rulings become the controlling law, we will see more exclusion payment settlements and less generic competition. Although the Commission will continue to be vigilant in this area, litigating another case to conclusion will take years, the outcome of such litigation is uncertain given the Schering and Tamoxifen decisions, and in any event such litigation will provide little relief for those harmed in the interim. The cost to consumers, employers, and government programs will be substantial.

Prozac provides a telling example. In the course of patent litigation, the brand name company, asked if it would pay the generic challenger $200 million to drop the patent challenge, rejected the idea, stating that such a settlement would violate the antitrust laws.46 The generic ultimately won that patent litigation, and consumers - and federal and state governments - saved over two billion dollars.47 Under the legal standard articulated in the Schering and Tamoxifen cases, however, the proposed settlement would have been legal, generic entry would not have occurred, and consumers would have had to pay higher prices until the patent expired.

IV. Addressing Anticompetitive Hatch-Waxman Settlements through Legislation

The Commission strongly supports a legislative remedy for the problem of exclusion payment settlements between branded pharmaceutical firms and would-be generic entrants. Congressional action on this issue is warranted for several reasons. First, the threat that such agreements pose to our nation's health care system is a matter of pressing national concern. The enormous costs that result from unwarranted delays in generic entry burden consumers, employers, state and local governments, and federal programs already struggling to contain spiraling costs.

Second, the problem is prevalent. Because exclusion payment settlements are so profitable for both branded and generic firms, if they are legal they would threaten to eliminate most pre-patent-expiration generic competition. The settlements filed with the FTC in 2006 demonstrate that it is now common for settlements of Hatch-Waxman patent litigation to involve compensation to the generic drug applicant and an agreement by the generic to stay off the market, typically for several years.

Third, the problem of exclusion payment patent settlements has arisen in - and, to our knowledge, only in - the context of the special statutory framework that Congress created with the Hatch-Waxman Act. The special rules that apply in this area were designed to balance the two policy goals that are of critical significance in the pharmaceutical industry: speeding generic drugs to market and maintaining incentives for new drug development. Legislative action concerning exclusion payment settlements can be tailored to the special circumstances of pharmaceutical patent settlements and help to ensure that this unique framework works as Congress intends.

Fourth, the reasoning underlying the recent appellate court rulings underscores the need for action by Congress. These decisions reflect judicial judgments about the policy choice that Congress made in Hatch-Waxman. Indeed, the Eleventh Circuit's Schering opinion emphasized that its decision was based on "policy."48 As the court saw it, the Hatch-Waxman framework Congress created gave generic firms "considerable leverage in patent litigation," and could therefore "cost Schering its patent."49 Congress, however, is the body with constitutional responsibility to set patent policy. Striking the balance so as to promote innovation while also promoting generic entry is fundamentally a legislative choice. Accordingly, it is fitting that Congress address the use of exclusion payments in drug patent settlements.

Finally, a legislative remedy offers the prospect of a relatively swift solution to this important issue. While the Commission's enforcement activities are continuing, we recognize the time and uncertainty involved in litigation challenges to anticompetitive settlements. Legislation could provide a speedier and more comprehensive way to address this pressing concern.

For these reasons, the Commission strongly supports the intent behind the bipartisan legislation introduced by Senators Kohl, Leahy, Grassley, and Schumer." We would welcome the opportunity to work with the Committee as it considers the bill.

Certain principles may be useful to consider in crafting the precise form and scope of a legislative remedy. A law must be broad enough to prevent evasion or other anticompetitive practices that could render the legislation ineffective, but it should avoid unwarranted deterrence of settlement. The fundamental concern underlying exclusion payment settlements is the sharing of profits preserved by an agreement not to compete, whatever form the compensation to the

generic takes. Thus, legislation must be sufficiently broad to encompass the various ways that a branded firm may share its profits with the generic, including not only the ways we have seen to date, but also those that may arise in the future.

