PREPARED STATEMENT OF
THE FEDERAL TRADE COMMISSION ON

"Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements"

Before the

COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE

Washington, D.C.

May 24, 2001

Mr. Chairman and Members of the Senate Judiciary Committee, I am Molly Boast, Director of the Federal Trade Commission's Bureau of Competition. I am pleased to appear before you to present the Federal Trade Commission's ("Commission" or "FTC") testimony on our activities involving the pharmaceutical industry in general and patent settlement cases in particular.[(1)] The benefits to consumers from generic competition are dramatic. A Congressional Budget Office ("CBO") report estimates that consumers saved $8 billion to $10 billion on prescription drugs at retail pharmacies in 1994 by purchasing generic drugs instead of brand name products.[(2)] The CBO also noted that the 1984 Hatch-Waxman Act had "greatly increased the number of drugs that experience generic competition and, thus, contributed to an increase in the supply of generic drugs."[(3)]

The surging cost of prescription drugs is a pressing national issue. Recent reports suggest expenditures for retail outpatient prescription drugs rose in the year 2000 to $131.9 billion, an 18.8% increase from the previous year.[(4)] This dramatic increase has helped focus attention on the need to ensure competition in pharmaceutical markets. The Commission is encouraged that Congress, and particularly the members of this Committee, have shown a strong interest in this issue, both in Chairman Hatch's decision to convene this hearing and in recent bills introduced by Senators Leahy, Schumer, Kohl, Durbin and McCain, among others.[(5)]

The Commission has gained substantial recent experience concerning competition in the pharmaceutical industry from its antitrust enforcement activities affecting both the branded and generic drug industries.[(6)] In 1999, the staff of the FTC's Bureau of Economics released a report on competition issues in the pharmaceutical industry.[(7)] In addition, the Commission's staff has submitted comments over the past two years in connection with the Food and Drug Administration's ("FDA") regulation of generic drugs,[(8)] and has recently filed a Citizen Petition with the FDA seeking clarification of certain issues relating to patent listings with the FDA.[(9)]

The Commission's recent activity includes three challenges to alleged anticompetitive

agreements between pioneer pharmaceutical manufacturers and generic manufacturers. These actions address agreements reached in the context of the 1984 Hatch-Waxman Act. The Act was crafted to balance the legitimate but different interests of the pioneer and generic manufacturers. Recently, however, the Commission has observed conduct suggesting that some firms may be exploiting the statutory and regulatory scheme by reaching agreements to delay the introduction of generic drugs to the market. Pioneer firms have strong incentives to delay generic entry. Delaying or preventing the generic entry that Hatch-Waxman seeks to promote could preserve millions of dollars of ongoing profits for pioneer drug companies. The typical steep price decline upon generic entry results in an enormous drop in market share and profits for the pioneer firm. The Commission has reason to believe the agreements it has challenged were designed to forestall that result.

The complexity of the strategies prompted by the operation of the Hatch-Waxman Act and the regulatory framework for introducing new drugs to the market cannot be fully comprehended through any particular enforcement action. Accordingly, the Commission is undertaking a study, pursuant to its authority under Section 6(b) of the FTC Act, of pharmaceutical industry practices relating to the Hatch-Waxman Act. The study will examine:

> the extent to which agreements between brand-name pharmaceutical manufacturers and generic drug firms may have delayed generic competition;
> the operation of provisions in the Hatch-Waxman Act that award a 180-day period of market exclusivity to a generic firm;
> the impact of provisions in the Act on the listing of patents by brand-name pharmaceutical companies in the FDA "Orange Book," and of provisions that trigger a stay on FDA approval of a proposed generic drug; and
> the use of the FDA's Citizen Petition process by brand-name drug companies to oppose potential generic entrants.

The Commission hopes that this study will provide valuable information to Congress as it considers possible reform of the Hatch-Waxman Act.

This testimony provides an overview of the significance of generic drugs in the pharmaceutical industry and a brief description of the statutory and regulatory schemes governing generic drugs, and then turns to a discussion of recent FTC enforcement actions challenging settlement agreements between certain branded pharmaceutical manufacturers and their generic competitors. The testimony also briefly describes the generic drug study currently underway at the agency.

I. BACKGROUND

A. *Significance of Generic Drugs*

Generic drugs contain active ingredients that are the same as their branded counterparts, but typically are sold at substantial discounts from the branded price. Generic drugs

account for approximately 40% of all prescriptions, but for only about 9% of total prescription drug expenditures.[(10)] The first generic manufacturer to enter a market typically charges 70% to 80% of the brand manufacturer's price. As additional generic versions of the same drug enter the market, the price continues to drop, sometimes decreasing to a level of 50% or less of the brand price.[(11)]

Within the next 5 years, patents on brand-name drugs with combined U.S. sales approaching $20 billion will expire.[(12)] This provides an enormous opportunity for the generic drug industry. Presumably the brand-name industry views the situation in quite the opposite way. The successful entry of generic versions of these drugs should affect dramatically the amount consumers pay for the drugs they need.

