PREPARED STATEMENT OF THE
FEDERAL TRADE COMMISSION

Before the

SPECIAL COMMITTEE ON AGING

of the

UNITED STATES SENATE

on

BARRIERS TO GENERIC ENTRY

July 20, 2006

Chairman Smith, Ranking Member Kohl, and Members of the Committee, I am Jon Leibowitz, Commissioner of the Federal Trade Commission ("FTC" or "Commission"). I am pleased to appear before you today to testify on behalf of the Commission regarding barriers to generic entry in the pharmaceutical industry.[1]

Advances in the pharmaceutical industry continue to bring enormous benefits to Americans. Because of pharmaceutical innovations, a growing number of medical conditions often can be treated more effectively with drugs and drug therapy than with alternative means (*e.g.*, surgery). The development of new drugs is risky and costly, however.

At the same time, the escalating cost of health care in the United States – and in particular, of prescription drugs – is an enormous, nationwide problem. As the Government Accountability Office reported last year: "Prescription drug spending as a share of national health expenditures increased from 5.8 percent in 1993 to 10.7 percent in 2003 and was the fastest growing segment of health care expenditures."[2] Older Americans, typically those in greatest need of health care in our population and often living on fixed incomes, bear a disproportionate share of these costs. Although people over 65 are only 13 percent of the population, they account for 42 percent of all drug expenditures.[3] Pharmaceutical expenditures are a concern not only to individual consumers, but also to government payers, private health plans, and employers. Generic drugs play an important role in containing rising prescription drug costs, by offering consumers therapeutically identical alternatives to brand-name drugs, at a significantly reduced cost.

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[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] Government Accountability Office, *PRESCRIPTION DRUGS: Price Trends for Frequently Used Brand and Generic Drugs from 2000 through 2004* at 1 (Aug. 2005).

[3] Families USA, *Cost Overdose: Growth in Drug Spending for the Elderly*, 1992-2010 at 2, 13 (July 2000).

To address the issue of escalating drug expenditures, and to ensure that the benefits of pharmaceutical innovation would continue, Congress passed the Hatch-Waxman Amendments[4] ("Hatch-Waxman" or "the Amendments") to the Food, Drug and Cosmetic Act ("FDC Act") in 1984.[5] Hatch-Waxman established a regulatory framework that sought to balance incentives for continued innovation by research-based pharmaceutical companies, on the one hand, and opportunities for market entry by generic drug manufacturers, on the other hand.[6] Without question, Hatch-Waxman has increased generic drug entry. The Congressional Budget Office estimated that, by purchasing generic equivalents of brand-name drugs, consumers saved $8-10 billion on retail purchases of prescription drugs in 1994 alone.[7] The federal and state governments also are significant purchasers of pharmaceuticals, and they likewise reap substantial savings from generic drugs.

Yet, in spite of this remarkable record of success, there have been, and continue to be, competitive problems in pharmaceutical markets. Although many drug manufacturers – including both brand-name and generic companies – have settled their patent suits in a manner that does not harm competition, others have entered anticompetitive settlements without providing a corresponding benefit to consumers. Responding to some of these abuses, in 2003 Congress included provisions in the Medicare Modernization Act ("MMA") that amended the

[4] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585

Hatch-Waxman Act to require notice of settlement between brand and generic firms to the FTC and Department of Justice.

For its part, the Commission has aggressively protected competition in the pharmaceutical industry, including pursuing numerous antitrust enforcement actions affecting both brand-name and generic drug manufacturers.[8] The Commission also has filed amicus briefs on competition-related issues in a variety of pharmaceutical cases.[9] On a policy level, the Commission has promoted a greater understanding of the role of competition in the industry through multiple studies including our 2002 study entitled "Generic Drug Entry Prior to Patent Expiration" ("Generic Drug Study"), which recommended some of the changes made in the MMA.[10] Since the MMA filing requirement became effective in January 2004, Commission staff have issued annual reports on the types of patent settlements being entered.[11] Commission staff