In addition, it is important that the law encompass all arrangements that are part of the settlement, even if not part of a written settlement agreement. That is, it should be clear that substance, not form, governs in assessing what transactions are actually part of the parties' settlement agreement.

At the same time, settlement avenues should not be unduly limited. All settlements provide some value to the generic, even if it is nothing more than termination of the litigation. And settlements in which the value received by the generic amounts to nothing more than the right to sell a generic version of the branded drug the innovator firm is seeking to protect - whether it be the right to sell the generic drug product before patent expiration, a waiver of the brand's market exclusivity based on testing of a drug for pediatric use, or a waiver of patent infringement damages against a generic for entry that has already occurred - are unlikely to involve a sharing of profits preserved by avoiding competition. Legislation should preserve such settlement options.

Finally, a statutory bar on exclusion payment settlements should include meaningful remedies. Delaying generic competition to a blockbuster drug can be enormously profitable for the brand-name-drug seller. Remedies should take into account the economic realities of the pharmaceutical industry.

V. The 180-Day Exclusivity as a Bottleneck to Prevent Generic Entry

Hatch-Waxman patent settlements present an additional issue that warrants a legislative remedy. The operation of the Hatch-Waxman Act's 180-day exclusivity creates the potential for a settlement between a brand-name company and a first generic filer to generate a bottleneck that prevents any generic competition. When they enter into an agreement for the generic to delay market entry, whether with or without an accompanying payment, the agreement does not trigger the running of the exclusivity period. Although Hatch-Waxman was designed to provide a mechanism to eliminate the bottleneck when the later filer can get a court ruling that it does not infringe, forcing the first filer to "use or lose" its exclusivity period, court decisions have prevented generic firms from using this mechanism. Consequently, the exclusivity creates a bottleneck that prevents any subsequent generic applicant from entering the market until after the first generic enters and the period runs.50

A subsequent generic can relieve the bottleneck only by obtaining a court decision that the patent supporting the 180-day exclusivity period is invalid or not infringed.51 That decision acts as a forfeiture event that forces the first filer to either use or lose its exclusivity period within 75 days. 52 A problem arises if the brand-name company does not sue the subsequent generic filer on every patent supporting the exclusivity, thereby eliminating the possibility that the generic company will obtain a favorable court decision on every patent and relieve the bottleneck. Having settled with the first challenger, perhaps for delayed entry, a brand-name company can preempt all subsequent generic challenges and the chance of any earlier generic entry by declining to sue subsequent filers.

A brand name drug firm has a significant incentive to use this strategy, and a trend by brand-name companies to do so is increasingly evident.53 Some generic companies facing this scenario have attempted to bring declaratory judgment actions of non-infringement and invalidity, but these efforts have been unsuccessful thus far because the courts have dismissed those actions for lack of a Constitutionally-required "case or controversy."54 However, even if a generic company could bring that declaratory judgment action, the brand company could still prevent an adjudicated court decision on the patent merits by granting the generic a covenant not to sue. Dismissal of a declaratory judgment action, even when based on a covenant not to sue, is not a "court decision" sufficient to trigger a forfeiture event.55

As a result, a subsequent generic filer that faces a bottleneck but has not been sued, or has been offered a covenant not to sue, has no mechanism to relieve that bottleneck. Even if the subsequent filer has a strong case for noninfringement, the bottleneck postpones consumer access to any lower-priced generic version of the drug. In such circumstances, it is contrary to the Hatch-Waxman Act's purposes of encouraging meritorious patent challenges and promoting generic entry to delay market entry by later applicants when the brand-name manufacturer and first generic applicant are involved in protracted litigation or have settled their litigation without resolving the issues of validity or infringement.

