

**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 approval is being sought.

The Commission's recent enforcement actions involve agreements between pioneer manufacturers and ANDA applicants that filed a certification under paragraph IV of these provisions.⁽²¹⁾ A certification under paragraph IV requires the ANDA applicant to give notice of the ANDA filing to the patent owner and the firm that obtained the new drug approval for the listed drug (typically the pioneer manufacturer). This notice must include a detailed statement of the factual and legal basis for the ANDA applicant's opinion that the patent is not valid, is unenforceable, or will not be infringed.⁽²²⁾ An applicant whose ANDA is pending when additional patents are listed must certify to the new patents, unless the patent owner or NDA holder fails to submit the additional patents within 30 days after their issuance by the Patent and Trademark Office.⁽²³⁾ In addition, if the ANDA applicant does not seek approval for a use of the drug claimed in a listed patent, the

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 version of the relevant product until the first filer's 180-day exclusivity period has expired.⁽²⁷⁾

II. FTC CASES CHALLENGING SETTLEMENTS

The FTC has taken a lead role in promoting competition in the pharmaceutical industry and has been significantly involved in antitrust cases arising in the context of the Hatch-Waxman regulatory framework. In three recent cases, the Commission challenged agreements between brand-name and generic drug companies that allegedly delayed or were intended to delay generic drug competition in order to maintain higher prices.⁽²⁸⁾ In each case the Commission alleged that as part of a settlement agreement, the branded firm made payments to the generic firm in exchange for delayed entry. The Commission further alleged in each case that the agreements in question also delayed or were intended to delay entry of generic manufacturers other than those to which payments were made.

A. Abbott/Geneva

In May 2000, the Commission issued a complaint and consent order against Abbott Laboratories and Geneva Pharmaceuticals, Inc.⁽²⁹⁾ The complaint charged that Abbott paid Geneva approximately \$4.5 million per month to keep Geneva's generic version of Abbott's proprietary drug (Hytrin) off the U.S. market, potentially costing consumers hundreds of millions of dollars a year. Hytrin is used to treat hypertension and benign prostatic hyperplasia (BPH or enlarged prostate) - chronic conditions that affect millions of Americans each year. BPH alone afflicts at least 50% of men over 60. In 1998, Abbott's sales of Hytrin amounted to \$542 million (over 8 million prescriptions) in the United States. Abbott projected that Geneva's entry with a generic version of Hytrin

would eliminate over \$185 million in Hytrin sales in just six months.⁽³⁰⁾

According to the complaint, Geneva agreed not to enter the market with any generic version of Hytrin, even if it were non-infringing, until the earlier of: (1) the final resolution of the patent infringement litigation involving Geneva's generic version of Hytrin tablets, including review through the U.S. Supreme Court; or (2) entry of another generic Hytrin product. Geneva also agreed not to transfer, assign, or relinquish its 180-day exclusivity right. These provisions ensured that no other company's generic version of Hytrin could obtain FDA approval and enter the market during the term of the agreement, because Geneva's agreement not to launch its product meant the 180-day exclusivity period would not begin to run.⁽³¹⁾

Under the terms of the Commission's consent order, Abbott and Geneva are barred from entering into agreements pursuant to which a first-filing generic company agrees with a manufacturer of a branded drug that the generic company will not (1) give up or transfer its exclusivity or (2) bring a non-infringing drug to market. In addition, agreements to which Abbott or Geneva is a party that involve payments to a generic company to stay off the market must be approved by the court when undertaken during the pendency of patent litigation (with prior notice to the Commission), and the companies are required to give the Commission 30 days' notice before entering into such agreements in other settings. In addition, Geneva was required to waive its right to a 180-day exclusivity period for its generic version of Hytrin tablets, so other generic tablets could immediately enter the market.

B. Hoechst Marion Roussel/Andrx

In a second matter, the Commission charged that Hoechst Marion Roussel (now Aventis), the maker of Cardizem CD, a widely prescribed drug for treatment of hypertension and angina, paid Andrx Corporation over \$80 million to refrain, during the pendency of patent litigation, from bringing to market any competing generic drug, without regard to whether it was allegedly infringing.⁽³²⁾ Hoechst's Cardizem sales in 1998 exceeded \$700 million, and over 12 million prescriptions were sold. Hoechst forecasted internally that a generic version of Cardizem CD, sold at 70% of the brand price, would capture approximately 40% of Cardizem CD sales within the first year.

