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

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[4] 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)).

[5] 21 U.S.C. § 301 *et seq.*

[6] *See infra* notes 16-33 and accompanying text. The Amendments also were intended to encourage pharmaceutical innovation through patent term extensions.

[7] Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (July 1998), *available at* <http://www.cbo.gov/showdoc.cfm?index=655&sequence=0> (hereinafter "CBO Study").

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*

also have conducted empirical analyses of competition in the pharmaceutical industry, including in-depth studies by the staff of the FTC's Bureau of Economics.[12] The Commission's efforts also have included filing comments with the United States Food and Drug Administration ("FDA") regarding the competitive aspects of Hatch-Waxman implementation,[13] as well as submitting testimony before Congress.[14] Furthermore, individual Commissioners have addressed the subject

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of Competition (Jan. 2005), *available at* <http://www.ftc.gov/os/2005/01/050107medicareactrpt.pdf>.

[12] Federal Trade Commission, Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies (August 2005), *available at* <http://www.ftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf>; Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (Oct. 2003), *available at* <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>; David Reiffen & Michael R. Ward, *Generic Drug Industry Dynamics*, Bureau of Economics Working Paper No. 248 (Feb. 2002) ("Reiffen and Ward"), *available at* <http://www.ftc.gov/be/econwork.htm>; Bureau of Economics Staff Report, Federal Trade Commission, *The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change* (Mar. 1999), *available at* <http://www.ftc.gov/reports/pharmaceutical/drugrep.pdf>.

[13] *Response to Citizen Petition by Ivax Pharmaceuticals, Inc.* (Apr. 5, 2005), *available at* <www.ftc.gov/os/2005/04/050407ltrivaxpharm.pdf> (recommending that FDA deny Ivax's request that the FDA prohibit delisting of patents from the Orange Book); *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*, Comment of the Federal Trade Commission (Dec. 23, 2002) ("30-Month Stay Comment"), *available at* <http://www.ftc.gov/be/v030002.pdf> (recommending modifications to FDA proposed rule on patent listing requirements and providing suggestions to the proposed patent declaration); *FDA: Citizen Petition*, Comment of the Staff of the Bureau of Competition and the Office of Policy Planning of the Federal Trade Commission Before the Food and Drug Administration (Mar. 2, 2000), *available at* <http://www.ftc.gov/be/v000005.pdf> (recommending modifications to the FDA's Proposed Rule on citizen petitions intended to discourage anticompetitive abuses of the FDA's regulatory processes); *FDA: 180-DayGeneric Drug Exclusivity for Abbreviated New Drug Applications*, Comment of the Staff of the Bureau of Competition and the Office of Policy Planning of the Federal Trade Commission Before the Food and Drug Administration (Nov. 4, 1999) ("Marketing Exclusivity Comment"), *available at* <http://www.ftc.gov/be/v990016.htm> (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).

[14] Testimony of the Federal Trade Commission before the Committee on Judiciary, United States Senate, *Competition in the Pharmaceutical Industry* (June 17, 2003), *available at* <http://www.ftc.gov/os/testimony/108hearings.htm>; Testimony of the Federal Trade Commission before the Committee on Energy and Commerce, Subcommittee on Health, United States House of Representatives, *Study of Generic Drug Entry Prior to Patent Expiration* (Oct. 9, 2002), *available at* <http://www.ftc.gov/os/2002/10/genericte stimony021009.pdf>; Testimony of the Federal Trade Commission before the Committee on Commerce, Science, and Transportation, United States Senate, *Competition in the Pharmaceutical Industry* (Apr. 23, 2002), *available at* <http://www.ftc.gov/os/2002/04/pharmtestimony.htm>; 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* <http://www.ftc.gov/os/2001/05/pharmtstmy.htm>.

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,

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[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 Payments to Settle Pharmaceutical Patent Cases: They're B-a-a-a-ck! (The Role of the Commission, Congress, and the Courts)* (Apr. 24, 2006), *available at* <http://www.ftc.gov/speeches/leibowitz/060424PharmaSpeechACI.pdf>; Timothy J. Muris, *Competition and Intellectual Property Policy: The Way Ahead*, at 5-6 (Nov. 15, 2001), *available at* <http://www.ftc.gov/speeches/muris/intellectual.htm>.

