Testimony of

The Honorable Timothy J. Muris

June 17, 2003

I. Introduction

Mr. Chairman, I am Timothy J. Muris, Chairman of the Federal Trade Commission. I am pleased to appear before the Committee today to testify on behalf of the Commission regarding competition in the pharmaceutical industry, and, in particular, findings and recommendations in the July 2002 FTC Study of Generic Drug Entry Prior to Patent Expiration.

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. 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." 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 ("Hatch-Waxman" or "the Amendments") to the Food, Drug and Cosmetic Act ("FDC Act"). 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. 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. With patents set to expire within the next several years (or those that have recently expired) on brand-name drugs having combined U.S. sales of almost $20 billion, 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 and generic companies - have acted in good faith, others have attempted to "game" the system, securing greater profits for themselves without providing a corresponding benefit to consumers. Responding to these abuses, the Senate last year passed S. 812, the Greater Access to Affordable Pharmaceuticals Act introduced by Senators McCain and Schumer and S. 754 , the Drug Competition Act, introduced by Senator Leahy. In addition, last October, the Food and Drug Administration ("FDA") proposed rules to limit certain of these abuses, and just last week the FDA finalized these proposals. This testimony will describe the Commission's past and present response to the anticompetitive conduct of some drug manufacturers.

The Commission has pursued numerous antitrust enforcement actions affecting both brand-name and generic drug manufacturers. In addition, the Commission released a study entitled "Generic Drug Entry Prior to Patent Expiration" ("FTC Study") in July 2002. 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. 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 the pharmaceutical industry, including in-depth studies by the staff of the Bureau of Economics. The Commission's efforts have included filing comments with the FDA regarding the competitive aspects of Hatch-Waxman implementation, as well as previous testimony before Congress. Furthermore, individual Commissioners have addressed the subject of pharmaceutical competition before a variety of audiences, both to solicit input from affected parties and to promote discussion about practical solutions.

After reviewing the relevant Hatch-Waxman provisions, this testimony will address the Commission's vigorous enforcement of the antitrust laws with respect to branded and generic drug competition. One type of conduct involves allegedly anticompetitive settlements between brand-name and generic companies. Because the Commission became aware of and challenged such settlements first, this testimony refers to those matters as "first-generation litigation." Other, more recent types of conduct, such as allegedly improper Orange Book listings and potentially anticompetitive settlements between generic manufacturers themselves, are the subject of the Commission's "second-generation actions."

Next, the testimony will address the Commission's industry-wide study of generic drug entry prior to patent expiration. An understanding of the Commission's cases in this area will provide the framework for the issues that the Commission examined in this study. The testimony also provides a brief overview of how the FDA's new regulations will hep curb some of the problems identified by the FTC Study.

II. Regulatory Background: The Hatch-Waxman Drug Approval Process

A. The Hatch-Waxman Balance

One of the stated purposes of Hatch-Waxman is to "make available more low cost generic drugs." The concern that the FDA's lengthy drug approval process was unduly delaying market entry by generic versions of brand-name prescription drugs motivated Congress's passage of the Amendments. Because a generic drug manufacturer was required to obtain FDA approval before selling its product, and could not begin the approval process until any conflicting patents on the relevant brand-name product expired, the FDA approval process essentially functioned to extend the term of the brand-name manufacturer's patent. To correct this problem, Congress provided in the Amendments that certain conduct related to obtaining FDA approval, which would otherwise constitute patent infringement, would be exempted from the patent laws.

Congress continued to regard patent protection, however, as critical to pharmaceutical innovation and an important priority in its own right. Hatch-Waxman thus represented a compromise: an expedited FDA approval process to speed generic entry balanced by additional intellectual property protections to ensure continuing innovation. As one federal appellate judge explained, the Amendments "emerged from Congress's efforts to balance two conflicting policy objectives: to induce brand-name pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market."

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"). At the time the NDA is filed, the NDA filer must also provide the FDA with certain categories of information regarding patents that cover the drug that is the subject of its NDA. 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."