The complaint further alleged that Andrx's agreement not to market its product was intended to delay the entry of other generic drug competitors, thereby denying consumers access to lower priced generic drugs.⁽³³⁾ As in *Abbott*, the ability to preclude other generic competitors flows from the exclusive 180-day marketing right granted to the first generic to file an ANDA.⁽³⁴⁾ This case was settled before trial, and the Commission issued final consent orders on May 11, 2001. The orders entered against Hoechst and Andrx contain relief similar to that in the *Abbott* and *Geneva* orders.

C. Schering-Plough/Upsher-Smith/ESI Lederle

In its most recent case, the Commission issued an administrative complaint on March 30,

2001, against Schering-Plough Corporation and two generic pharmaceutical manufacturers - Upsher-Smith Laboratories, the first ANDA filer, and ESI Lederle, Inc. (a division of American Home Products Corp.). The complaint charges the three companies with entering into agreements aimed at delaying the entry of generic versions of Schering's product - K-Dur 20, a widely prescribed potassium chloride supplement used to treat patients with insufficient levels of potassium, a condition that can lead to serious cardiac problems.⁽³⁵⁾ Schering's K-Dur products (in two different strengths) had 1998 sales of over \$220 million. In 1997, Schering allegedly projected that the first year of low priced generic competition would reduce branded K-Dur 20's sales by over \$30 million.⁽³⁶⁾

The Commission alleged in its complaint that Schering and Upsher-Smith settled a patent infringement lawsuit by agreeing that Schering would pay Upsher-Smith not to enter the market. Upsher-Smith allegedly agreed not to sell either the product for which it had filed an ANDA, or any other generic version of Schering's K-Dur 20 (regardless of whether Schering had any basis to claim infringement), until September 2001.⁽³⁷⁾ In exchange, Schering paid Upsher-Smith \$60 million. Upsher-Smith also licensed five of its products to Schering but, according to the complaint, the \$60 million had little relation to the value of those products. It is alleged that Schering's agreement with Upsher-Smith created a bottleneck by preventing other potential generic competitors from entering the market because of the 180-day exclusivity granted to Upsher-Smith as the first generic company to file an ANDA.

The Commission complaint alleges that Schering entered into a second agreement with ESI Lederle to delay further the marketing of a generic version of K-Dur-20. Schering and ESI Lederle allegedly settled a patent infringement case with an agreement by which ESI Lederle, in exchange for payments from Schering, promised not to market any generic version of K-Dur 20 until January 2004, and thereafter to market only one generic version until September 2006 (when Schering's patent expires). In addition, ESI Lederle allegedly agreed that it would not help any other firm with studies in preparation for an ANDA for a generic version of K-Dur 20 until September 2006. The Commission complaint alleges that Schering agreed to pay \$30 million in exchange for these agreements and for licenses to two ESI Lederle products that the complaint alleges were not as valuable as the \$15 million designated for them.

The Commission complaint alleges that the Schering/Upsher and the Schering/ESI Lederle agreements are unreasonable restraints of trade and that the companies conspired to monopolize the market for potassium chloride supplements, in violation of Section 5 of the FTC Act. In addition, the complaint charges Schering with unlawful acts of monopolization. The case is now in a pretrial stage before an Administrative Law Judge.

III. OTHER COMMISSION ACTIONS

A. *FTC v. Mylan*

Although competition between manufacturers of branded and generic drugs is critical and

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 competition. This study is designed to examine more closely the business relationships between brand-name and generic drug manufacturers in order to better understand the extent to which the process of bringing new low-cost generic alternatives to the marketplace -- and into the hands of consumers -- is being impeded in ways that are anticompetitive. The study will provide a more complete picture of how generic drug competition has developed under the Hatch-Waxman Act, including whether agreements between brand-name pharmaceutical manufacturers and generic drug firms of the type challenged by the FTC are isolated instances or are more typical of industry practices. In addition, the Commission will examine whether particular provisions of the Hatch-Waxman Act have operated as intended -- to balance the legitimate interests of pharmaceutical companies in protecting their intellectual property and the legitimate interests of generic companies in providing competition -- or whether some provisions unintentionally have enabled anticompetitive strategies that delay or deter the entry of generic drugs into the market.

