CLIENT ALERT

FDA Gives Boost to Generics

Jun.13.2003

The Hatch-Waxman Amendments, enacted almost 20 years ago, represented a watershed event in the regulation of pharmaceuticals. Intended to make the generic market viable while retaining incentives for development of innovator drugs, Hatch-Waxman was, in many ways, the quintessential legislative compromise. Everybody got something and nobody was completely happy.

Nonetheless, the devil was in the details, and everybody *wasn't* happy about the statute or, more importantly, FDA's implementing regulations. It's not surprising, then, that FDA has over the years issued interpretations and re-interpretations, addressed petitions from industry, and dealt with court decisions in suits involving the agency, as well as those among competitors. Clearly, while the game remained the same, some of the rules changed – sometimes significantly – as the generic and innovator industries jockeyed for advantage.

The latest change came on June 12, when FDA announced (1) a final rule revising the Hatch-Waxman regulations in ways that cut back on innovator drug companies' ability to combat generic competition, along with (2) administrative changes intended to speed consideration of generic applications for approval.[1] It is clear who benefited from this latest move. PhRMA, representing innovators, expressed concern about the changes, and generic advocates – notwithstanding the movement in their favor – called for legislation to enact further revisions.[2]

New NDA/ANDA Regulations[3]

Highlights of the new regulations, effective August 18, 2003, include:

- Innovator drug companies are limited to one 30-month stay to resolve allegations of patent infringement by the generic company submitting an ANDA or 505(b)(2) NDA with a Paragraph IV certification. NDA holders will be able to seek a 30-month stay as to each ANDA or 505(b)(2) application, but only one stay per application.
- NDA applicants will be required to list the following patents:
    - Patents claiming the active ingredient.
    - Formulation/composition patents.
    - Method of use patents.
    - Product-by-process patents, if the product is novel.
    - Polymorph patents claiming the same active ingredient, but only if there is test data demonstrating that the drug product containing the polymorph will perform the same as the drug product that is the subject of the NDA.[4]
- NDA holders will be prohibited from submitting the following patents:
    - Patents claiming packaging.
    - Patents for metabolites or intermediates.

- Process patents.
- Patents claiming unapproved uses.

FDA's "Improving Access to Generic Drugs" Initiative[5]

Although limiting innovator drug companies' ability to use patents and patent challenges should improve generics' access to the market, FDA recognized that enhanced administrative efficiencies at the agency could also contribute to generic drugs becoming available sooner. With that in mind, the new regulations are accompanied by reforms in FDA's generic drug review program that the agency says will reduce the typical time for approval of generic drugs by three months or more. Components of the initiative include:

- Seeking a $13 million increase in FY2004 funding for FDA's generic drug programs. This almost one-third increase over FY2003 funding will, among other things allow FDA to hire about 40 additional staff in the Office of Generic Drugs.
- Conducting research to develop ways other than clinical trials to demonstrate therapeutic equivalence between generics and branded drugs in certain areas, such as dermatologic drugs, inhaled suspension products, and liposomes.
- Revising policies and developing procedures for earlier and more comprehensive communication with generic applicants, with the goal of reducing the number of review cycles.[6]
- Developing guidances to assist manufacturers in understanding what is required to submit complete applications of sufficient quality.

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[1] "FDA Generic Drugs Final Rule and Initiative."
[2] See, *e.g.*, New Drug Rule Aims to Speed Generics, *Washington Post*, June 13, 2003, Page A27.
[3] Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug is Invalid or Will Not Be Infringed, 68 *Fed. Reg.* 36676 (June 18, 2003), available at www.fda.gov/OHRMS/DOCKETS/98fr/061803a.pdf.
[4] Although the effective date of the rule is August 18, 2003, the compliance date for the submission of polymorph patent information is December 18, 2003.
[5] See, *e.g.*, "FDA White Paper: New FDA Initiative on 'Improving Access to Generic Drugs.'"
[6] According to FDA, more than 9 out of 10 generic applications received in 2001 and 2002 were not approved in the first cycle of review, and two-thirds were not approved after the second review cycle.

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