Prepared Statement ofThe Federal Trade Commission

Before the

Committee on Judiciary
United States Senate

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Introduction

Mr. Chairman, I am Tim Muris, Chairman of the Federal Trade Commission. I am pleased to appear before the Committee today to testify on behalf of the Commission regarding the Senate's and House of Representatives' versions of the "Greater Access to Affordable Pharmaceuticals Act." This statement supplements the Commission statement dated June 17, 2003 (attached) in which the Commission described the Hatch-Waxman provisions that govern the generic drug approval process, its vigorous enforcement of the antitrust laws with respect to generic drug competition, and the Commission's industry-wide study of generic drug entry prior to patent expiration entitled: Generic Drug Entry Prior to Patent Expiration: An FTC Study.[(1)]

Earlier this year, both the Senate and House passed versions of the Greater Access to Affordable Pharmaceuticals Act that reform the Hatch-Waxman generic drug approval process. The reforms are nearly identical to the FTC Study's recommendations. With one important exception highlighted below, the language in both bills is very similar. This testimony will describe the legislative changes to Hatch-Waxman in both the Senate and House bills, compare them to the FTC Study's recommendations, and explain the Commission's concern about the "failure to market" forfeiture event provision in both bills.

Limits Brand-Name Companies to Only One 30-Month Stay

Both the Senate and House bills amend Hatch-Waxman to allow only one 30-month stay per drug product, per Abbreviated New Drug Application (ANDA) for patents listed in the Orange Book prior to the generic company filing its ANDA. The FTC Study recommended this exact change. This provision, had it been in effect previously, would have eliminated all eight instances the FTC Study identified in which a brand-name company's later listing of patents resulted in the start of an additional 30-month stay of FDA approval.

Under both bills, a district court decision of patent invalidity or non-infringement terminates the 30-month stay. This change codifies current FDA interpretation. If the generic applicant includes more than one paragraph IV certification in its ANDA, the district court decision on the last patent terminates the 30-month stay for which the generic applicant submitted a paragraph IV certification. Both bills clarify that if the district court finds the patent infringed, the FDA cannot approve the ANDA unless an appeals court overturns the district court's decision. The Commission supports these changes.

A New Counterclaim to Correct Orange Book Patent Listing Information

Consistent with an FTC Study recommendation, both the Senate and House bills provide generic applicants a new tool to correct patent information listed in the Orange Book. Under both bills, if a brand-name company initiates a patent infringement suit against a generic applicant, the generic applicant may assert a counterclaim seeking an order requiring the brand-name company to correct or delete the patent information listed in the Orange Book. The

generic applicant may argue that the patent claims neither the drug for which the brand-name drug was approved, nor an approved method of using the drug.

The patent listing statute also requires that the patent holder list patents only "for which a claim of patent infringement could reasonably be asserted." The bills, however, do not include this prong as a basis for the counterclaim. The Commission suggests that Congress consider modifying the counterclaim provision to parallel the bases for listing patents in the Orange Book.

Declaratory Judgment/Case or Controversy Provisions

The Senate bill adds a provision clarifying that if the brand-name company fails to bring an infringement action within 45 days of receiving notice of an ANDA containing a paragraph IV certification, the generic applicant can bring a declaratory judgment action that the patent is invalid or not infringed. To overcome possible jurisdictional limits to bringing such an action, the bill adds a provision stating that the failure of the patent owner to bring an action for patent infringement before the expiration of the 45-day period shall establish a controversy between the applicant and the patent owner sufficient to confer subject matter jurisdiction in the courts of the United States.

The House bill does not include a similar provision establishing a controversy between the parties. Rather, the bill allows a generic applicant to bring a declaratory judgment action after the expiration of the 45-day period (assuming the brand-name company has not sued for patent infringement) only if the generic applicant provides a "right of confidential access" to its ANDA. This right would allow the brand-name company to make an informed decision about whether it should sue for patent infringement during the 45-day period.

Without addressing the constitutional issues involved, the Senate provision may help ensure that a federal court has subject matter jurisdiction to resolve the patent issues. In addition, the Commission does not believe that the House's "right of confidential access" to a generic applicant's ANDA is necessary. A generic applicant currently has incentives to provide brand-name companies with sufficient information about whether its ANDA infringes the brand-name company's patents to ensure that the dismissal or adjudication of any suit precludes future infringement suits.

The 180-Day Exclusivity Provision

Both bills change how the FDA administers Hatch-Waxman in two fundamental ways. First, the FDA will be able to grant the 180-day exclusivity provision on a product basis. This change eliminates the exclusivity problems the FDA encountered by awarding exclusivity to generic applicants on a patent basis (*i.e.*, some drug products have multiple patents on which different generic applicants have been first to file an ANDA containing a paragraph IV certification). Second, both bills institute a "multiple first applicant" system in which all ANDAs filed on the first day an ANDA is filed for a particular drug product would be eligible for the 180-day exclusivity period. Both of these provisions should provide certainty to the FDA and industry about the administration of the 180-day exclusivity provisions.

Filing of Patent Settlement Agreements with the FTC

The Senate and House bills require brand-name companies and generic applicants to file patent settlement agreements with the FTC within 10 days of execution. The filing of agreements is the main requirement of the Drug Competition Act (S. 946, 108th Congress) which the Commission endorsed in the FTC Study. The House bill also requires the filing of agreements between generic applicants. This provision recognizes the possibility of anticompetitive agreements in light of the "multiple first applicant" system described above. The Commission supports this provision.