Rather than requiring a generic manufacturer to repeat the costly and time-consuming NDA process, the Amendments permit the company to file an Abbreviated New Drug Application ("ANDA"), which references data that the "pioneer" manufacturer has already submitted to the FDA regarding the brand-name drug's safety and efficacy. Under the ANDA process, an applicant must demonstrate that the generic drug is "bioequivalent" to the relevant brand-name product. The ANDA must contain, among other things, a certification regarding each patent listed in the Orange Book in conjunction with the relevant NDA. One form of certification is a "Paragraph IV certification," asserting that the patent in question is invalid or not infringed.

Filing a Paragraph IV certification potentially has significant regulatory implications, as it is a prerequisite to the operation of two provisions of the statute. The first of these is the automatic "30-month stay" protection afforded to patent holders and the NDA filer - most typically, brand-name companies. An ANDA filer that makes a Paragraph IV certification must provide notice to both the patent holder and the NDA filer, including a detailed statement of the factual and legal basis for the ANDA filer's assertion that the patent is invalid or not infringed. Once the ANDA filer has provided such notice, a patent holder wishing to take advantage of the statutory 30-month stay provision must bring an infringement suit within 45 days. If the patent holder does not bring suit within 45 days, the FDA may approve the ANDA as soon as other regulatory conditions are fulfilled. If the patent holder does bring suit, however, the filing of that suit triggers an automatic 30-month stay of FDA approval of the ANDA. During this period, unless the patent litigation is resolved in the generic's favor, the FDA cannot approve the generic product.

The second significant component of Hatch-Waxman is the "180-day period of exclusivity." The Amendments provide that the first generic manufacturer to file an ANDA containing a Paragraph IV certification is awarded 180 days of marketing exclusivity, during which the FDA may not approve a subsequent applicant's ANDA. The 180-day exclusivity period increases the economic incentives for a generic company to be the first to file an ANDA, because the generic applicant has the potential to reap the reward of marketing the only generic product (and, thus, to charge a higher generic price until more generic products enter). Through this 180-day provision, the Amendments provide an increased incentive for companies to challenge patents and develop alternatives to patented drugs. The 180-day period is calculated from the date of the first commercial marketing of the generic drug product or the date of a court decision declaring the patent invalid or not infringed, whichever is sooner. Of course, during the 180 days, the brand-name company is still marketing its brand-name product. After the 180 days, subject to regulatory approvals, other generic companies can enter the market. When additional generic competitors enter the market, competition drives the price for the generic product below the price established by the first generic entrant that was entitled to the 180-day exclusivity.

B. Competitive Implications

The 30-month stay and the 180-day period of exclusivity were both parts of the Hatch-Waxman balance. The imposition of a 30-month stay of FDA approval of an eligible ANDA could forestall generic competition during that period of time. The 180-day period of exclusivity can, in some circumstances, limit the number of generic competitors during this 180-day period. Over the past few years the Commission has observed through its investigations, law enforcement actions, and industry-wide study that some brand-name and generic drug manufacturers may have "gamed" these two provisions, attempting to restrict competition beyond what the Amendments intended. The next section of this testimony discusses the Commission's efforts to investigate vigorously and to prosecute such abuses.

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 in a short period of time. 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 generic products.

The Commission has challenged conduct by firms that allegedly have "gamed" the Hatch-Waxman framework to deter or delay generic competition. Our "first generation" of such matters involved agreements through which a brand-name drug manufacturer allegedly paid a generic drug manufacturer not to enter and compete. The complaints in these cases also alleged that the brand-name company used the generic company's rights to the 180-day exclusivity under Hatch-Waxman to impede entry by other generic competitors. Two leading cases illustrate the Commission's efforts in the area: Abbott/Geneva and Hoechst/Andrx. The Commission resolved both cases by consent order. Very recently, the Commission settled another case involving a drug settlement in which the brand-name company, Bristol-Myers, allegedly had paid a generic drug manufacturer $72.5 million to abandon its challenge to a Bristol-Myers patent and to stay off the market until the patent expired.

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

Our "second generation" of enforcement activities has involved allegations that individual brand-name manufacturers have delayed generic competition through the use of improper Orange Book listings that trigger a Hatch-Waxman provision prohibiting the FDA from approving a generic applicant for 30 months. Brand-name drug manufacturers may sometimes act strategically to obtain more than one 30-month stay of FDA approval of a particular generic drug. The Commission recently described the consumer harm that occurs when an invalid patent forms the basis of such 30-month stays.