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[8] *See, e.g.*, Federal Trade Commission, Petition for a Writ of Certiorari, *FTC v. Schering-Plough Corp.*, No. 05-273 (June 26, 2006) (denying cert. petition); *Schering-Plough Corp. v. F.T.C.*, 402 F.3d 1056 (11th Cir. 2005); *Schering-Plough Corp.*, No. 9297, 2003 WL 22989651 (F.T.C.) (Dec. 8, 2003) (Commission decision and final order); *Schering-Plough Corp., Upsher-Smith Labs., and American Home Products Corp.*, Dkt. No. 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. 13, 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, 2002) (consent order); *Geneva Pharms., Inc.*, Dkt. No. C-3946 (May 22, 2000); *Hoechst Marion Roussel, Inc.*, Dkt. No. 9293 (Apr. 4, 2001) (consent order); *FTC v. Mylan Labs., Inc. et al.*, 62 F. Supp. 2d 25 (D.D.C. 1999).

[9] *See, e.g.*, Brief for the Federal Trade Commission as Amicus Curiae Supporting *en banc* petition, *In re Tamoxifen Litigation*, (No. 03-7641) (2d Cir. Dec. 2, 2005); Brief for the Federal Trade Commission as Amicus Curiae Supporting *en banc* petition, *Teva Pharm. v. Pfizer Inc.*, (03CV-10167) (Fed. Cir. Feb. 5, 2005); Brief for the Federal Trade Commission as Amicus Curiae Supporting Appellants, *Teva Pharm. v. Pfizer Inc.*, (03CV-10167) (Fed. Cir. Feb. 5, 2005).

[10] Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002), *available at* <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf> (hereinafter "Generic Drug Study").

[11] 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* <http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf>; 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 pharmaceutical competition before a variety of audiences, both to solicit input from affected parties and to promote discussion about practical solutions.[15]

This testimony will address the Commission's vigorous enforcement of the antitrust laws with respect to brand-name and generic drug competition, as well as current policy issues that implicate that competition and affect senior citizens' drug purchasing costs. The first two sections address how settlements of patent litigation, either alone or in combination with the 180-day exclusivity period, can delay generic entry. The testimony discusses (I) the types of patent settlements the Commission believes are anticompetitive, including possible legislative solutions to this problem, and (II) how brand companies have used 180-day exclusivity to block generic entry.

Next, the testimony reviews the antitrust implications of agreements entered outside the context of patent litigation. The testimony discusses (III) the Commission's ongoing litigation against Warner-Chilcott and Barr Laboratories, and (IV) the Commission's enforcement actions against agreements between generic companies that delay generic competition.

Finally (V), the testimony discusses the Commission's plan to study the impact of authorized generics on pharmaceutical markets.

I. Settlement of Patent Disputes in the Pharmaceutical Industry

Settlements of patent litigation are a significant threat to competition in the pharmaceutical industry when they include so-called "exclusion payments." These settlements,

[15] *See, e.g.*, Deborah Platt Majoras, *A Government Perspective on IP and Antitrust Law* (June 21, 2006), *available at* <http://www.ftc.gov/speeches/majoras.htm>; Jon Leibowitz, *Exclusion Paym*

which appear to be unique to the pharmaceutical industry, occur when a branded company shares a portion of its future profits with a potential generic entrant in exchange for the generic's agreement not to market its product. Although both the brand company and the generic company are better off financially, these settlements restrict competition at the expense of consumers, whose access to lower-priced generic drugs may be deferred for years.

A. The Benefits of Generic Competition

Generic competition in the pharmaceutical industry provides a significant benefit to consumers and, in particular, the elderly. Studies of the pharmaceutical industry indicate that the first generic competitor typically enters the market at 70 to 80 percent of the brand-name counterpart, and gains substantial share from the brand-name product in a short period of time.[16] Subsequent generic entrants may enter at even lower prices and cause the earlier 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.[17]

[16] *See* CBO Study, n. 6; *see generally* Reiffen & Ward, *Generic Drug Industry Dynamics*, 87 REVIEW OF ECON. & STAT. 37-79 (2005).

[17] CBO Study, xiii.

