Prepared Statement of
The Federal Trade Commission

Before the

Committee on Energy and Commerce
Subcommittee on Health
United States House of Representatives

Washington, D.C.

October 9, 2002

I. Introduction

Mr. Chairman, I am Timothy J. Muris, Chairman of the Federal Trade Commission. I am pleased to appear before the Subcommittee today to testify on behalf of the Commission regarding competition 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, which increases the prices of prescription drugs. Expenditures on pharmaceutical products continue to grow. The growth of prescription drug spending at retail outlets has "exceeded that of other health services by a wide margin, increasing 17.3 percent in 2000, the sixth consecutive year of double-digit growth."[2] Pharmaceutical expenditures are thus a concern not only to individual consumers, but also to government payers, private health plans, and employers.

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[3]

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[1] The 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 other Commissioner.

[2] K. Levit, C. Smith, C. Cowan, H. Lazenby & A. Martin, "Inflation Spurs Health Spending in 2000," 21:1 *Health Affairs* 179 (2002), citing data from the Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group, of which the authors are members.

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

("Hatch-Waxman" or "the Amendments") to the Food, Drug and Cosmetic Act ("FDC Act").[4] Hatch-Waxman established a regulatory framework that sought to balance incentives for continued innovation by research-based pharmaceutical companies and opportunities for market entry by generic drug manufacturers.[5] Without question, Hatch-Waxman has increased generic drug entry. The Congressional Budget Office estimates that, by purchasing generic equivalents of brand-name drugs, consumers saved $8-10 billion on retail purchases of prescription drugs in 1994 alone.[6] With patents set to expire within the next four years on brand-name drugs having combined U.S. sales of almost $20 billion,[7] the already substantial savings are likely to increase dramatically.

Yet, in spite of this remarkable record of success, the Amendments have also been subject to some abuse. Although many drug manufacturers – including both brand-name companies and generics – have acted in good faith, others have attempted to "game" the system, securing greater profits for themselves without providing a corresponding benefit to consumers. This testimony will describe the Commission's past and present response to these anticompetitive efforts.

The Commission has pursued numerous antitrust enforcement actions affecting both brand-name and generic drug manufacturers.[8] In addition, the Commission recently released a study entitled "Generic Drug Entry Prior to Patent Expiration" ("FTC Study"). That study examines whether the conduct that the FTC has challenged represented isolated instances or is more typical of business practices in the pharmaceutical industry, and whether certain provisions of Hatch-Waxman are susceptible to strategies to delay or deter consumer access to generic alternatives to brand-name drug products.[9] The Commission has gained expertise regarding competition in the pharmaceutical industry through other means as well. The Commission staff has conducted empirical analyses of competition in

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[4] 21 U.S.C. § 301 *et seq*.

[5] *See infra* note 14 and accompanying text. The Amendments also were intended to encourage pharmaceutical innovation through patent term extensions.

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

[7] *Id.* at 3.

[8] *See, e.g., Biovail Corp. and Elan Corp. PLC*, Dkt. No. C-4057 (Aug. 20, 2002) (consent order); *Biovail Corp*., Dkt. No. C-4060 (Oct. 2, 2002) (consent order); *FTC v. Mylan Laboratories, Inc. et al*., 62 F. Supp. 2d 25 (D.D.C. 1999); *Roche Holding Ltd.*, 125 F.T.C. 919 (1998) (consent order); *Ciba-Geigy Ltd.*, 123 F.T.C. 842 (1997) (consent order).

[9] 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>.

[10] 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>; David Reiffen and 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>.

[11] *FDA: Citizen Petition*, Comment of the Staff of the Bureau of Competition and of 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-Day Marketing Exclusivity for Generic Drugs*, Comment of the Staff of the Bureau of Competition and of 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).

[12] 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*

a <http://432.ftc.gov/os/2002/04/pharmtestimony.ht1/05j ET 17stm.5 233.25 0.753Tc 0.24f -0214 456 TD 0

[14] H.R. Rep. No. 98-857, pt. 1, at 14 (1984), *reprinted in*

[16] 21 U.S.C. § 355(b)(1).

[17] *Id.* at § 355(j)(7)(A).

[18] *Id.* at § 355(j)(2)(A)(iv

[24] *Id.* at § 355(j)(5)(B)(iii).