1. Clarification of Noerr-Pennington Doctrine: In re Buspirone

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. The Noerr doctrine provides antitrust immunity for parties "petitioning" government. While the Noerr doctrine is an important limitation on the antitrust laws that protects the right of parties to communicate with government entities, some courts have interpreted the doctrine too broadly in ways that are inconsistent with Supreme Court precedent and harm consumers.

To address the concern that the Noerr doctrine was being interpreted too expansively, a Noerr-Pennington Task Force of Commission staff began work in June 2001. One of the objectives of the Task Force was to examine certain aspects of the Noerr doctrine, such as the scope of "petitioning" conduct and the continuing existence of a misrepresentation exception to Noerr immunity.

One of the first potential abuses the Task Force considered was the improper listing of patents in the FDA's Orange Book. Pursuant to current policy, the FDA does not review patents presented for listing in the Orange Book to determine whether they do, in fact, claim the drug product described in the relevant NDA. Instead, the FDA takes at face value the declaration of the NDA filer that the listing is appropriate. As a result, an NDA filer acting in bad faith can successfully list patents that do not satisfy the statutory listing criteria. Once listed in the Orange Book, these patents have the same power to trigger a 30-month stay of ANDA approval as any other listed patent, thereby delaying generic entry and potentially costing consumers millions of dollars without valid cause.

In January of last year, private lawsuits relating to Bristol-Myers's alleged monopolization through improper listing of a patent on its brand-name drug BuSpar presented the Commission with an opportunity to clarify the Noerr doctrine. Specifically, plaintiffs alleged that, through fraudulent 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.

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, the Commission filed an amicus brief opposing the motion to dismiss. 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.

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 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.

The Commission's own, more recent, law enforcement action against Bristol-Myers also raised a significant Noerr-Pennington issue. Specifically, the case provided an opportunity for the Commission to emphasize the continuing existence of a "pattern exception" to Noerr. As the Analysis to Aid Public Comment that accompanied the proposed consent agreement explains, "the logic and policy underlying the Supreme Court's decision in California Motor Transport . . . support the application of a pattern exception for BMS's alleged pattern of conduct . . . and thus provide a separate reason to reject Noerr immunity here." California Motor Transport involved allegations that a group of trucking companies had agreed to routinely oppose every application of additional motor carrier operating rights filed with state or federal agencies. After evaluating the competitive implications of this conduct, the Court concluded that "a pattern of baseless, repetitive claims . . . effectively barring respondents from access to the agencies and courts . . . cannot acquire immunity by seeking refuge under the umbrella of 'political expression.'" In the Bristol-Myers Analysis, the Commission contends that this pattern exception to Noerr should not be limited to repetitive lawsuits, but rather should be applicable to any predatory, repetitive use of government process. Specifically, the Analysis states that "[j]ust as the repeated filing of lawsuits brought without regard to the merits . . . warrants rejection of Noerr immunity," so too does the repeated filing of knowing and material misrepresentations with the PTO and FDA.

2. Enforcement Action Against Improper Orange Book Listings: Biovail (Tiazac) and Bristol-Myers Squibb (BuSpar, Taxol, and Platinol)

In October 2002, the Commission issued a consent order against Biovail Corporation, 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 been lifted by February 2001. According to the Commission's complaint, Biovail, in anticipation of pending competition from Andrx, undertook a series of anticompetitive actions to trigger a new stay and maintain its Tiazac monopoly. Just before the stay was to terminate, Biovail acquired exclusive rights to a newly issued patent from a third party and listed that patent in the Orange Book as claiming Tiazac - thereby requiring Andrx to re-certify to the FDA and opening the door to Biovail's suit against Andrx for infringement of the new patent and commencement of a second 30-month stay.