In April, the Commission received clearance from the Office of Management and Budget to conduct the study.⁽⁴¹⁾ The Commission has since issued 75 special orders to brand-

name pharmaceutical manufacturers and generic drug companies to provide the Commission with information about certain practices that were outlined in the Federal Register notices that preceded OMB clearance to pursue the study.⁽⁴²⁾ The Commission staff focused each special order on specific name-brand drug products that were the subject of paragraph IV certifications filed by potential generic competitors, and, for generic companies, on specific drug products for which they had filed an ANDA containing a paragraph IV certification. Responses from the companies are expected by June 25, 2001.

The Commission plans to compile the information received to provide a factual description of how the 180-day marketing exclusivity and 30-month stay provisions of the Hatch-Waxman Act have influenced the development of generic drug competition. For example, the Commission staff anticipates analyzing how often the 180-day marketing exclusivity provision has been used, how it has been triggered (by commercial marketing or court orders), the frequency with which innovator companies initiate patent litigation, and the frequency with which patent litigation has been settled or litigated to a final court decision. The Commission will use the agreements provided, along with underlying documents related to the reasons for executing the agreement, to examine whether it appears that agreements between innovator and generic companies (or between generic companies) may have operated to delay generic drug competition.⁽⁴³⁾

In addition, the study will provide evidence about innovator companies' patent listings in the Orange Book, the timeliness of the listings, and how frequently challenges are made to those listings by generic companies. Some have raised concerns that manufacturers of pioneer drugs are listing additional patents shortly before the expiration of previously listed patents, thereby starting procedures through which branded manufacturers can sue ANDA applicants who have filed a paragraph IV certification and can thus invoke the automatic 30-month stay for generic approval under the Hatch-Waxman Act.⁽⁴⁴⁾

The study also will provide information about innovator companies' use of Citizen Petitions in connection with generic versions of their brand-name drug products. In March 2000, FTC staff provided some preliminary input to FDA in connection with its proposed rule concerning Citizen Petitions. The proposed rules are aimed at improving the efficiency of FDA's Citizen Petition process and narrowing the types of actions that can be requested of FDA through the Citizen Petition process.⁽⁴⁵⁾ Concerns have been raised about the potential for abuse, for example, by companies filing petitions to keep a rival drug product or medical device off the market for as long as possible. The FTC is concerned about the potential for abusing the regulatory process, but recognizes that some of this activity may implicate First Amendment rights that may present a barrier to antitrust enforcement.⁽⁴⁶⁾ Thus, the staff supported the FDA's attempt to maintain the Citizen Petition process for legitimate purposes, while limiting the ability of firms to use the process solely to hinder competitors.⁽⁴⁹⁾

Finally, the study will examine whether the size of a drug product's sales influences the use of strategies to delay generic competition. The Commission expects to complete the

study by the end of 2001.

IV. CONCLUSION

The Commission appreciates the opportunity to share with the Committee its observations about the pharmaceutical industry. The Commission looks forward to working with the Committee to address problems that may arise in this important sector of the U.S. economy. Thank you.

Endnotes:

1. The views expressed in this statement reflect the views of the Commission. My oral statement and responses to questions are my own and are not necessarily those of the Commission or any individual Commissioner.
2. Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (July 1998) <<http://www.cbo.gov>>.
3. *Id.*
4. See National Institute for Health Care Management Research and Educational Foundation, "Prescription Drug Expenditures in 2000: The Upward Trend Continues" at 2 (May 2001) (available at www.nihcm.org).
5. See S. 754, "Drug Competition Act of 2001," introduced by Senators Leahy, Kohl, Schumer, and Durbin; S. 812, "Greater Access to Affordable Pharmaceuticals Act of 2001," introduced by Senators Schumer and McCain.
6. *E.g.*, *Federal Trade Commission v. Mylan Laboratories, Inc. et al.*, 1999-2 Trade Cas. (CCH) ¶72,573 (D.D.C. 1999); *Roche Holding Ltd.*, C-3809 (February 25, 1998) (consent order); *Ciba-Geigy, Ltd.*, 123 F.T.C. 842 (1997) (consent order); *Hoechst AG*, 120 F.T.C. 1010 (1995) (consent order). For a discussion of recent FTC pharmaceutical enforcement actions, see FTC Antitrust Actions Involving Pharmaceutical Services and Products, <<http://www.ftc.gov/bc/rxupdate>>; see also David A. Balto & James Mongoven, Antitrust Enforcement in Pharmaceutical Industry Mergers, 54 *Food & Drug Law Journal* 255 (1999).
7. Staff of the Federal Trade Commission, "The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change" (March 1999) <<http://www.ftc.gov/reports/pharmaceutical/drugexsum.htm>>. The report reviews significant informational, institutional, and structural changes that have influenced price and non-price competition strategies of brand-name pharmaceutical companies, particularly during the last 15 years. The study considers the possible antitrust implications of these changes by examining alternative anticompetitive and procompetitive explanations for the pricing, vertical contracting, and vertical and horizontal consolidation strategies that have emerged in this environment of change.
8. Comment of the Federal Trade Commission Staff, *In the Matter of Citizen Petitions; Actions That Can be Requested by Petition; Denials, Withdrawals, and Referrals for Other Administrative Action*, Docket No. 99N-2497 (Mar. 2, 2000), <<http://www.ftc.gov/be/v000005.pdf>>; 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>>.
9. The Bureau of Competition and Policy Planning Staff of the Federal Trade Commission's Citizen Petition

to the Commissioner of Food and Drugs pursuant to 21 C.F.R. §§ 10.25(a) and 10.30 concerning certain issues relating to patent listings in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") and requesting that the FDA clarify these issues via industry guidance or other means that the FDA considers appropriate (May 16, 2001).

10. See National Institute for Health Care Management Research and Educational Foundation, "Prescription Drug Expenditures in 2000: The Upward Trend Continues" at 2 (May 2001).

11. Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (July 1998), <<http://www.cbo.gov>>.

12. *Id.* at 3. See also Amy Barrett, "Crunch Time in Pill Land," *Business Week* 52 (Nov. 22, 1999).

13. Pub. L. No. 98-417, 98 Stat. 1585 (1984), *codified at* 21 U.S.C. 355, 360cc, and 35 U.S.C. 156, 271, 282.

14. See *Tri-Bio Labs, Inc. v. United States*, 836 F.2d 135, 139 (3d Cir. 1987), *cert. denied*, 488 U.S. 818 (1988). See also *Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 15 USPQ2d 1121 (1990); and *Bristol-Myers Squibb Company v. Royce Laboratories, Inc.*, 69 F.3d 1130, 1132, 1133-34, 36 USPQ2d 1641 (Fed. Cir. 1995).

15. See H.R. Rep. No. 98-857(I), at 14-15 (1984), reprinted in 1984 U.S.C.C.A.N. 2647-48 (stating that the purposes of the Hatch-Waxman Act are "to make available more low cost generic drugs [and] to create a new incentive for increased expenditures for research and development of certain products which are subject to pre-market approval").

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

17. The relevant statutory and regulatory framework for the ANDA approval process has been described in *Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. at 676-78; *Mova Pharmaceutical Corp. v. Shalala*, 140 F.3d 1060, 1063-65, 46 USPQ2d 1385 (D.C. Cir. 1998); and *Bristol-Myers Squibb Company v. Royce Laboratories, Inc.*, 69 F.3d at 1131-32, 1135.

18. 21 U.S.C. 355(j)(2).

19. 21 U.S.C. 355(a), (b).

20. 21 U.S.C. 355(j)(2)(A)(vii). By regulation, the FDA has defined the "listed drug" to mean the approved new "drug product." 21 C.F.R. 314.3(b).

21. If a certification is made by the generic manufacturer under paragraph I or II - indicating that patent information pertaining to the drug or its use has not been filed with FDA or the patent has expired - the ANDA may be approved immediately, and the generic drug may be marketed. 21 U.S.C. 355(j)(5)(B)(i). A certification under paragraph III indicates that the ANDA applicant does not intend to market the drug until after the applicable patent expires, and approval of the ANDA may be made effective on the expiration date. 21 U.S.C. 355(j)(5)(B)(ii).