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 available more low cost generic drugs," while fully protecting legitimate patent claims.[18] 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.[19] It also encourages the development of generic drugs by declaring various research and development activities noninfringing.[20]

Pursuant to the FDC Act, 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.[21] 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."[22]

Rather than requiring a generic manufacturer to repeat the costly and time-consuming NDA process, the Hatch-Waxman Amendments permit the company to file an Abbreviated New Drug Application ("ANDA"), which incorporates data that the "pioneer" manufacturer has

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[18] H.R. Rep. No. 857, 98th Cong., 2nd Sess., Pt. 1, at 14 (1984).

[19] 21 U.S.C. 355(j).

[20] 35 U.S.C. 271(e)(1); *see Merck KGaA* v. *Integra Lifesciences I, Ltd.*, No. 03-1237, 125 S. Ct. 2372 (June 13, 2005).

[21] 21 U.S.C. § 355(b)(1).

[22] *Id.* § 355(j)(7)(A).

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.

[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 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* <http://commerce.senate.gov/hearings/042302jaegar.pdf>.

Examples of Generic Entry Prior to Patent Expiration from Successful Patent Challenges

Drug	First Generic Entrant	Generic Entry Date	Brand Sales Prior to Generic Entry	Expiration Date of Last Patent
Zantac	Granutec	1997	$1.6 billion	2002
Taxol	Baker Norton	2000	$1.6 billion	2013
Prozac	Barr	2001	$2.5 billion	2004
Prilosec	Kudco	2002	$3.7 billion	2018
Paxil	Apotex	2003	$2.2 billion	2017

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

[38] Cheryl Gay Stolberg et al., *Keeping Down the Competition; How Companies Stall Generics and Keep Themselves Healthy*, N.Y. TIMES, July 23, 2000, at A11 (quoting Rep. Waxman). *See also* Statement of Sen. Orrin Hatch, Senate Floor Debates on S. 812 (2002), *available at* http://hatch.senate.gov/index.cfm?FuseAction=PressReleases.Detail&PressRelease_id ("As a coauthor of the Drug Price Competition and Patent Term Restoration Act, I can tell you that I find these type of reverse payment collusive arrangements appalling. I must concede, as a drafter of the law, that we came up short in our draftsmanship. We did not wish to encourage situations where payments were made to generic firms not to sell generic drugs and not to allow multi-source generic competition. . . . However the K-Dur case ultimately is decided, I commend [the FTC for] zealously reviewing these type of reverse payments cases to determine whether such agreements run afoul of the antitrust laws.").

resulting profits.[39] Although some have argued that all settlements include some form of consideration between the parties,[40] it is the type of consideration that matters. Other types of consideration, an early entry date or 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. Indeed, Section 1 of the Sherman Act's primary purpose is to prevent such sharing.

Initially, the Commission's enforcement efforts in this area appeared significantly to deter anticompetitive behavior. In the seven years between 1992 and 1999, there were fourteen final settlements between brand-name manufacturers and the generic first-filer.[41] Eight of those settlements between brand-name and generic first-filers included a payment from the brand-name to the generic company in exchange for the generic company's agreement not to market its product. In 1999, it was reported that the Federal Trade Commission was investigating agreements involving such payments. The Commission is not aware of any pharmaceutical settlement between a brand-name manufacturer and a generic filer that included both a payment

[39] *Abbott Labs.*, Dkt. No. C-3945 (May 22, 2000) (consent order), complaint *available at* <http://www.ftc.gov/os/2000/05/c3945complaint.htm>; *Geneva Pharms., Inc.*, Dkt. No. C-3946 (May 22, 2000) (consent order), complaint *available at* <http://www.ftc.gov/os/2000/05/c3946complaint.htm>. The consent order in *Abbott Laboratories* is *available at* <http://www.ftc.gov/os/2000/03/abbot.do.htm>. The consent order in *Geneva Pharmaceuticals* is *available at* <http://www.ftc.gov/os/2000/03/genevad&o.htm>. The consent order in *Hoechst/Andrx* is *available at* <http://www.ftc.gov/os/2001/05/hoechstdo.htm>. *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. No. C-4076, *available at* <http://www.ftc.gov/os/caselist/c4076.htm>.

[40] *Schering*, 402 F.3d at 1074.

[41] 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>.