[25] *Id.* at § 355(j)(5)(B)(iv).

[26] *See Granutec, Inc. v. Shalala*, 139 F.3d 889, 891 (4th Cir. 1998).

[27] 21 U.S.C. § 355(j)(5)(B)(iv).

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III. Promoting Competition Through Antitrust Enforcement

A. First-Generation FTC Litigation: Settlements Between Brand-Name Companies and Generic Applicants

Studies of the pharmaceutical industry indicate that the first generic competitor typically enters the market at a significantly lower price than its brand-name counterpart, and gains substantial share from the brand-name product.[29] Subsequent generic entrants may enter at even lower prices and cause the earlier entrants to reduce their prices. These are precisely the procompetitive consumer benefits that the Amendments were meant to facilitate.

This competition substantially erodes the profits of brand-name pharmaceutical products. Although successful generic applicants are profitable, their gain is substantially less than the loss of profits by the brand-name product, because of the typical difference in prices between brand-name and generic products. As a result, both parties may have economic incentives to collude to delay generic entry. By blocking entry, the brand-name manufacturer may preserve monopoly profits. A portion of these profits, in turn, can be used to fund payments to the generic manufacturer to induce it to forgo the profits it could have realized by selling its product. Furthermore, by delaying the first generic's entry – and with it, the triggering of the 180 days of exclusivity – the brand-name and first-filing generic firms can sometimes forestall the entry of other generics.

The Commission's first-generation litigation focused on patent settlement agreements between brand-name companies and generic applicants that the Commission alleged had delayed the entry of one or more generic applicants. Of course, resolving patent infringement litigation through settlement can be efficient and procompetitive. Certain patent settlements between brand-name companies and generic applicants, however, drew the Commission's attention when it appeared that their terms may have reduced competition through abuses of the Hatch-Waxman regime.

Two leading cases illustrate the Commission's efforts in the area: *Abbott/Geneva* and *Hoechst/Andrx*. The first of these cases involved an agreement between Abbott Laboratories and Geneva Pharmaceuticals, Inc. relating to Abbott's brand-name drug Hytrin. The Commission's complaint alleged that Abbott paid Geneva approximately $4.5 million per month to delay the entry of its generic Hytrin product, potentially costing consumers hundreds of millions of dollars a year.[30] The

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[29] *See* CBO Study, *supra* note 6; *see generally* Reiffen and Ward, *supra* note 10.

[30] *Abbott Laboratories*, Dkt. No. C-3945 (May 22, 2000) (consent order), complaint *available at* <http://www.ftc.gov/os/2000/05/c3945complaint.htm>; *Geneva Pharmaceuticals, Inc.*, Dkt. No. C-3946 (May 22, 2000) (consent order), complaint *available at* <http://www.ftc.gov/os/2000/05/c3946complaint.htm>.

Geneva's generic Hytrin tablets, or (2) market entry by another generic Hytrin manufacturer. Geneva also allegedly agreed not to transfer its 180-day marketing exclusivity rights.

The second case involved an agreement between Hoechst Marion Roussel, Inc. and Andrx Corp. relating to Hoechst's brand-name drug Cardizem CD. The Commission's complaint alleged that Hoechst paid Andrx over $80 million, during the pendency of patent litigation, to refrain from entering the market with its generic Cardizem CD product.[31] As in the *Abbott/Geneva* case, the Commission's complaint also asserted that the agreement called for Andrx, as the first ANDA filer, to use its 180-day exclusivity rights to impede entry by other generic competitors.

The Commission resolved both cases by consent order.[32] The orders prohibit the respondent companies from entering into brand/generic agreements pursuant to which a generic company that is the first ANDA filer with respect to a particular drug agrees not to (1) enter the market with a non-infringing product, or (2) transfer its 180-day marketing exclusivity rights. In addition, the orders require the companies to obtain court approval for any agreements made in the context of an interim settlement of a patent infringement action that provide for payments to the generic to stay off the market, with advance notice to the Commission to allow it time to present its views to the court. The orders also require advance notice to the Commission before the respondents can enter into such agreements in non-litigation contexts.