22. 21 U.S.C. 355(j)(2)(B); 21 C.F.R. 314.95(c)(6).

23. 21 C.F.R. 314.94(a)(12)(vi).

24. 21 U.S.C. 355(j)(2)(A)(viii); 21 C.F.R. 314.94(a)(12)(iii). In the event of a dispute as to the accuracy or relevance of patent information submitted to the FDA and subsequently listed in the Orange Book, the FDA

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 case, there has been no admission or final determination of unlawfulness in any of these matters.

29. *Abbott Laboratories*, C-3945 (May 26, 2000) (Analysis to Aid Public Comment), <<http://www.ftc.gov/os/2000/03>>.

30. *Id.* (complaint).

31. *Abbott Laboratories*, C-3945 (May 26, 2000) (complaint).

32. *Hoechst Marion Roussel, Inc.*, Docket 9293 (March 16, 2000) (complaint), <<http://www.ftc.gov/os/2000/03>>.

33. *Id.*

34. In each of the cases brought by the Commission - *Abbott*, *Hoechst*, and *Schering* - it is not the general principle of the 180-day exclusivity that is at issue; rather, the complaints alleged that the parties entered into agreements that delayed or prevented the triggering of the first ANDA filer's exclusivity period, thereby also blocking other generic firms from entering.

The Commission's cases challenging settlement agreements also do not mean that parties to patent litigation cannot settle their disputes. Indeed settlement of litigation can serve important public purposes. But the antitrust laws have long condemned settlements that unreasonably limit competition. *See, e.g., United States v. Singer Mfg. Co.*, 374 U.S. 174 (1963).

35. *In the Matter of Schering-Plough Corporation, et al.*, Docket No. 9297 (Mar. 30, 2001).

36. K-Dur 20 is the 20 mg version of the product and is the product version at issue in this matter. Schering also makes a 10 mg version.

37. Upshur-Smith received final FDA approval in November 1998 to market a generic version of K-Dur 20.

38. CV-98-3115 (D.D.C., filed Dec. 22, 1998; amended complaint filed Feb. 8, 1999). Over 20 million prescriptions are written for these drugs each year.

39. The Commission approved the settlement on November 29, 2000. *FTC v. Mylan Laboratories, Inc.*, FTC File No. X990015 (Nov. 29, 2000). The Commission vote to accept the proposed agreement was 4-1,

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).

45. *In the Matter of Citizen Petitions; Actions That Can be Requested by Petition; Denials, Withdrawals, and Referrals for Other Administrative Action*, Docket No. 99N-2497, 64 Fed. Reg. 66822 (Nov. 30, 1999).

46. *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961); *United Mine Workers v. Pennington*, 381 U.S. 657 (1965). The Noerr-Pennington doctrine shields private parties from antitrust liability when they engage in certain concerted and genuine efforts to influence governmental action, even though the conduct is undertaken with an anticompetitive intent and purpose. For a further discussion of the Noerr-Pennington doctrine, *see* James D. Hurwitz, "Abuse of Governmental Processes, the First Amendment, and the Boundaries of Noerr," 74 *Geo. L.J.* 601 (1985). There are some exceptions to the application of the Noerr-Pennington doctrine. The Supreme Court has made clear that where one uses "the governmental process - as opposed to the outcome of that process - as an anticompetitive weapon," the protection of the Noerr doctrine may not apply.⁽⁴⁷⁾

47. *Professional Real Estate Investors, Inc. v. Columbia Pictures Indus. Inc.*, 508 U.S. 49, 61 (1993) (quoting *Columbia v. Omni Outdoor Advertising, Inc.*, 499 U.S. 365, 380 (1991)). " " ,⁽⁴⁸⁾

48. *Id.* " " " "

49. *See* Comment of the Federal Trade Commission Staff, *In the Matter of Citizen Petitions; Actions That Can be Requested by Petition; Denials, Withdrawals, and Referrals for Other Administrative Action*, Docket No. 99N-2497 (Mar. 2, 2000), <<http://www.ftc.gov/be/v000005.pdf>>.