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 priced drugs.

C. The Threat Exclusion Payment Settlements Currently Pose to Consumers

Two recent court decisions, however, have taken a lenient view of exclusion payment settlements, essentially holding that such settlements are legal unless the patent was obtained by fraud or that the infringement suit itself was a sham.[44] In the *Schering* case,[45] the Eleventh Circuit vacated a decision by the Commission finding two patent settlements to be anticompetitive. 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").

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[42] *Id.*

[43] 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.

[44] *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).

[45] 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. 2, 2002) (consent order as American Home Products).

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.[46] The court began with the startling premise that "neither the rule of reason nor the *per se* analysis is appropriate" in an antitrust case involving patents.[47] The court purported to assess whether the agreement exceeded the exclusionary potential of Schering's patent, but in doing so, the court relied on the incorrect supposition that the patent provided Schering with "the legal right to exclude Upsher and ESI from the market until they proved either that the . . . patent was invalid or that their products . . . did not infringe Schering's patent,"[48] and noted that there was no allegation that the patent claim was a "sham."[49] In particular, the court ruled that a payment by the patentee, accompanied by an agreement by the challenger to defer entry, could not support an inference that the challenger

[46] *Schering*, 403 F.3d at 1058.

[47] *Id.* at 1065-66 (citing *Valley Drug Co.* v. *Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003).

[48] *Id.* at 1066-67.

[49] *Id.* at 1068.

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 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>.

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.

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[54] *See* Leibowitz, *supra* note 15.

[55] In 2002 alone, for example, Americans spent over $160 billion for prescription drugs. *See* The Henry J. Kaiser Family Foundation, *Prescription Drug Trends*, at 1 (Oct. 2004). Retail prescription prices have increased an average of 7.4% annually from 1993-2003, almost triple the average inflation rate of 2.5% during that same period. *Id.; see also* Centers for Medicare & Medicaid Services, *Highlights – National Health Expenditures*, 2003, at 1 (Jan. 1, 2005) (prescription drug spending rose 14.9% in 2002 and 10.7% in 2003). They are projected to increase at an even higher average rate over the next decade (10.7% annually between 2004 and 2013). *Prescription Drug Trends* at 2. For the past two decades, spending for prescription drugs has been the fastest growing component of the national healthcare spending. *Id*. at 1.

[56] *See* Drug Topics, *Top 200 Brand-Name Drugs by Retail Dollars in 2004* (Feb. 21, 2005), <http://www.drugtopics.com> (listing top-selling drugs). SEC filings and public statements by the manufacturers of the twenty top-selling drugs indicate that the following eleven drugs are subject to litigation by generic rivals: Lipitor, Effexor-XR, Plavix, Celebrex, Neurontin, Protonix, Norvasc, Zyprexa, OxyContin, Fosamax, and Risperdal. See, e.g., Pfizer Inc., Form 10-Q (Aug. 8, 2005); Wyeth, Form 10-Q (Aug. 5, 2005); Purdue Pharma, L.P., Press Release (June 8, 2005).

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 can be little doubt that, should those rulings become the controlling law, we will see more of these settlements and less generic competition. Already, we are seeing their return. The cost to consumers, insurers, employers, and the government will be tremendous. Although the Commission will continue to be vigilant in this area, litigating another case to conclusion will take years and provide little relief for those consumers harmed in the interim.

Prozac provides a telling example. In the course of the patent litigation, the generic company offered to drop its challenge if the brand-name company would pay it $200 million. The brand-name company refused because, in part, it believed such a settlement would violate the antitrust laws. The generic won the patent litigation, and consumers – and federal and state governments – saved over two billion dollars.[59] Under the legal standard articulated in the

[59] Stephanie Kirchgaessner & Patti Waldmeir, *Drug patent payoffs bring a scrutiny of side-effects,* FIN. TIMES UK, Apr. 25, 2006, 2006 WLNR 6910048.

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. § 355(j)(5)(B)(iv). Prior to the MMA's amendment of the Hatch-Waxman Act, a court decision holding a challenged patent to be invalid or not infringed would trigger the running of the 180-day exclusivity period, rather than triggering a forfeiture event. In the MMA, however, Congress did not change the *type* of court decision (*e.g.,* one holding that the patent is invalid or not infringed) that would forfeit the exclusivity.