Although each case turns on its own specific facts, these cases highlight the Commission's concern about settlements whose primary effect appears to be to delay generic entry, leading to less vigorous competition and higher prices for consumers. Of course, not all settlements are problematic. The Commission has not attempted to provide a comprehensive list of potentially objectionable settlement provisions. However, it is possible to identify from the Commission's reported matters a few provisions that, within the Hatch-Waxman context, have drawn antitrust scrutiny. These include:

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[31] *Hoechst Marion Roussel, Inc.*, Dkt. No. 9293 (May 8, 2001) (consent order), complaint *available at* <http://www.ftc.gov/os/2000/03/hoechstandrxcomplaint.htm>.

[32] 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.pdf>. In another matter, *Schering-Plough*, the Commission resolved all claims against one of three respondents, American Home Products ("AHP"), by issuing a final consent order. *Schering-Plough Corp.*, Dkt. No. 9297 (consent order as to AHP issued Apr. 2, 2002), *available at* <http://www.ftc.gov/os/2002/04/scheringplough_do.htm>.

The case against the other two respondents is in litigation before the Commission. *See Schering-Plough Corp., et al.*, Dkt. No. 9297 (Initial Decision) (July 2, 2002), *available at* <http://www.ftc.gov/os/2002/07/scheringinitialdecisionp1.pdf>.

(1) *Provisions that provide for "reverse" payments.* "Reverse" payments (*i.e.*, payments from the patent holder to the alleged infringer) may merit antitrust scrutiny because they may represent an anticompetitive division of monopoly profits.

(2) *Provisions that restrict the generic's ability to enter with non-infringing products.* Such provisions can extend the boundaries of the patent monopoly without providing any additional public disclosure or incentive to innovate, and therefore have the potential to run afoul of the principles of antitrust law.[33]

(3) *Provisions that restrict the generic's ability to assign or waive its 180-day marketing exclusivity rights.* Because a second ANDA filer may not enter the market until the first filer's 180-day period of marketing exclusivity has expired, restrictions on assignment or waiver of the exclusivity period can function as a bottleneck, potentially delaying subsequent generic entry for an extended period.[34]

B. Second-Generation FTC Actions: Improper Orange Book Listings

1. *In re Buspirone*

A principal focus of the Commission's second-generation activities has been improper Orange Book listings.[35] Unlike the settled cases discussed above, which involved alleged collusion between private parties, an improper Orange Book listing strategy involves unilateral abuse of the Hatch-Waxman process itself to restrain trade. Such conduct has raised *Noerr-Pennington* antitrust immunity issues, an area of longstanding Commission interest.

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[33] *Cf. Brulotte v. Thys Co.*, 379 U.S. 29, 33 (1964) (holding that "enlarg[ing] the monopoly of the patent" by collecting post-expiration royalties constitutes patent misuse).

[34] *But see* Leary, Part II, *supra* note 13, at 7 (arguing that agreements regarding waiver of 180-day exclusivity period may have no anticompetitive effect absent reverse payment).

[35] The Commission first raised concerns about the potential anticompetitive impact of improper Orange Book listings in *American Bioscience, Inc. v. Bristol-Myers Squibb Co., et al.*, Dkt. No. CV-00-08577 (C.D. Cal. Sept. 7, 2000). *See* Federal Trade Commission Brief as *amicus curiae*, *available at* <http://www.ftc.gov/os/2000/09/amicusbrief.pdf>. In that case, the parties sought court approval of a settlement containing a specific factual finding that Bristol-Myers was required to list American Bioscience's patent of Bristol-Myers's branded drug Taxol in the Orange Book. The Commission was concerned that the court's approval of the settlement would amount to a judicial finding that the patent met the statutory requirements for listing in the Orange Book and would prejudice parties who might later challenge the listing.

[36] The *Noerr* doctrine was first articulated as an interpretation of the Sherman Act in *Eastern R.R. Presidents Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961), and *United Mine Workers of America v. Pennington*, 381 U.S. 657 (1965).