Triggers for the 180-Day Marketing Exclusivity

Both the Senate and House bills eliminate the current court decision trigger for the 180-day exclusivity. Only commercial marketing by the first generic will trigger the 180-day exclusivity period. Both bills adopt the FTC Study's

Minor Recommendation #1 that clarifies marketing of the brand-name drug product by the first generic applicant constitutes commercial marketing to trigger the 180-day period.

The bills also contain a forfeiture provision that attempts to safeguard against the possibility that first generic applicants will delay the start of commercial marketing. When a forfeiture event occurs, the 180-day exclusivity would not roll to the next generic applicant. The forfeiture events include: (a) failing to market within prescribed time periods (described more below); (b) withdrawing the ANDA application; (c) changing a paragraph IV to a paragraph III certification; (d) failing to obtain tentative approval within 30 months; and (e) entering into an agreement with the brand-name company, or another generic applicant, that an FTC or court decision, from which no appeal can be taken, finds violates the antitrust laws.

The Commission believes that the bills ensure that the first generic applicant will receive the 180-day exclusivity, unless it faces significant problems obtaining final approval of its ANDA. The 180-day exclusivity near-guarantee arises because the "failure to market" forfeiture provision is triggered when the first generic applicant fails to market within 75 days of *the later of* (a) receiving final approval of its ANDA (which, for purposes of this provision, will not extend beyond 30 months)[(2)] or (b) an appeals court decision on the patents that were subject to paragraph IV certifications by the first applicant. The appeals court decision can relate to any generic applicant's ANDA, not just the first generic applicant to file.

The Commission has two concerns about this provision's likely effect on generic entry, and the Commission offers suggestions to address these concerns. First, the provision may cause first generic applicants to delay commercial marketing as compared to the current regulatory structure. Under the current rule, the 180-day exclusivity is triggered by *any district* court decision, not an appeals court decision. This rule has the effect of encouraging the first generic applicant to market as soon as possible thereafter or risk loss of the exclusivity period. Moreover, the FTC Study found that appeals courts overturn less than 10 percent of district court decisions of patent invalidity or non-infringement in the Hatch-Waxman context.

The FTC Study found that an appeals court decision, on average, occurs approximately 12 months after a district court decision (25 months, 15 days for a district court decision versus 37 months, 20 days for appeals court decision). Thus, the bills' effect could be to further delay generic entry, on average, by 10 months (75 days plus 7 months, 20 days (which is the time between *the later of* (a) the latest approval ANDA date of 30 months and (b) the average time for an appeals court decision)). If the 180-day period starts only after an appeals court decision, then consumers may wait longer for the price reductions caused by generic entry.

Second, the district court decision trigger for the 180-day exclusivity is important to encourage subsequent generic entry. The FTC Study's Minor Recommendations #2 and # 3 suggested that a district court decision in a case involving a subsequent generic applicant trigger the first applicant's 180-day period. If a subsequent generic applicant is "ready to go," the first applicant's exclusivity should not block its entry. On balance, the Commission stated that this result was right because it provided the first applicant a reasonable period for which to begin commercial marketing, but reduced the potential that the first applicant's failure to market commercially would block another generic that was ready to compete.

To address these issues, the Commission suggests that the failure to market provision be amended so that the generic applicant forfeits the 180-day exclusivity if it does not begin commercial marketing within 75 days of the later of (a) receiving final approval of its ANDA (which, for purposes of this provision, will not extend beyond 30 months) or (b) a district court decision on the patents that were subject to paragraph IV certifications by the first applicant.

In theory this rule could deprive the first generic applicant of its ability to market exclusively for 180 days and, therefore, arguably dampen a company's incentive to become the first applicant to challenge complex patents, especially if the potential damages for infringement could bankrupt the company. The Commission, however, does not believe that this will be the case. Because we are suggesting changes that modify the bills to resemble more closely the FDA's current rules, the Commission staff examined FDA data to determine whether the number of

ANDAs containing paragraph IV certifications has decreased since the current rules became effective in March 2000. From January 1992 through December 2000, generic companies filed ANDAs with paragraph IV certifications for 104 brand-name drug products. During the two and one-half year period beginning January 2001 through the end of June 2003, generic applicants have filed ANDAs containing paragraph IV certifications for over 80 different brand-name drug products. The data suggest that, despite the FDA's rule change to a district court decision, generic companies retained the incentive to submit ANDAs with paragraph IV certifications.

The Commission also suggests an amendment to the language of the "failure to market" forfeiture provision to accommodate Minor Recommendation #3 of the FTC Study. In this recommendation the Commission sought to ensure that court decisions dismissing a declaratory judgment action for lack of subject matter jurisdiction trigger the first applicant's 180-day period. The need for this amendment could occur, for example, if a subsequent generic applicant develops a clearly non-infringing product and the brand-name company does not sue the applicant for patent infringement. Without such a change to the language of the bills, the subsequent generic applicant would be blocked from marketing until the first applicant begins commercial marketing. This change is necessary to ensure that the 180-day period does not unreasonably block a subsequent generic applicant's market entry after allowing the first applicant a reasonable time to begin commercial marketing.

Conclusion

Thank you for this opportunity to share the Commission's views on the Senate and House of Representatives versions of the "Greater Access to Affordable Pharmaceuticals Act." 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.

Endnotes:

1. The written statement represents the views of the Federal Trade Commission. My oral presentation and responses to questions are my own and do not necessarily reflect the views of the Commission or of any other Commissioner.

2. The 30-month savings clause ensures that the generic applicant does not attempt to game or delay final FDA approval.