[65] *See, e.g., Teva Pharms. USA, Inc., v. FDA*, 2005 WL 2692489 (D.D.C. Oct. 21, 2005); *Apotex, Inc. v. Pfizer Inc.*, 385 F. Supp.2d 187 (S.D.N.Y. 2005), *aff'd*, 159 Fed.Appx. 1013, 2005 U.S. App. LEXIS 28102 (Fed. Cir. 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).

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, Ivax's 180-day exclusivity blocked Teva, the subsequent generic applicant, from entering. After Pfizer refused to bring suit against Teva or to provide it with a covenant not to sue, Teva filed an action seeking a declaration of non-infringement and invalidity. The district court dismissed the case without prejudice for lack of controversy and the Federal Circuit affirmed.[68]

Quite recently, the situation worsened. In March of this year, the D.C. Circuit revisited the issue and held that its prior decision did not bind FDA to treat dismissal of a declaratory judgment action as a court decision sufficient to trigger the exclusivity period.[69] Following that

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[66] The MMA amendments to the Hatch-Waxman Act state that the district courts, "shall, to the extent consistent with the Constitution, have subject matter jurisdiction" over such declaratory judgment actions. MMA § 1101(d). Those same amendments specify that a court decision of invalidity or non-infringement in a declaratory judgment action triggers a forfeiture event. MMA § 1102(a)(2).

[67] *Teva Pharms. USA, Inc. v. Pfizer Inc.*, 395 F.3d 1324 (Fed. Cir.), *cert. denied*, 126 S. Ct. 473 (2005).

[68] On appeal to the Federal Circuit, the Commission filed an amicus in support of Teva's position that there was a case or controversy. 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). The Commission argued that declaratory judgment actions by generic applicants play a vital role in the Hatch-Waxman regime by permitting them to eliminate the bottlenecks that delay them from entering the market. The Commission further argued that Teva's action satisfied the Supreme Court's test for identifying an actual controversy under Article III of the Constitution.

[69] *Teva Pharms. USA, Inc. v. FDA*, 441 F.3d 1 (D.C. Cir. 2006).

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 meritorious patent challenges

[70] *Apotex, Inc. v. FDA*, 449 F.3d 1249 (D.C. Cir. 2006).

[71] *Teva Pharms. USA, Inc. v. FDA*, 182 F.3d 1003 (D.C. Cir. 1999).

[72] *Generic Drug Study* at x-xi.

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.

The case is pending in the U.S. District Court for the District of Columbia. The Commission is seeking appropriate injunctive relief. Thirty-four states and the District of Columbia also filed a case against Warner Chilcott and Barr Laboratories in the same court. In addition, plaintiffs representing both direct purchasers and indirect purchasers have filed suit, seeking treble damages. Discovery in the government enforcement actions closes at the end of this year. The court has not set a trial date.

IV. Agreements between Generic Manufacturers

Although agreements between generic entrants have attracted significantly less attention than those between brand-name and generic companies, they too can raise competitive concerns and may draw antitrust scrutiny, and the Commission challenges agreements between generic entrants when they are anticompetitive. As in the case of agreements between brand-name companies and generic applicants, the economic incentives to collude can be strong. Studies indicate that the first generic typically enters the market at 70 to 80 percent of the price of the corresponding brand[75] and rapidly secures as much as a two-thirds market share. The second generic typically enters at an even lower price and, like the first, rapidly secures market share.

[75] *Supra* page 6.

Collusion between the generic firms can thus be a means of preventing price erosion in the short term, though it may become substantially less feasible if subsequent ANDAs are approved and additional competitors enter the market.

In August 2004, the Commission entered a stipulated judgment with two generic drug manufacturers to resolve charges that they entered into a horizontal market allocation.[76] According to the Commission's complaint, Perrigo and Alpharma were the only two approved manufacturers of a generic over-the-counter product that is bioequivalent to Children's Motrin (store-brand Children's Motrin), a drug product to relieve pain and inflammation in children.[77] The Commission's complaint alleges that, prior to entering the challenged agreement, Perrigo and Alpharma aggressively competed to secure customers for their respective product launches in June 1998.