1. **Statutory Background**

Congress intended that the Hatch-Waxman Act would "make availab

already submitted to the FDA regarding the branded drug's safety and efficacy. The ANDA filer must demonstrate that the generic drug is "bioequivalent" to the relevant branded product.[23] The ANDA must contain, among other things, a certification regarding each patent listed in the Orange Book in conjunction with the relevant NDA.[24] One way to satisfy this requirement is to provide a "Paragraph IV" certification, asserting that the patent in question is invalid or not infringed.[25]

Filing a Paragraph IV certification potentially has significant regulatory implications, as it is a prerequisite to operation of the two most competitively sensitive provisions of the statute. The first of these is the automatic 30-month stay. An ANDA filer that makes a Paragraph IV certification must provide notice, including a detailed statement of the factual and legal bases for the ANDA filer's assertion that the patent is invalid or not infringed, to both the patent holder and the NDA filer.[26] Once the ANDA filer has provided such notice, a patent holder wishing to take advantage of the statutory stay provision must bring an infringement suit within 45 days.[27] If the patent holder does not bring suit within 45 days, the FDA may approve the ANDA immediately.[28] If the patent holder does bring suit, however, the filing of that suit triggers an

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[23] *Id.* § 355(j)(2)(A)(iv).

[24] *Id.* § 355(j)(2)(A)(vii).

[25] *Id.* ' 355(j)(2)(A)(vii)(IV).

[26] *Id.* § 355(j)(2)(B). Although the patent holder and the NDA filer will often be the same person, this is not always the case. The Hatch-Waxman Amendments require that all patents that claim the drug described in an NDA must be listed in the Orange Book. Occasionally, this requirement will cause an NDA filer to list a patent that it does not own.

[27] *Id.* § 355(j)(5)(B)(iii).

[28] *Id.*

automatic 30-month stay of FDA approval of the ANDA.[29] And, without FDA approval, a generic manufacturer cannot bring its product to market. The imposition of a stay can, consequently, forestall generic competition for a substantial period of time.

The second competitively sensitive consequence is the 180-day period of marketing exclusivity. To encourage generic drug manufacturers to challenge questionable patents by filing Paragraph IV certifications – a move that can potentially subject the company to costly and burdensome patent infringement litigation – the Hatch-Waxman Amendments provide that the first generic manufacturer (first-filer) 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.[30] The 180-day period is calculated from the date of the first commercial marketing of the generic drug product.[31] The potential impact of the 180-day exclusivity period is further magnified by the fact that, under the prevailing interpretation of the Hatch-Waxman Amendments, a second ANDA filer may not enter the market until the first filer's 180-day period of marketing exclusivity has expired, even if the first filer substantially delays commencement of the exclusivity period.[32] A first-filer can forfeit its exclusivity under certain conditions.[33]

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[29] *Id.*

[30] *Id.* § 355(j)(5)(B)(iv).

[31] *Id.*

[32] *See id.* § 355(j)(5)(B)(iv). As discussed in Section II, *infra*, the first ANDA filer's failure to commence its 180-day period of marketing exclusivity can create a bottleneck that prevents subsequent ANDAs from being approved and, consequently, prevents additional generic products from entering the market.

[33] *Id.* § 355(j)(5)(D); *see also infra* notes 62-64, and accompanying text.

2. Impact of Generic Competition

Experience has borne out the efficacy of the Hatch-Waxman process and the correctness of its premises – *i.e.*, that many patents will not stand in the way of generic entry if challenged, 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.[34] Many of these successes involved blockbuster drugs and allowed generic competition years before patent expiration (see chart).[35] Generic competition following successful patent challenges to Prozac, Zantac, Taxol, and Plantinol alone is estimated to have saved consumers more than $9 billion,[36] in addition to the savings to federal and state governments.