The Commission's complaint alleged that Biovail's patent acquisition, wrongful Orange Book listing, and misleading conduct before the FDA were acts in unlawful maintenance of its Tiazac monopoly, in violation of Section 5 of the Federal Trade Commission Act ("FTC Act"), and that the acquisition also violated Section 7 of the Clayton Act. The consent order requires Biovail to divest the exclusive rights to their original owner with certain exceptions; to achieve dismissal with prejudice of any and all claims relating to enforcement of the patent in relation to Tiazac; and to refrain from any action that would trigger another 30-month stay on generic Tiazac entry. Further, the order prohibits Biovail from unlawfully listing patents in the Orange Book and requires Biovail to give the Commission prior notice of acquisitions of patents that it will list in the Orange Book for Biovail's FDA-approved products. These measures should not only remedy Biovail's allegedly unlawful conduct, but also send a strong message that the Commission will act decisively to eliminate anticompetitive practices in the pharmaceutical industry.

In a second, more recent case, the Commission alleged a decade-long pattern of anticompetitive acts by Bristol-Myers to obstruct the entry of low-price generic competition for three of Bristol-Myers' widely-used pharmaceutical products: two anti-cancer drugs, Taxol and Platinol, and the anti-anxiety agent BuSpar, as noted earlier. Bristol-Myers allegedly abused FDA regulations to block generic entry, misled the U.S. Patent and Trademark Office (PTO) to obtain unwarranted patent protection, and filed baseless patent infringement lawsuits to deter entry by generics. According to the FTC's complaint, Bristol-Myers' illegal conduct protected nearly $2 billion in annual sales at a high cost to cancer patients and other consumers, who - being denied access to lower-cost alternatives - were forced to overpay by hundreds of millions of dollars for important and often life-saving medications.

The FTC resolved these allegations through a consent order with Bristol-Myers that contains strong -- and in some respects unprecedented -- relief. This consent order, among other restrictions, is designed to eliminate Bristol-Myers' alleged ability to abuse FDA regulations, and thereby reduce Bristol-Myers' incentive to engage in improper behavior before the PTO. The order includes a provision that prohibits Bristol-Myers from triggering a 30-month stay based on any patent Bristol-Myers lists in the Orange Book after the filing of an application to market a generic drug, and limits Bristol-Myers' ability to provide information about a patent to the FDA that is inconsistent with information it provided to the PTO.

C. Settlements Between Generic Manufacturers

Although agreements between first and second generic entrants have attracted significantly less attention to date, they too can raise competitive concerns and may draw antitrust scrutiny. 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 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. 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 2002, the Commission issued a consent order against two generic drug manufacturers to resolve charges that they entered into an agreement that unreasonably reduced competition in the market for a generic anti-hypertension drug. According to the Commission's complaint, Biovail Corporation (Biovail) and Elan Corporation PLC (Elan) agreed not to compete in marketing 30 mg and 60 mg generic Adalat CC products, and that the agreement lacked any countervailing efficiencies.

The order, which has a ten-year term, remedies the companies' alleged anticompetitive conduct by requiring them to terminate the agreement and barring them from engaging in similar conduct in the future. The order maintains commercial supply of the incumbent generic Adalat products while the companies unwind their agreement, and eliminates the anticompetitive obstacles to entry of a second 30 mg and a second 60 mg generic Adalat CC product.

IV. The Commission's Industry-Wide Generic Drug Competition Study

A. Background and Introduction

In light of the questions its various generic drug investigations raised, the Commission proposed an industry-wide study of generic drug competition in October 2000. The FTC Study focused solely on the procedures used to facilitate generic drug entry prior to expiration of the patent(s) that protect the brand-name drug product - that is, generic entry through the procedures involving Paragraph IV certifications. The Commission undertook the study for three reasons:

(1) To determine whether alleged anticompetitive agreements that relied on certain Hatch-Waxman provisions were isolated instances or more typical, and whether particular provisions of the Amendments are susceptible to strategies to delay or deter consumer access to generic alternatives to brand-name drug products;

(2) To respond to Representative Henry Waxman's request for the Commission to "investigate and produce a study on the use of agreements between and among pharmaceutical companies and potential generic competitors and any other strategies that may delay generic drug competition throughout the U.S."; and

(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. 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. The Commission issued nearly 80 special orders - pursuant to Section 6(b) of the FTC Act - 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. 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 factual description of how the 180-day marketing exclusivity and 30-month stay provisions affect the timing of generic entry prior to patent expiration. The FTC Study did not provide an antitrust analysis of each of the types of agreements submitted, nor did it examine other issues involved in the debate over generic drugs, such as bioequivalence or the appropriate length of patent restorations under Hatch-Waxman.