There is a potential legislative remedy, however. The Commission recommends that Congress pass legislation making dismissal of a declaratory judgment action of non-infringement or invalidity for lack of a case or controversy, when brought by a generic applicant, a forfeiture event for the 180-day exclusivity period.56 The brand's submission of a covenant not to sue the generic applicant should also constitute a forfeiture event. These provisions will give a generic applicant that has raised strong non-infringement or invalidity arguments that a brand company does not wish to litigate a mechanism for removing the bottleneck.

Conclusion

Thank you for this opportunity to share the Commission's views. The Commission looks forward to working with the Committee, as it has in the past, to protect competition in this critical sector of the economy.

1. This written statement represents the views of the Federal Trade Commission. My oral presentation and responses are my own and do not necessarily reflect the views of the Commission or of any Commissioner.

2. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585
(1984) (codified as amended 21 U.S.C. ? 355 (1994)).

3. See infra Section I.A. The Act also was intended to encourage pharmaceutical innovation through patent
term extensions.

4. See infra note 14.

5. Generic Pharmaceuticals Marketplace Access and Consumer Issues: Hearing Before the Senate Commerce Comm.,
107th Cong. (Apr. 23, 2002) (statement of Kathleen D. Jaeger, President & CEO, Generic Pharmaceutical Ass'n) at 12, available at .

6. See, e.g., Schering-Plough Corp., 2003 FTC LEXIS 187 (FTC Dec. 8, 2003), vacated, 402 F. 3d 1056 (11
Cir. 2005), cert. denied, 126 S. Ct. 2929 (2006); Schering-Plough Corp., Upsher-Smith Labs., and American Home
Products Corp., Dkt. N o. 9297 (Apr. 5, 2002) (consent order as to American Home Products); FTC v. Perrigo and
Alpharma, Civ. Action No. 1:04CV01397 (D.D.C. Aug. 12, 2004) (stipulated judgment); Bristol-Myers Squibb Co.,
Dkt. No. C-4076 (Apr. 14, 2003) (consent order); Biovail Corp. and Elan Corp. PLC, Dkt. No. C-4057 (Aug. 20,
2002) (consent order); Biovail Corp., Dkt. No. C-4060 (Oct. 4, 2002) (consent order); Abbott Labs., Dkt. No. C-
3945 (May 26, 2000) (co nsent order); Geneva Pharms., Inc., Dkt. No. C-3946 (M ay 26, 2000) (consent order);
Hoechst Marion Roussel, Inc., Dkt. N o. 9293 (Apr. 2, 2001) (consent order); FTC v. Mylan Labs., Inc. et al., 62 F.
Supp. 2d 25 (D.D.C. 1999).

7. See, e.g., Federal Trade Commission, Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies (Aug. 2005), available at ;
Federal Trade Commission, To Promote Innovation: The Proper Balance of Competition and Patent Law and
Policy (Oct. 2003), available at ; David Reiffen & Michael R.
Ward, Generic Drug Industry Dynamics, Bureau of Economics Working Paper No. 248 (Feb. 2002) ("Reiffen and
Ward"), available at ; Bureau of Economics
Staff Report, Federal Trade Commission, The Pharmaceutical Industry: A Discussion of Com petitive and Antitrust
Issues in an Environment of Change (Mar. 1999), available at
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8. Response to Citizen Petition by Ivax Pharmaceuticals, Inc. (Apr. 5, 2005), available at (recommending that FDA deny Ivax's request that the FDA
prohibit delisting of patents from the Orange Book); Comment of the Federal Trade Commission, FDA: Applications
for FDA Approval to Market a New Drug; Patent Listing Requirements and Application of 30-Month Stays on
Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug is Invalid or Will Not be