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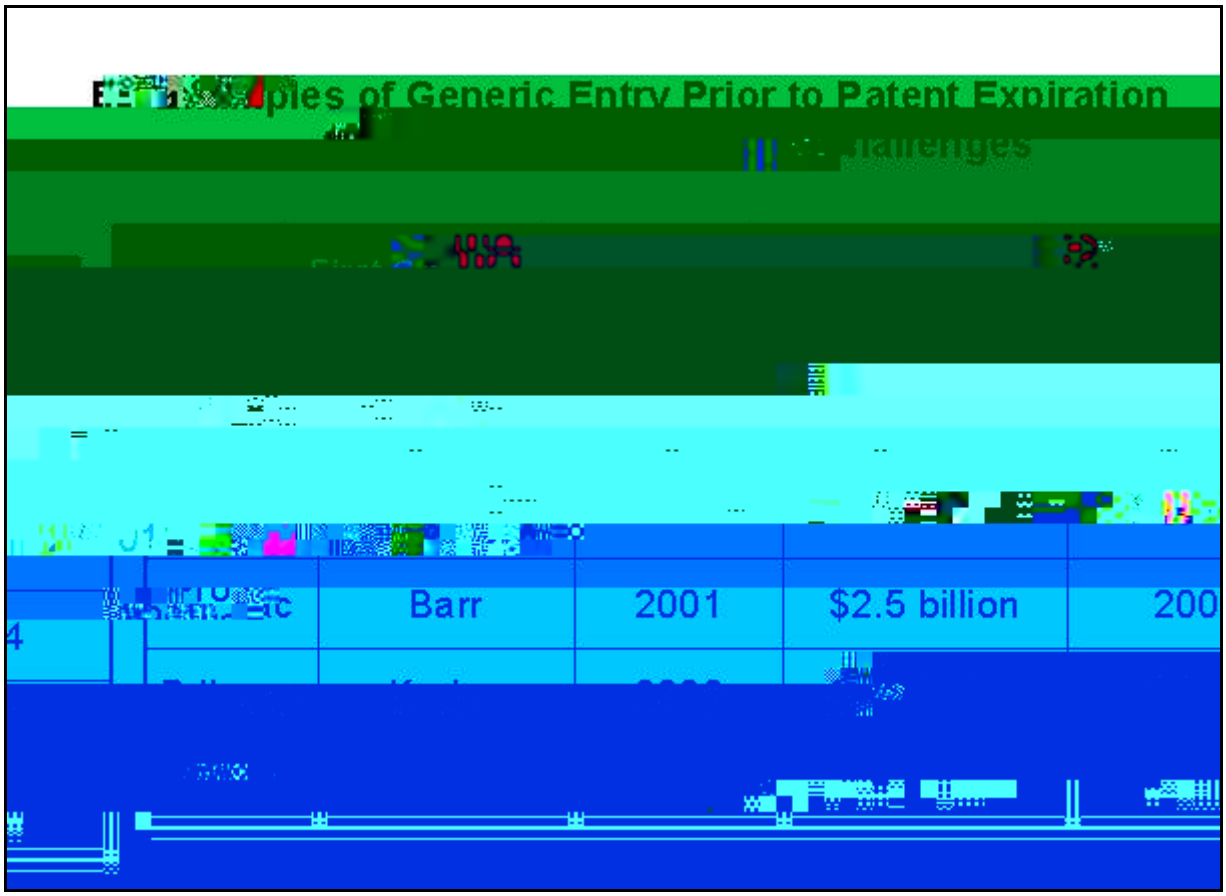
[34] *Generic Drug Study*, at 19-20.

[35] 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 anticancer 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).

[36] Generic Pharmaceuticals Marketp -1.307 Td(2002 3 0 2.573 0 ,xye/02 Tw 0.>>BcEFQTd(ing I,9.32 0 Td(.5jETEMCnEMC /



B. Exclusion Payments Harm Consumers

By increasing the likelihood of generic entry, however, the statute also increases the incentive for brand and generic manufacturers to conspire to share, rather than compete for, the expected profits generated by sales of both brand and generic drugs. In nearly any case in which generic entry is contemplated, the profit that the generic anticipates will be much less than the profit the brand-drug company makes from the same sales. Consequently, it typically will 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. Although both the brand-name company and

the generic company are better off with the settlement, consumers lose the possibility of an earlier generic entry, either because the generic company would have prevailed in the lawsuit or the parties would have negotiated a settlement with an earlier entry date but no payment. Instead, consumers are left with the guarantee of delayed generic entry and paying higher prices.