B. Findings: Litigation Frequency and Outcomes

The FTC Study sought to determine the frequency with which brand-name companies have triggered the 30-month stay provision by suing generic applicants for patent infringement within the required 45-day period. For 72 percent of drug products the study covered, brand-name companies initiated patent infringement litigation against the first generic applicant. There was no suit in the other 28 percent, and the FDA has approved most of the generic products, thus allowing generic entry to occur. FDA approval of these ANDAs took, on average, 25.5 months from the ANDA filing date.

In 70 percent of the cases (53 of the 75 drug products) in which the brand-name company sued the first generic applicant, either there has been a court decision (30 of the 53 drug products) or the parties have agreed to a final settlement without a court decision on the merits of the patent infringement lawsuit (20 of the 53 drug products). In the other 30 percent of the cases (22 of the 75 drug products), a district court had not yet ruled as of June 1, 2002.

Of all the patent infringement cases (with the first generic applicant) in which a court had rendered a decision as of June 1, 2002, generic applicants prevailed in 73 percent of the cases (22 out of 30) and brand-name companies prevailed in 27 percent (8 out of 30). Of the decisions favoring the first or any subsequent generic applicant, there were slightly more non-infringement decisions (14) than patent invalidity decisions (11). The U.S. Court of Appeals for the Federal Circuit overturned district court decisions of patent invalidity for drug products in this study in only eight percent of cases.

In 62 percent of the cases involving litigation with the first and second generic applicants, brand-name companies initiated patent litigation in just five federal judicial districts - the District of New Jersey, the Southern District of New York, the Southern District of Indiana, the Northern District of Illinois, and the Southern District of Florida.

C. Findings: Orange Book Patent Listing Practices

The 30-month stay provision of the Amendments protects brand-name companies beyond their existing intellectual property rights. It has received increased attention because it can have a significant impact on market entry by generic drugs. Since 1998, two new phenomena appear to be emerging in relation to patent listing practices that affect patent litigation: (1) an increase in the number of patents listed in the Orange Book for "blockbuster" drug products; and (2) the listing of patents after an ANDA has been filed for the particular drug product.

The Commission found that, for drug products with substantial annual net sales, brand-name companies are suing generic applicants over more patents. Since 1998, for five of the eight "blockbuster" drug products for which the brand-name company filed suit against the first generic applicant, the brand-name company alleged infringement of three or more patents. In comparison, in only one of the nine "blockbuster" suits filed before 1998 by a brand-name company against the first generic applicant did the complaint allege infringement of three or more patents.

In the future, patent infringement litigation brought by brand-name companies against generic applicants that have filed ANDAs with Paragraph IV certifications may take longer to resolve. The 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 the five 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 known drug product produced by a novel 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 or a district court decision on the patent infringement litigation that caused the 30-month stay. Moreover, generic applicants generally have not entered the market until a district court has held that the brand-name company's patent was invalid or not infringed. Thus, it does not appear that, on average, one 30-month stay provision per drug product per ANDA would have a significant potential to delay generic entry beyond the time already necessary for FDA approval of the generic applicant's ANDA or a district court decision in the relevant litigation.

Limiting brand-name drug companies to one 30-month stay per drug product per ANDA is likely to eliminate most problems related to potentially improper Orange Book listings. Nonetheless, the Commission notes that there is no private right of action to challenge an improper listing, nor does the FDA review the propriety of patent listings. 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 the first 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. The FTC Study recommends, at a minimum, that it would be useful for the FDA to clarify its listing requirements as the Commission suggests. Another remedy that may warrant consideration would be to permit a generic applicant to raise listability issues as a counterclaim in the context of patent infringement litigation that the brand-name company already initiated in response to a Paragraph IV notice from the generic applicant. A challenge limited to a counterclaim would avoid generating additional litigation.

One minor change to the patent statute, which would clarify when brand-name companies can sue generic applicants for patent infringement and allow for the resolution of patent issues prior to commercial marketing of a generic drug, would ensure that brand-name companies have recourse to the courts to protect their intellectual property rights in later-issued patents. To do this, the FTC Study suggested that Congress may wish to clarify that Section 271(e)(2) of the Patent Act permits a brand-name company to sue a generic applicant for patent infringement regarding patents not listed in the Orange Book.