Infringed (Dec. 23, 2002) ("30-Month Stay Comment"), available at
(recommending modifications to FDA proposed rule on patent listing requirements and providing suggestions to the
proposed patent declaration); Comment of the Staff of the Bureau of Competition and the Office of Policy Planning
of the Federal Trade Commission, FDA: Citizen Petition (Mar. 2, 2000), available at
(recommending modifications to the FDA's Proposed Rule on citizen
petitions intended to discourage anticompetitive abuses of the FDA's regulatory processes); Comment of the Staff of
the Bureau of Competition and the Office of Policy Planning of the Federal Trade Commission, FDA: 180-
DayGeneric Drug Exclusivity for Abbreviated New Drug Applications,(Nov. 4, 1999)
("Marketing Exclusivity
Comment"), available at (recommending that the FDA's Proposed Rule on
180-day marketing exclusivity be modified to limit exclusivity to the first ANDA filer and to require filing of patent
litigation settlement agreements).

9. Testimony of the Federal Trade Commission before the Special Committee on Aging, United States
Senate, Barriers to Generic Entry (July 20, 2006), available at
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Federal Trade Commission before the Committee on Judiciary, United States Senate, Competition in the
Pharmaceutical Ind ustry (June 17, 2003), available at ; Testimony of the Federal Trade Commission before the Committee on Energy and Commerce, Subcommittee on Health, United States House of Representatives,
Competition in the U .S. Pharmaceutical Ind ustry (Oct. 9, 2002), available at
; Testimony of the Federal Trade Commission before
the Committee on Commerce, Science, and Transportation, U nited States Senate, Competition in the Pharmaceutical
Industry (Apr. 23, 2002), available at ; Testimony of the
Federal Trade Commission before the Committee on the Judiciary, United States Senate, Competition in the
Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements (May 24, 2001), available at
.

10. See, e.g., Brief for the Federal Trade Commission as Amicus Curiae Supporting en banc petition, In re
Tamoxifen Litigation, (2d C ir. Nov. 30, 2005) ((N o. 03-7641), available at
: Brief for the Federal Trade Commission as Amicus
Curiae Supporting en banc petition, Teva Pharm. v. Pfizer Inc., (Fed. Cir. Feb. 5, 2005) (03CV-10167), available at
.

11. Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration: An FTC Study (July 2002),
available at (hereinafter "Generic Drug Study").

12. Bureau of Competition Report, Federal Trade Commission, Agreements Filed with the Federal Trade
Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of
Agreements Filed in FY 2005: A Report by the Bureau of Competition (Apr. 2006), available at
; Bureau of Competition Report, Federal Trade
Commission, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug,
Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2004: A Report by the Bureau
of Competition (Jan. 2005), available at .

13. See Congressional Budget Office, How Increased Competition from Generic Drugs Has Affected Prices
and Returns in the Pharmaceutical Industry (July 1998), available at
(hereinafter "CBO Study"); see generally David
Reiffen & Michael R. W ard, Generic Drug Industry Dynamics, 87 REVIEW OF ECON. & STAT. 37-79 (2005).

14. CBO Study, xiii.

15. H.R. Rep. No. 857, 98th C ong., 2nd Sess., Pt. 1 (1984), as reprinted in 1984 U.S.C.C.A.N. 2647, 2661.

16. 21 U.S.C. ? 355(j).

17. 21 U.S.C. ? 355(b)(1).