B. ***Statutory and Regulatory Scheme***

In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, known as the Hatch-Waxman Act,[(13)] to accomplish a delicate balancing of two policy goals:[(14)] (1) to facilitate and encourage the introduction of generic drugs, and (2) to protect the incentives of brand-name drug companies to invest in new drug development.[(15)]

The Hatch-Waxman Act permits pharmaceutical manufacturers to seek FDA approval of generic versions of previously approved drug products[(16)] by submitting an "abbreviated new drug application" ("ANDA").[(17)] Under the abbreviated procedure, an ANDA applicant that demonstrates bioequivalency with a pioneer drug may rely upon FDA findings of safety and efficacy for the relevant drug.[(18)] The Food, Drug and Cosmetics Act ("FDCA")[(19)] requires the ANDA applicant to provide a certification showing one of the following for each patent that "claims the listed drug" or the method of the drug's use for which patent information is required to be filed:[(20)]

> (I) that the required patent information relating to such patent has not been filed;
> (II) that such patent has expired;
> (III) that the patent will expire on a particular date; or
> (IV) that such patent is invalid or will not be infringed by the drug for which

FDCA allows the ANDA to include a statement (commonly referred to as a "Section viii Statement") that the ANDA does not seek approval for such a use.[(24)]

The filing of a paragraph IV certification triggers an important process that reflects the Hatch-Waxman Act's core purpose of encouraging generic competition while protecting pioneer companies' incentives to innovate. If an action for patent infringement is brought against the ANDA applicant within 45 days of the date the patent owner receives notice of the paragraph IV certification,[(25)] final approval of the ANDA cannot become effective until 30 months from the receipt of notice. That timing cannot be changed unless a final court decision is reached earlier in the patent case or the patent court otherwise orders a longer or shorter period.[(26)]

The Hatch-Waxman Act also provides an incentive for generic drug companies to bear the cost of patent litigation that may arise when they challenge allegedly invalid patents or design products they contend are non-infringing. The Act grants to the first ANDA filer a 180-day period during which it has the exclusive right to market a generic version of the brand name drug. The 180-day exclusivity period begins running on the earlier of (1) the date the first ANDA filer begins commercial marketing of its generic drug, or (2) the date a court decides that the patent addressed by the paragraph IV certification is invalid or not infringed. No other generic manufacturer may obtain final FDA approval to market its

a continuing focus of Commission resources, the Commission also is concerned about maintaining competition among generic firms. In *FTC v. Mylan Laboratories, Inc.*, the Commission, along with several states, sued Mylan Laboratories, one of the nation's largest generic pharmaceutical manufacturers, charging Mylan and other companies with monopolization, attempted monopolization, and conspiracy in connection with agreements to eliminate much of Mylan's competition by tying up supplies of the key active ingredients for two widely-prescribed drugs - lorazepam and clorazepate - used by millions of patients to treat anxiety.[(38)]

The FTC's complaint charged that Mylan's agreements allowed it to impose enormous price increases - over 25 times the initial price level for one drug, and more than 30 times for the other. For example, in January 1998, Mylan raised the wholesale price of clorazepate from $11.36 to approximately $377.00 per bottle of 500 tablets, and in March 1998, the wholesale price of lorazepam went from $7.30 for a bottle of 500 tablets to approximately $190.00. The price increases resulting from Mylan's agreements allegedly cost American consumers more than $120 million in excess charges.

The Commission filed this case in federal court under Section 13(b) of the FTC Act seeking injunctive and other equitable relief, including disgorgement of ill-gotten profits. In July 1999, the U.S. District Court for the District of Columbia upheld the FTC's authority to seek disgorgement and restitution for antitrust violations. In settlement of the Commission's case Mylan agreed to pay $100 million for disbursement to qualified purchasers of lorazepam and clorazepate.[(39)] On April 27, 2001, the federal court granted preliminary approval to a distribution plan for these funds.[(40)]

B. ***FTC Pharmaceutical Industry Study***

In light of the serious questions raised by its various generic drug investigations, in October 2000 the Commission proposed a focused industry-wide study of generic drug

may request the NDA holder to confirm the correctness of the patent information and listing. Unless the patent information is withdrawn or amended by the NDA holder, however, the FDA will not change the patent information listed in the Orange Book. *Id*.

25. 21 U.S.C. 355(j)(5)(B)(iii); 21 C.F.R. 314.107(f)(2). The statute also states that "[u]ntil the expiration of forty-five days from the date the notice made under paragraph (2)(B)(i) is received, no action may be brought under section 2201 of Title 28, for a declaratory judgment with respect to the patent." *Id.*

26. 21 U.S.C. 355(j)(5)(B)(iii). A court may shorten or lengthen the period if either party to the action fails to reasonably cooperate in expediting the case. *Id.*

27. 21 U.S.C. 355(j)(5)(B)(iv).

28. It is important to note that the first two cases discussed below, *Abbott-Geneva* and *Hoechst-Andrx*, were resolved by settlement, while the third, *Schering-Upsher-ESI Lederle*, is pending administrative trial. Thus, although the Commission found reason to believe that there was a violation of the antitrust laws in each

with Commissioner Thomas Leary dissenting in part and concurring in part.

40. *FTC v. Mylan, et al.*, CV 1:98CV03114(TFH), Order Preliminarily Approving Proposed Settlements (Apr. 27, 2001).

41. The Commission obtained OMB clearance because the number of Special Orders being sent triggered the requirements of the Paperwork Reduction Act of 1995, 44 U.S.C. Ch. 35, as amended.

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

43. Commission staff commented to the FDA on the 180-exclusivity issue in connection with a proposed rulemaking. *See* Comment of the Federal Trade Commission Staff, *In the Matter of 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications*, Docket No. 85N-0214 (Nov. 4, 1999), <http://www.ftc.gov/be/v990016.htm>.

44. *See, e.g., Mylan v. Bristol-Myers Squibb*, Civ. Action 00CV2876 (D.D.C. Mar. 13, 2001) (case alleging last-minute Orange Book listing by Bristol-Myers Squibb ("BMS") of another patent in connection with BuSpar, a leading anti-anxiety drug produced by BMS, just as BMS's patent exclusivity for BuSpar was about to expire; the propriety of that listing and the issue of whether the potential generic competitor can challenge the listing are currently the subject of this litigation).