E. Findings: Patent Settlements and the 180-Day Marketing Exclusivity

Certain patent settlement agreements between brand-name companies and potential generic competitors have received antitrust scrutiny in recent years because not only might they affect when the generic applicant may begin commercial marketing, but they also may affect when the FDA can approve subsequent generic applicants after the first generic applicant's 180-day exclusivity runs. Parties have debated whether these settlements increased or harmed consumer welfare. Twenty final and four interim agreements that settled litigation between the brand-name company and the first generic applicant were produced in response to the FTC's special orders.

The final patent settlements can be classified into three categories:

(1) Nine of these settlements contained a provision by which the brand-name company, as one part of the settlement, paid the generic applicant (settlements involving "brand payments");

(2) Seven of the 20 settlements involved the brand-name company licensing the generic applicant to use the patents for the brand-name drug product prior to patent expiration; and

(3) Two of the settlements allowed the generic applicant to market the brand-name drug product as a generic product, under the brand-name company's NDA but not under not the generic applicant's own ANDA.

Fourteen of the final settlements with the first generic applicant had the potential to "park" the 180-day marketing exclusivity for some period of time such that the first generic applicant would not trigger the exclusivity, and thus FDA approval of any subsequent eligible generic applicant would be delayed. (If the 180-day exclusivity for the first generic applicant does not run, the FDA cannot approve subsequent eligible generic applicants.) The data from the FTC Study suggest, however, that the 180-day exclusivity provision by itself generally has not created a bottleneck to prevent FDA approval of subsequent eligible generic applicants.

In addition to the final settlements with the first generic applicant, brand-name companies entered final patent settlements with the second generic applicant in seven instances. In six of the seven, the brand-name company also had settled with the first generic applicant.

F. Recommendations: The 180-Day Exclusivity Provision

To mitigate the possibility of abuse of the 180-day exclusivity provision, the FTC Study recommended that Congress pass the Drug Competition Act to require brand-name companies and first generic applicants to provide copies of certain agreements to the Federal Trade Commission and the Department of Justice. The Commission believes that review of these agreements by these agencies will help ensure that the 180-day provision is not manipulated in a way to delay entry of additional generic applicants. Indeed, the Senate did pass the Drug Competition Act last year and the Commission urges passage of the Act again this year.

Empirical research demonstrates that as additional generic competitors enter the market, generic prices decrease to lower levels, thus benefitting consumers. The FTC Study makes three minor recommendations to ensure that, once a subsequent generic applicant is ready to market, the 180-day exclusivity is not a roadblock to that entrant's beginning commercial marketing. Under the second and third recommendations, we note that the first generic applicant does not lose the 180-day period, but rather it is triggered by one of two events. During this 180-day period, the first generic applicant can then decide whether to enter the market prior to a subsequent applicant entering after the 180-day period has expired.

Recommendation 1: To clarify that "commercial marketing" includes the first generic applicant's marketing of the brand-name product.

The data revealed two instances when the brand-name company and the first generic applicant settled the patent infringement lawsuit with a supply agreement. These agreements contemplated that the brand-name company would supply the generic applicant with the brand-name drug product, so that the generic applicant could market the brand-name product as a generic version, rather than seeking approval of its ANDA. To avoid the situation in which the running of the 180 days is not triggered and, thus, forestalling a second generic from obtaining FDA approval, the Commission recommended this type of marketing be deemed sufficient to trigger the 180-day exclusivity period.

Recommendation 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.

There is some question about which court's decision is sufficient to activate the "court decision" trigger of the 180-day exclusivity. Two courts of appeal have held, and the FDA has issued guidance, that any court's decision on whether the patent at issue is invalid or not infringed is sufficient to trigger the running of the first generic applicant's 180-day exclusivity.

On balance, the Commission believes that this is the correct result, but there are pros and cons. On the one hand, the rule would make it less likely that agreements between brand-name and generic companies that had the effect of "parking" the 180-day exclusivity for some period of time could forestall FDA approval of a subsequent eligible generic applicant. If the brand-name company sues the second (or later) generic applicant, and that generic applicant won its patent litigation, then the 180-day exclusivity of the first generic applicant would begin to run from the date of the later generic applicant's favorable court decision. Such circumstances may arise; the data showed that brand-name companies sued later generic applicants in nearly 85% of the cases. The rule would be consistent with the mandate in the legislative history of Hatch-Waxman to "make available more low-cost drugs," because the rule would assist in eliminating potential bottlenecks to FDA approval of subsequent eligible generic applicants.