18. Id. ? 355(j)(7)(A).

19. Id. ? 355(j)(2)(A)(vii)(IV).

20. Id. ? 355(j)(5)(B)(iv).

21. Id. ? 355(j)(5)(D)

22. Id.

23. See id. ? 355(j)(5)(B)(iv).

24. Generic Drug Study, at 19-20.

25. SmithKline Beecham Corp. v. Apotex Corp., 247 F. Supp.2d 1011 (N.D. Ill. 2003), aff'd on other

grounds, 403 F.3d 1331 (Fed. Cir. 2005) (patent claiming Paxil held invalid); Astra Aktiebolag v. Andrx Pharms.,
Inc., 222 F. Supp.2d 423 (S.D.N.Y. 2002), aff'd sub nom., In re Omeprazole Patent Litig., 84 Fed. App. 76 (Fed.
Cir. 2003) (noninfringement of patents claiming Prilosec); American Biosciences, Inc. v. Baker Norton Pharms. Inc.,
2002 U.S. Dist. LEXIS 512 (C.D. Cal. Jan. 10, 2002) (patent claiming Taxol held invalid); Eli Lilly & Co. v. Barr
Labs., Inc., 251 F.3d 955 (Fed. Cir. 2001) (patent claiming antidepressant Prozac held invalid); Glaxo, Inc. v.
Novopharm, Ltd., 110 F.3d 1562 (Fed. Cir. 1997) (noninfringement of patents claiming Zantac).

26. S. Rep. No. 167, 107th Cong., 2nd Sess., at 4 (2002).

27. Abbott Labs., Dkt. N o. C-3945 (May 22, 2000) (co nsent order), complaint available at ; Geneva Pharms., Inc., Dkt. No. C-3946 (May 22, 2000)
(consent order), complaint available at . The consent order in Abbott Laboratories is available at . The consent order in Geneva Pharmaceuticals is available at . The consent order in Hoechst/ Andrx is available at . Hoechst Marion Roussel, Inc., Dkt. No. 9293 (May 8, 2001) (consent order), complaint available at http://www.ftc.gov/os/2000/03/hoechstandrxcomplaint.htm. Bristol-Myers Squibb Co., Dkt. N o. C-4076, available
at .

28. The Commission ultimately determined that, in the seven years between 1992 and 1999, there were fourteen final settlements between brand-name manufacturers and the generic first-filer, and that eight of those settlements included a payment from the brand name drug company to the generic drug applicant in exchange for the generic company's agreement not to market its product. Bureau of Competition Report, Federal Trade Commission, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2005: A Report by the Bureau of Competition (Apr. 2006), available at .

29. We lack data for the approximately three year period between the end of the Generic Drug Study and the beginning of the MMA reporting period. It is quite likely that there are additional settlements that occurred during this period for which we do not have information.

30. Schering-Plough Corp. v. F.T.C., 403 F.3d 1056 (11th Cir. 2005); In re Tamoxifen Citrate Antitrust Litig., 429 F.3d 370 (2d Cir. 2005) (Pooler, J., dissenting).

31. In re Cardizem Antitrust Litigation, 332 F.3d 896 (6th Cir. 2003).

32. Schering-Plough Corp., 2003 FTC LEXIS 187 (FTC Dec. 8, 2003), vacated, 402 F.3d 1056 (11 Cir. 2005), cert. denied, 126 S. Ct. 2929 (2006); Schering-Plough Corp., Upsher-Smith Labs., and American Home Products Corp., Dkt. No. 9297 (Apr. 2, 2002) (consent order as American Hom e Products).

33. Schering, 402 F.3d at 1058.

34. Id. at 1066-67.

35. Id. at 1068.

36. Id. at 1076.

37. See, e.g., In re Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514, 539 (E.D.N.Y. 2005), appeal docketed, No. 05-2851 (2d Cir. June 7, 2005) ("Cipro") (the ruling below "is more fairly read as requiring an
evaluation of the scope of the patent's claims, and not a post hoc analysis of the patent's validity").

38. In re Tamoxifen Citrate Antitrust Litig., 429 F.3d 370 (2d Cir. 2005) , amended, 466 F.3d 187 (Aug 10, 2006), petition for cert. filed, http://www.supremecourtus.gov/docket/06-830.htm (Dec. 13, 2006) (N o. 06-830).

39. Stephanie Kirchgaessner & Patti Waldmeir, Drug Patent Payoffs Bring a Scrutiny of Side-Effects, FINANCIAL TIMES UK, Apr. 25, 2006, 2006 WLNR 6910048 (quoting S.G. Cowen & Co. analyst's report).

40. Bureau of Competition Report, Federal Trade Commission, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2005: A Report by the Bureau of Competition (Apr. 2006), available at .