[37] *See* 21 C.F.R. § 314.53(f);

filings with the FDA, Bristol-Myers caused that agency to list the patent in question in the Orange Book, thereby blocking generic competition with its BuSpar product, in violation of Section 2 of the Sherman Act.[39]

Bristol-Myers responded to these allegations by filing a motion to dismiss that raised, principally, a claim of *Noerr-Pennington* immunity. Given the importance of the issue to competition in the pharmaceutical industry, as well as to the Commission's ongoing investigations, the Commission filed an *amicus* brief opposing the motion to dismiss.[40] On February 14, 2002, the court issued an opinion denying Bristol-Myers's immunity claim and accepting most of the Commission's reasoning on the *Noerr-Pennington* issue.[41]

In light of the *Buspirone* decision, the *Noerr-Pennington* doctrine may not prove as large an obstacle to using the antitrust laws to remedy improper Orange Book filings as some may have anticipated. It is worth noting, and indeed emphasizing, that *Buspirone* does not mean that all improper Orange Book filings will give rise to antitrust liability. Any antitrust liability must be predicated on a clear showing of a violation of substantive antitrust law. *Buspirone* makes it clear, however, that Orange Book filings are not *immune* from those laws or *exempt* from their scrutiny.

2. *Biovail (Tiazac)*

Last week, the Commission announced that it had issued a consent order against Biovail Corporation,[42] settling charges that Biovail illegally acquired an exclusive patent license and wrongfully listed that patent in the Orange Book for the purpose of blocking generic competition to its brand-name drug Tiazac. This was the Commission's first enforcement action to remedy the effects of an allegedly improper, anticompetitive Orange Book listing.

Prior to the events giving rise to the Commission's complaint, Biovail already had triggered a 30-month stay of FDA final approval of Andrx's generic Tiazac product, by commencing an infringement lawsuit against Andrx. Andrx prevailed in the courts, however, so that the stay would have

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[39] 15 U.S.C. § 2.

[40] Memorandum of Law of *Amicus Curiae* Federal Trade Commission in Opposition to Defendant's Motion to Dismiss, *available at* <http://www.ftc.gov/os/2002/01/busparbrief.pdf>. (The Commission argued that Orange Book filings are not "petitioning activity" immune from antitrust scrutiny.)

[41] *In re Buspirone*, *supra* note 38

[42] *Biovail Corp.*, *supra* note 8.

[43] The Commission's complaint against Biovail is available at <http://www.ftc.gov/os/2002/04/biovailcomplaint.htm>.

(3) To ensure that there are no roadblocks in the way of generic competition for the substantial sales volume of brand-name drug products coming off patent in the next several years.[51] Brand-name companies seeking to protect the sales of brand-name drugs may have an incentive and ability to enter into agreements with would-be generic competitors, or engage in other types of activities, that would slow or thwart the entry of competing generic drug products.

In April 2001, the Commission received clearance from the Office of Management and Budget ("OMB") to conduct the study.[52] The Commission issued nearly 80 special orders – pursuant to Section 6(b) of the FTC Act[53] – to brand-name companies and to generic drug manufacturers, seeking information about certain practices that were outlined in the Federal Register notices that preceded OMB clearance to pursue the study.[54] The Commission staff focused the special orders on brand-name drug products that were the subject of Paragraph IV certifications filed by generic applicants. Only those NDAs in which a generic applicant notified a brand-name company with a Paragraph IV certification after January 1, 1992, and prior to January 1, 2001, were included in the FTC Study. The selection criteria resulted in 104 drug products, as represented by NDAs filed with the FDA, within the scope of the study and included so-called "blockbuster" drugs such as Capoten, Cardizem CD, Cipro, Claritin, Lupron Depot, Neurontin, Paxil, Pepcid, Pravachol, Prilosec, Procardia XL, Prozac, Vasotec, Xanax, Zantac, Zocor, Zoloft, and Zyprexa.

Responses from the 28 brand-name companies and nearly 50 generic applicants generally were completed by the end of 2001. The Commission staff compiled the information received to provide a

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[51] National Institute for Health Care Management, "Prescription Drugs and Intellectual Property Protection" at 3 (Aug. 2000).

[52] The Commission was required to obtain OMB clearance before it could begin the study because the number of special orders to be sent triggered the requirements of the Paperwork Reduction Act of 1995, 44 U.S.C. Ch. 35, as amended.

[53] 15 U.S.C. § 46(b).

[54] *See* 65 Fed. Reg. 61334 (Oct. 17, 2000); 66 Fed. Reg. 12512 (Feb. 27, 2001).