In April 1998, because of a change in the interpretation of the FDA's regulations, Alpharma became entitled to the 180-day exclusivity. Alpharma's exclusivity rights blocked the FDA from granting final approval to Perrigo's ANDA. The complaint alleges that Perrigo approached Alpharma about entering an agreement that would allow Perrigo to compete during the 180-day exclusivity period.

On June 16, 1998, Alpharma and Perrigo signed an agreement that eliminated the companies' vigorous competition to secure customers of store-brand children's liquid ibuprofen. Under the agreement, Alpharma relinquished its exclusivity but promised not to compete with its

[76] *FTC v. Perrigo and Alpharma*, Civ. Action No. 1:04CV01397 (D.D.C. Aug. 12, 2004); *see also*, *Biovail Corp.* and *Elan Corp.* PLC, Dkt. No. C-4057 (Aug. 15, 2002), consent order *available at* <http://www.ftc.gov/os/2002/08/biovaldo.pdf>.

[77] The Commission's complaint against Alpharma and Perrigo is *available at* <http://www.ftc.gov/os/caselist/0210197/040812comp0210197.pdf>.

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]

V. Authorized Generics

A new strategy in the pharmaceutical industry is the brand-name company's marketing of a so-called "authorized generic" during the 180-day exclusivity period. An authorized generic is chemically identical to a particular brand-name drug, which the brand-name manufacturer authorizes to be marketed as a generic version under the approval that the FDA granted for the brand-name drug. The brand-name manufacturer either sells the authorized generic itself through a subsidiary or licenses a generic firm to sell the authorized generic. The label typically differs for the brand-name drug and its authorized generic equivalent, but the drug product is exactly the same.

Issues have been raised regarding the impact of authorized generics and the 180-day exclusivity period. As discussed above, the first generic applicant to file an application with a

[78] The stipulated order against Alpharma is *available at* <http://www.ftc.gov/os/caselist/0210197/040812alpharma.pdf>. The stipulated order against Perrigo is *available at* <http://www.ftc.gov/os/caselist/0210197/040812perrigo.pdf>.

The Commission also is active in merger enforcement involving the pharmaceutical industry. In a consent order finalized in March 2006, the Commission ordered Teva Pharmaceutical Industries and IVAX Corporation to divest 15 generic pharmaceutical products before allowing Teva's $7.4 billion acquisition of IVAX to proceed. *Teva Pharm. Indus. Ltd., and IVAX Corp.*, File No. 051 0214, Dkt. No. C-4155 (Mar. 7, 2006), *available at* http://www.ftc.gov/os/caselist/0510214/0510214do060307.pdf.

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 marketing exclusivity period does not preclude competition from NDA-approved authorized generics, however.[79]

In recent years and with increasing frequency, brand-name drug manufacturers have begun to market authorized generic drugs at precisely the same time that a paragraph IV generic is beginning its period of 180-day marketing exclusivity. The likely effects of this practice on generic competition have been subject to some debate. In the short run, the entry of an authorized generic drug may benefit consumers by creating additional competition that lowers generic prices further than if only the paragraph IV generic were marketed. Many generic manufacturers assert, however, that in the long run consumers will be harmed because an expectation of competition from authorized generics will significantly decrease the incentives of generic manufacturers to pursue entry prior to patent expiration, especially for "non-blockbuster" drugs. For a generic manufacturer, the additional competition from an authorized generic may result in significantly less profit during the period of 180-day exclusivity than if the generic manufacturer had no authorized-generic competition during that time. Another concern is that, in the context of settlement, the brand-name manufacturer will promise to forego introducing an authorized generic in exchange for the first-filer agreeing to push back its entry date.

There is no publicly available, comprehensive economic study that assesses the likely short- and long-run effects of entry by authorized generics on generic competition. Thus, the

[79] *Teva Pharm. Indus. v. FDA*, 410 F.3d 51 (D.C. Cir. 2005).

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. In March of this year, the Commission issued a notice in the Federal Register describing the study and the types of information it would be seeking. The Commission received public comments through the end of June and is now reviewing those comments. After the Commission finishes reviewing those comments and makes any changes to the study, it will publish a second notice and seek OMB's approval for the subpoenas.

Conclusion

Thank you for this opportunity to share the Commission's views on the barriers to generic entry. The Commission looks forward to working closely with the Committee, as it has in the past, to ensure that competition in this critical sector of the economy remains vigorous.