Congress expressly recognized the risk that the Act might promote such market allocation agreements, and implicitly directed the enforcement agencies to prosecute such agreements by amending 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."[37] In the words of Rep. Waxman, "[t]he law has been turned on its head. . . . We were trying to encourage more generics and through different business arrangements, the reverse has happened."[38]

The Commission has challenged patent settlements when it believes that brand-name and generic companies have eliminated the potential competition between them and shared the

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to the generic company and an agreement by the generic company not to market its product between 2000 and the end of fiscal year 2004.[42]

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.[43] The parties simply found different ways to resolve their disputes. In other words, we were effectively enforcing the antitrust laws, and our enforcement efforts were an effective deterrent that benefitted consumers with lower p

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 simTj/TTnt 9Cl a pa1

must have agreed to a later date in return for such payment, even if there was no other plausible explanation for the payment.[50]

The Commission sought Supreme Court review. Thirty-five states, AARP, and a patent policy think tank supported the Commission's petition. Last month, however, the Supreme Court denied certiorari review.

The Eleventh Circuit's decision already is having a negative legal and practical effect. Other courts have understood the ruling below to demand only an inquiry into the nominal reach of the patent, and not an assessment of the likelihood that the patent-holder could successfully effect exclusion through patent litigation.[51] Indeed, the Second Circuit, in ruling in similar cases, followed the Eleventh Circuit's holding and expressly embraced the "sham" standard.[52] Although there was a five-year hiatus in pay-offs to generics after the Commission commenced 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.[53] There were three such agreements in fiscal 2005, two of which occurred after the Eleventh Circuit's decision in *Schering*. In the current fiscal year, we have seen significantly more settlements with payments and a restriction on entry– seven of ten agreements between brand-name and generic companies

[50] *Id.* at 1076.

[51] *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").

[52] *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005).

[53] Bureau of Competition Repo

included a payment from the brand-name to the generic company and an agreement to defer generic entry.[54]

The economic implications of the courts of appeals' rulings, which seem to invite collusive arrangements between brand-name drug companies and generic challengers, are staggering. American consumers and health plans spend over a hundred billion dollars on prescription drugs each year.[55] Of the twenty top-selling prescription drugs in the United States in 2004, eleven (with annual sales of nearly $25 billion) were the subject of litigation by generic firms seeking to enter the market under the terms of the Hatch-Waxman Act.[56] The prospect of consumer benefit from such challenges is enormous, to the extent that they lead to early, non-infringing generic entry. Under the courts of appeals' rulings, however, the parties in such cases will have the strong economic incentive discussed above to enter into settlements that share the benefits of continued monopoly prices and deprive consumers of the benefit of low-cost, non-infringing generic drugs.

One need look no further than the investment community for confirmation of the danger these rulings present. One analyst report describes the Eleventh Circuit's *Schering* decision as having "opened a Pandora's box of settlements" and observes that the decision provided "significant value" to both brand-name and generic companies.[57] Left out of the equation is the impact of the decision on consumers.

The issue of exclusion payments has been the subject of significant debate, but the Commission's position is clear. 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.[58] Some who disagree with the Commission's position argue that we must presume the validity of the patent, and even infringement, and its exclusionary power for the full term unless patent litigation proves otherwise. They also argue that we must permit parties to settle patent litigation, which they may choose to do regardless of their positions on the merits, according to their own risk calculus at the time. These arguments, however, ignore both the law and the facts. There is no question that the result of patent litigation, and therefore the timing of generic entry, is uncertain. But the antitrust laws prohibit the paying of a potential competitor, as well as an existing competitor, to

[57] Stephanie Kirchgaessner and 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).

[58] For example, to return to the hypothetical patent claim with a 50% chance of success, if there are 10 years remaining in the patent term, continued litigation between the parties affords consumers an overall expected value of 5 years' 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 court of appeals' approach, by contrast, would automatically endorse such a settlement because it is within the outer, nominal bounds of the patentee's claims.

stay out of the market, even if the entry is uncertain. We disagree with the argument that generic entry before the end of a patent term is too uncertain or unlikely to be of competitive concern, because Congress spoke on the issue and we know that would-be generic entrants have enjoyed a nearly 75 percent success rate in patent litigation initiated under Hatch-Waxman. As for the argument that challenging such payoffs will deter settlements, which generally are favored, legitimate patent settlements – using means other than exclusion payments – continued to occur without hindrance from the Commission decision.

