CLIENT ALERT

FTC Report Recommends Changes in Hatch-Waxman Law

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On July 30, 2002, the Federal Trade Commission issued "Generic Drug Entry Prior to Patent Expiration: An FTC Study," recommending changes in the Hatch-Waxman law to encourage quicker entry of generic drugs into the marketplace. The report contains findings of an FTC study begun in April 2001, focusing on the procedures used to facilitate generic drug market entry prior to the expiration of patents that protect the brand-name drug product. The study examines whether the 180-day exclusivity and the 30-month stay provisions of the Hatch-Waxman Amendments ("Hatch-Waxman") are susceptible to strategies to delay or deter consumer access to generic alternatives to brand-name drug products. As part of the study, the FTC gathered information from 28 brand-name companies and over 50 generic drug companies.

The report recommends legislation to ensure that two provisions of Hatch-Waxman do not delay generic drug entry into the marketplace. The first recommendation is to permit only one automatic 30-month stay 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.

Currently, if a brand-name company receives notice of a generic applicant's paragraph IV certification and files suit for patent infringement within 45 days of that notice, the 30-month stay provision is invoked. This stays FDA approval of the ANDA until either the date the patents expire, a determination of non-infringement or patent invalidity by a court in the patent litigation, or the expiration of 30 months from the receipt of notice of the paragraph IV certification.

Historically, the 30-month stay approximated the time required for FDA review and approval of the paragraph IV ANDAs of generic applicants that were not sued, or for district and appellate court resolutions of ANDA-related patent infringement litigation. This may no longer be the case. The FTC study suggests that patent infringement litigation brought by brand-name companies relating to ANDAs with paragraph IV certifications may take longer to resolve because more frequently, these suits involve multiple patents. The report noted that as of June 1, 2002, for 6 out of the 7 patent infringement cases that have been pending for more than 30 months before a decision from the district court, the brand-name company has alleged infringement of 3 or more patents. The report also noted that prior to 1998, only 1 out of the 9 instances where the brand-name company sued the first generic applicant for infringement relating to a "blockbuster" drug involved three patents. Since 1998, 5 out of the 8 suits involving "blockbuster" drugs have involved allegations of infringement of 3 or more patents.

The study also identified instances where brand-name companies prevented FDA approval of generic ANDAs beyond 30 months. If a brand-name company lists an additional patent in the Orange Book after the generic applicant has filed its ANDA, more than one 30-month stay may be triggered. The filing of the additional patent requires the generic applicant to re-certify to the new patent, giving the brand-name company another 45-day window in which to sue for infringement of the new patent and thus, triggering another 30-month stay. Between 1992 and 2000, there were 8 instances where a brand-name company listed a new patent in the Orange Book after and ANDA had been filed; 6 of these instances occurred since 1998. The additional delay of FDA approval caused by the triggering of another 30-month stay ranged from 4 to 40 months and in all 4 of the cases where a court reached a decision, the later-issued patent was found either invalid or not infringed by the ANDA.

As a result, the FTC report concludes that to permit only one 30-month stay per drug product per ANDA should eliminate most of the potential for improper Orange Book listings to generate unwarranted 30-month stays. This recommendation is distinct from legislative initiatives that would eliminate provision for automatic stays, and require brand name manufacturers to seek preliminary injunctive relief based on an evidentiary showing.

The second primary recommendation coming out of the FTC study is to pass legislation requiring brand-name companies and first generic applicants to provide copies of certain agreements to the FTC and Department of Justice. This recommendation stems from the potential for misuse and/or abuse of the 180-day marketing exclusivity period.

Currently, the first generic applicant to file an ANDA containing a paragraph IV certification is awarded 180 days of marketing exclusivity during which the FDA may not approve another generic applicant's ANDA for the same drug product. This 180-day exclusivity period runs from either the date of the first commercial marketing of the drug, or the date of a court decision declaring the patent for the brand-name drug invalid or not infringed.

In looking at the frequency with which the FDA granted 180 days of marketing exclusivity to a generic applicant, the FTC found that between 1992 and 2000, 31 out of 104 drug products for which the first generic applicant filed an ANDA with a paragraph IV certification were granted a 180-day exclusivity period. The FTC also found that of these 31 generic drug products, commercial marketing triggered the 180-day exclusivity period for 19 of the drugs, while a court decision favorable to the generic applicant triggered the 180-day period for the other 12. In addition, the study showed that generic applicants have prevailed in 73 percent of the cases in which a court reached a decision on the patent dispute.

During the course of the study, the FTC discovered instances where the 180-day exclusivity period was "parked" for some period of time so that the first generic applicant did not trigger it and FDA approval of subsequent generic products was delayed. Of the 20 final settlements of ANDA-related patent litigation, the FTC found that at the time the agreements were executed, 14 of them had the potential to "park" the 180-day exclusivity period.

The potential for "parking" the 180-day exclusivity period, combined with the FTC's findings that generic applicants have brought appropriate patent challenges, they have waited to enter the market until at least a district court ruled on the patent dispute, and when not sued, the generic applicants went to market in a timely fashion upon receipt of FDA approval, led to the FTC's recommendation that certain agreements between brand-name companies and first generic applicants should be provided to the FTC and DOJ. Consequently, the FTC has pledged its support for the Drug Competition Act of 2001 introduced by Senator Leahy which would require that if a brand-name company and a generic applicant enter into an agreement that relates to the 180-day exclusivity period or which concerns the manufacture, marketing or sale of either the brand-name drug or its generic equivalent, both parties must file with the FTC and DOJ a copy of the agreement or a complete written summary of any oral agreement, along with any related agreements.

Finally, in addition to the two primary recommendations, the FTC also suggests three minor changes that would clarify the circumstances that should trigger the 180-day exclusivity period. First, clarify that "commercial marketing" includes the first generic applicant's marketing of the brand-name product. Second, codify 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. Finally, 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 period. The report also provided an interesting discussion of the FDA citizen petition process and the potential for its misuse.

The study does not address other procedures for generic entry, nor does it address the patent restoration aspects of Hatch-Waxman.

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