[55] There were three additional suits that had other resolutions.

data suggest that cases involving multiple patents take longer than those involving fewer patents. As of June 1, 2002, for six out of the seven cases that were pending for more than 30 months before a decision from a district court, the brand-name company has alleged infringement of three or more patents.

By the timely listing of additional patents in the Orange Book after a generic applicant has filed its ANDA ("later-issued patents"), brand-name companies can obtain additional 30-month stays of FDA approval of the generic applicant's ANDA. In eight instances, brand-name companies have listed later-issued patents in the Orange Book after an ANDA has been filed for the drug product. For those eight drug products, the additional delay of FDA approval (beyond the first 30 months) ranged from four to 40 months. In all of the four cases so far with a court decision on the validity or infringement of a later-issued patent, the patent has been found either invalid or not infringed by the ANDA.

Moreover, several of the later-issued patents in the Orange Book raise questions about whether the FDA's patent listing requirements have been met. For example, several of the later-issued patents do not appear to claim the approved drug product or an approved use of the drug. The FTC Study describes three categories of patents that raise significant listability questions – *i.e.*, issues concerning whether the listed patents fall within the statutorily defined class. These categories include (1) patents that may not be considered to claim the drug formulation or method of use approved through the NDA; (2) product-by-process patents that claim a drug product produced by a specific process; and (3) patents that may constitute double-patenting because they claim subject matter that is obvious in view of the claims of another patent obtained by the same person.

D. Recommendations: The 30-Month Stay Provision

To reduce the possibility of abuse of the 30-month stay provision, the Commission recommended in its study that only one 30-month stay be permitted per drug product per ANDA to resolve infringement disputes over patents listed in the Orange Book prior to the filing date of the generic applicant's ANDA. This should eliminate most of the potential for improper Orange Book listings to generate unwarranted 30-month stays. One 30-month stay period alone has historically approximated the time necessary for FDA review and approval of the generic applicant's ANDA[56] or a

[56] FDA approval of ANDAs submitted by first generic applicants who were not sued by the brand-name company took, on average, 25.5 months from the ANDA filing date.

the FDA review the propriety of patent listings.[57] The lack of a mechanism to review or delist patents may have real-world consequences. For example, the Commission is aware of at least a few instances in which a 30-month stay was generated solely by a patent that raised legitimate listability questions. One proposal to deal with this problem has been to establish an administrative procedure through which generic applicants could obtain substantive FDA review of listability. At a minimum, it appears useful for the FDA to clarify its listing requirements as the FTC Study suggests. Another remedy that may warrant consideration would be to permit a generic applicant to raise listability issues as a counterclaim

[57] *See supra* note 37 and accompanying text.

[58] One of these agreements is subject to litigation currently pending at the FTC. *See Schering-Plough Corp., et al.*, Dkt. No. 9297 (Initial Decision) (July 2, 2002) *supra* note 32.

[59] For three out of the four interim agreements, *see Abbott Laboratories*, Dkt. No. C-3945 (May 22, 2000) (consent order) (relating to two drug products, Hytrin tablets and Hytrin capsules); *Geneva Pharmaceuticals, Inc*., Dkt. No. C-3946 (May 22, 2000) (consent order); and *Hoechst Marion Roussel, Inc*., Dkt. No. 9293 (May 8, 2001) (consent order), all *supra* note 32.

(2) To clarify that the decision of any court on the same patent being litigated by the first generic applicant constitutes a "court decision" sufficient to start the running of the 180-day exclusivity; and

(3) To clarify that a court decision dismissing a declaratory judgment action for lack of subject matter jurisdiction constitutes a "court decision" sufficient to trigger the 180-day exclusivity.

V. Conclusion

Thank you for this opportunity to share the Commission's views on competition in the pharmaceutical industry. As you can see, the Commission has been and will continue to be very active in protecting consumers from anticompetitive practices that inflate drug prices. The Commission looks forward to working closely with the Subcommittee, as it has in the past, to ensure that competition in this critical sector of the economy remains vigorous. In keeping with this objective, the Commission will likewise endeavor to ensure that the careful Hatch-Waxman balance – between promoting innovation and speeding generic entry – is scrupulously maintained.