Under the rulings in the Second Circuit's *Tamoxifen* decision and the Eleventh Circuit's *Schering* decision, exclusion payment settlements are legal unless the patent was obtained by fraud or the suit is a sham. Given that the brand-name and generic company are both better off avoiding the possibility of competition and sharing the resulting profits, there may be little doubt that, should those rulings become the controlling law, we will see more of the ofoel3- iTj2re

Schering and *Tamoxifen* cases,[60] the settlement would have been legal, generic entry would not have occurred, and consumers would have had to pay higher prices until patent expiration.

D. Legislative Solutions to Anticompetitive Settlements

The Commission supports legislation addressing this problem. We recognize that crafting legislation that accomplishes those goals may be challenging, however. 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 to settlement of suits. For these reasons, we strongly support the intent behind S. 3582, the "Preserve Access to Affordable Generics Act" – bipartisan legislation introduced by Senators Kohl, Leahy, Grassley, and Schumer. We would welcome the opportunity to work with Congress on any such legislative initiatives.

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

The impact of the courts of appeals' decisions sanctioning settlements incorporating exclusionary payments will be magnified by the effect of the Hatch-Waxman Act's 180-day exclusivity. Because of recent court decisions, settlements between a brand-name company and a first generic filer for a delayed entry date are more likely to create a bottleneck that prevent *any* generic competition through operation of the first generic filer's 180-day exclusivity.

When a first generic applicant enters into an agreement with a brand-name manufacturer to delay entering the market, either with or without an accompanying payment, the generic typically will not trigger the running of its 180-day exclusivity period until it enters the market on the agreed-upon date. For that reason, the first generic applicant's 180-day exclusivity period

[60] *See supra* notes 44-50 and accompanying text.

will create a bottleneck that prevents any subsequent generic applicant from entering the market until the period runs.[61] Such a bottleneck would obviously benefit only the brand manufacturer and the first generic applicant, to the detriment of subsequent generic applicants and consumers. A subsequent generic can relieve the bottleneck only by triggering a forfeiture event that forces the first generic filer to either use or lose its exclusivity period within 75 days. One such forfeiture event[62] is a court decision[63] that the patent supporting the 180-day exclusivity period is invalid or not infringed.[64]

A problem arises if the brand-name company does not sue the subsequent ANDA filer, thereby eliminating the possibility that the generic company will obtain a favorable court decision 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 ANDA filers. Indeed, a troubling trend by brand-name companies towards employing just such a strategy is increasingly evident.[65]

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[61] *See Generic Drug Study* at vii-xi, 57-58, 62-63.

[62] The other forfeiture events established by Title XI of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 P.L. No. 108-173 (hereinafter "MMA") 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), amending 21 U.S.C. § 355(j)(5)(B)(iv).

[63] The decision must be "a final decision from which no appeal (other than a petition to the Supreme Court for a writ of *certiorari)* has been or can be taken that the patent is invalid or not infringed." MMA, § 1102(a)(1), amending 21 U.S.C. § 355(j)(5)(B)(iv).

[64] MMA § 1102(a)(1), amending 21 U.S.C. § 35

Some generic companies facing this scenario have attempted to bring declaratory judgment actions of non-infringement and invalidity,[66] but that strategy has been unsuccessful thus far. A recent decision of the Federal Circuit, *Teva v. Pfizer*,[67] held that declaratory judgment is unavailable in this situation for lack of a Constitutionally-required case or controversy unless the brand-name company has raised a reasonable apprehension of suit in the subsequent ANDA filer. In that case, Pfizer, the brand-name manufacturer, had settled patent litigation with Ivax, the first generic applicant, with Ivax agreeing to delay entering the market for approximately two years. As a result, I

decision, FDA reversed its previous policy and no longer treats any dismissal of a declaratory judgment action, even those made with prejudice and having preclusive effect on the issues of infringement and validity, as a court decision for purposes of triggering the exclusivity period. Last month, the D.C. Circuit upheld that decision in *Apotex v. FDA.*[70]

There is a potential legislative remedy, however. At the time that the Commission released its Generic Drug Study in 2002, the D.C. Circuit had held that a dismissal of a declaratory judgment action for lack of a case or controversy was a court decision of non-infringement sufficient to trigger the 180-day exclusivity and clear the bottleneck.[71] Because of its concern with the bottleneck scenario described here, the Commission recommended that Congress codify this decision and clarify that dismissal of a declaratory judgment action brought by a generic applicant could trigger the 180-day exclusivity.[72] The 2003 amendments to the Hatch-Waxman Act did not incorporate this recommendation.