Such a rule also could speed generic entry when the second generic applicant's lawsuit is resolved prior to that of the first applicant. This appears to be appropriate given the low reversal rate of district court opinions of patent invalidity and non-infringement. For example, under this rule, if both the first and second generic applicants are sued, but the court hearing the second generic applicant's case is the first to arrive at a decision, then that court's decision would trigger the running of the first generic applicant's 180-day exclusivity, regardless of whether the first generic applicant had received FDA approval. The data revealed one such case.

On the other hand, the operation of this rule could deprive the first generic applicant of its ability to market under the 180-days exclusivity if the district court hearing its suit had not yet ruled, even though the first generic applicant had been diligently pursuing resolution of its patent litigation. This result could dampen the incentive to become the first generic applicant. Moreover, if the later court issues a non-infringement decision, the reasoning underlying the holding may not apply to the first generic applicant's ANDA, depending upon the facts of the case.

Recommendation 3: 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.

One court of appeals has held that a dismissal of a declaratory judgment action for lack of a case or controversy is a "court decision" of non-infringement sufficient to trigger the 180-day exclusivity. In the FTC Study, the Commission found the court's reasoning persuasive, and recommended that Congress adopt such a rule.

The U.S. Court of Appeals for the District of Columbia confronted a situation in which the brand-name company did not sue any of the generic applicants for patent infringement. To trigger the first generic applicant's 180-day exclusivity (because it had not yet been approved by the FDA), the second generic applicant sought a declaratory judgment that its ANDA did not infringe the brand-name product's patents. The district court hearing the case dismissed the lawsuit for lack of subject matter jurisdiction, because the brand-name company indicated that it would not sue the second generic applicant for patent infringement, thus eliminating its reasonable apprehension of a patent infringement suit and the existence of a case or controversy. This dismissal also estopped the brand-name company from suing the generic applicant in the future.

The Court of Appeals determined that the dismissal for lack of case or controversy was, in fact, a court decision, because the brand-name company indicated that the second generic applicant's ANDA did not infringe the relevant patent. As a result, the dismissal activated the court decision trigger. Such a rule eliminates the potential for a bottleneck created if a first generic applicant does not exercise its commercial marketing rights.

G. The FDA's New Rules on the 30-Month Stay and Orange Book Listings

Last week the FDA published final rules amending its regulations governing patent listing in the Orange Book and eligibility for the 30-month stay of ANDA approval. The FDA had proposed this rule last year, in part, based on the competitive problems with the current generic drug approval process the Commission identified in the FTC Study.

The final rule limits brand-name companies to one 30-month stay per drug product. Although this rule is not identical to the FTC Study's recommendation, it is an important reform that would eliminate most of the potential for unwarranted delay of FDA approval of generic drugs the FTC Study identified. In particular, the rule, if upheld against legal challenge, would eliminate seven of the eight instances the Commission identified in the Study in which brand-name companies filed patents in the Orange Book after a generic applicant had filed an ANDA application and, thus, delayed FDA approval of the ANDA for an additional 30 months. The final rule does not cover those situations in which the generic applicant has filed an ANDA with a paragraph III certification on a particular patent and seeks FDA approval after the expiration of that patent. If on the eve of that patent's expiration, the brand-name company files a new patent in the Orange Book, there is a potential for a 30-month stay to be granted. This is the situation for the drug product Platinol (the eighth of the eight drug products the FTC Study identified with multiple 30-month stays).

The final rule also tightens up the Orange Book patent listing requirements. The FTC Study had identified several types of patents that raise questions about whether they are properly listed in the Orange Book, and which can form the basis for a 30-month stay. The final FDA rule prohibits the listing of two of these types of patents (metabolites and product-by-process), and requires additional information from the brand name company if it seeks to list in the Orange Book the third type of patent (polymorphs) identified by the Study.

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 Committee, 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.