41. This pattern was observed in the FTC staff's review of Hatch-Waxman settlements from 1993 through 2000, which were collected in the Generic Drug Study, as well as all the settlements filed under the MM A. There were two exceptions to the observation that side deals do not occur in settlements that do not explicitly restrict entry. One of these settlement is under investigation.

42. See Aaron Catlin, et al., National Health Spending in 2005, 26 HEALTH AFFAIRS 142, Jan./ Feb. 2007,
available a t .

43. See supra note 6.

44. For example, for a hypothetical patent infringement claim with a 50% chance of success, with 10 years
remaining in the patent term, continued litigation between the parties affords consumers an overall expected value of
5 years of competition, taking into account the likelihood of the two possible outcomes. If the parties instead reach a
settlement in which the patent holder makes a payment to the challenger, and the challenger agrees to enter only one
year prior to the expiration date, consumers are worse off, on average, than had the litigation gone forward. The
appellate courts' approach, by contrast, would automatically endorse such a settlement because it

is within the outer,
nominal bounds of the patentee's claims.

45. Generic Drug Study at 19-20.

46. Bethany M cLean, A Bitter Pill, FORTUNE, Aug. 13, 2001, at 5, available at
.

47. Stephanie Kirchgaessner & Patti Waldmeir, supra note 41.

48. 402 F.3d at 1076.

49. Id. at 1074.

50. See Generic Drug Study at vii-xi, 57-58, 62-63.

51. The decision must be "a final decision from which no appeal (other than a petition to the Supreme Court
for a writ of certiorai) has been or can be taken that the patent is invalid or not infringed." Medicare Prescription
Drug, Improvement, and Modernization Act of 2003, ? 1102(a)(1), Pub. L. No. 108-173, 117 Stat. 2066, 2457
("MMA") (amending 21 U .S.C. ? 355(j)(5)(B)(iv)).

52. The other forfeiture events established by the Medicare M odernization Act are a court-entered settlement
that the patents are invalid or not infringed, or withdrawal of the patents from the Orange Book by the brand
company. MMA, ? 1102(a)(1), Pub. L. No. 108-173, 117 Stat. At 2457(amending 21 U.S.C. ? 355(j)(5)(B)(iv)).
Both require action by the brand company.

53. See, e.g., Teva Pharms. USA, Inc., v. FDA, 2005 W L 2692489 (D.D.C. Oct. 21, 2005); Apotex, Inc. v.
Pfizer Inc., 385 F. Supp.2d 187 (S.D.N.Y. 2005); Glaxo Group Ltd. v. Dr. Reddy's Labs, Ltd., 325 F. Supp.2d 502
(D.N.J. 2004); Mutual Pharm. Co. v. Pfizer, Inc., 307 F. Supp.2d 88 (D .D.C. 2004).

54. Teva Pharms. USA, Inc. v. P fizer Inc., 395 F.3d 1324 (Fed. Cir.), cert. denied, 126 S. Ct. 473 (2005).
The Supreme Court recently examined the availability of declaratory judgment jurisdiction in patent cases in
Medimmune, Inc. v. Genetech, Inc., No. 05-068 (U .S.S.Ct. Jan. 9, 2007). The Court held that the case or controversy
requirement did not require a patent licensee to breach its license agreement before seeking a declaratory judgment
that the underlying patent is invalid or not infringed. Although the Supreme Court criticized

language in Teva v. Pfizer, the effect of this decision on declaratory judgment jurisprudence in the Hatch-Waxman context awaits further development in the courts.

55. Apotex, Inc. v. FDA, 449 F.3d 1249 (D.C. Cir. 2006) (upholding FDA's decision to treat only an adjudicated holding on the patent merits as a "court decision" for purposes of triggering the 180-day exclusivity).

56. The Commission made a similar recommendation in its 2002 Generic Drug Study at x-xi.