As a result of the Federal Circuit's decision in *Teva v. Pfizer* and the D.C. Circuit's decision in *Apotex v. FDA*, a subsequent generic filer that faces a bottleneck but has not been sued has no mechanism to relieve that bottleneck. It cannot pursue a declaratory judgment action, and dismissal of that attempt will not trigger the 180-day exclusivity or a forfeiture event. 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. Indeed, in those circumstances, it is contrary to the Hatch-Waxman Act's purposes of encouraging me theo-37.831C /StyleSpan <</MCID 5 >>E

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.

For these reasons, the Commission reiterates the recommendation of the Generic Drug Study: Congress should clarify that dismissal of an action brought by a generic applicant seeking a declaratory judgment constitutes a forfeiture event for the 180-day exclusivity period.

III. Warner-Chilcott Barr: Challenging a Naked Agreement not to Compete

Agreements between brand-name and generic companies entered outside of patent litigation can also harm consumers. Last year the Commission filed an action against Warner Chilcott and Barr Laboratories, two sellers of prescription drugs.[73] The Commission alleges that two companies entered an agreement not to compete that was not part of a patent settlement.[74] Warner Chilcott sells Ovcon 35 ("Ovcon"), an oral contraceptive used to prevent pregnancy. Barr is the only company approved by the FDA to sell a generic version of the drug in competition with Warner Chilcott's brand Ovcon. Prior to the challenged agreement, Barr planned to compete with Warner Chilcott by selling Barr's lower-priced generic Ovcon once Barr received FDA approval. Both Warner Chilcott and Barr predicted that entry of Barr's lower-priced generic into the market would reduce Warner Chilcott's higher-priced brand Ovcon's sales, by capturing approximately 50 percent of Ovcon's business in the first year alone.

The complaint alleges that to forestall this competitive threat and to protect its Ovcon sales, Warner Chilcott entered into an agreement with Barr preventing entry of Barr's generic

[73] *F.T.C. v.Warner Chilcott et. al.*, Civ. Action No. 1:05-CV-2179 (D.D.C. Nov. 7, 2005).

[74] The Complaint is *available at* <http://www.ftc.gov/os/caselist/0410034/051107comp0410034%20.pdf>

Ovcon into the United States for five years. In exchange for Barr's agreement to keep its generic Ovcon off the market, Warner Chilcott paid Barr $20 million. Instead of entering and competing, Barr would agree to be available as a second supplier of Ovcon to Warner Chilcott if Warner Chilcott so requested. The complaint charges that the effect of this anticompetitive agreement between Warner Chilcott and Barr has been to deprive purchasers of the choice of a lower-cost generic alternative to Warner Chilcott's higher-priced brand Ovcon.

generic Children's Motrin product for seven years. Perrigo obtained the exclusive right to do so during that period. In exchange for Alpharma's promises not to compete, Perrigo agreed to pay Alpharma a lump sum fee and royalty on Perrigo's net sales of store-brand Children's Motrin.

The Commission sought and obtained a permanent injunction in federal court. Under the stipulated orders, the defendants (1) agreed to pay over six million dollars to customers that were allegedly overcharged, (2) agreed not to enter similar agreements in the future, and (3) agreed to provide notice of other generic-generic agreements that either defendant enters.[78]

Paragraph IV certification (claiming that patent protecting the brand drug is either invalid or not infringed) receives 180 days of market exclusivity, which means the FDA cannot approve any additional ANDA filers until 180 days after the first-filer begins marketing its product. The 180-day mar

Commission has proposed to undertake such a study to examine both the likely short-term competitive effects of authorized generic drug entry and, to the extent possible, the likely long-term impact of entry by authorized generic drugs on competition by generic manufacturers. The Commission stated its intention to rely on data and information from the FDA, brand manufacturers, independent generic manufacturers, and authorized generic companies. I