Authorized Generics: The Subpoenas Are Coming – Eventually

April 24, 2006
by Richard Liebeskind, Steven A. Dahm

June 6 Deadline to Comment on FTC Proposal

The Federal Trade Commission “FTC” has authorized the staff to use compulsory process to collect the information needed to study the likely short- and long-run effects of entry by authorized generics on generic competition. In doing so, the FTC is acknowledging the debate about whether the use of authorized generics by branded pharmaceutical companies reduces the incentives for generic entry created by the Hatch-Waxman Act.

Under the Hatch-Waxman Act, the first Paragraph-IV ANDA filer is entitled to a 180-day exclusivity period upon entry into the market. The 180-day exclusivity was created to give generic companies an economic incentive to develop generic products and take the legal risks related to challenging patents and possibly infringing. The stay is valuable to generic companies because of the greater revenues and the opportunity to establish a larger marketshare. Recently branded pharmaceutical companies have begun introducing their own generic products, or “authorized generics” at the same time the first generic product is introduced and within the 180-day exclusivity period. The incentives created by the Hatch-Waxman Act are potentially reduced by the introduction of the authorized generic products because there are two generic competitors where there would have otherwise been only one. On the other hand, the introduction of the additional competitor may have a significant impact on the price of the generic product, redounding to the benefit of consumers in the form of lower prices for drugs.

The FTC asserts that there is currently no publicly available, comprehensive economic study that assesses the likely short- and long-run effects of entry by authorized generics on generic competition. The Commission has issued a notice in the Federal Register proposing to undertake such a study, including the likely long-term impact of entry by authorized generic drugs on competition by generic manufacturers. Among other things, the proposed study will examine actual wholesale prices (including rebates, discounts, etc.) for brand-name and generic drugs, both with and without competition from authorized generics; business reasons (including profitability assessments) that support authorized generic entry; factors (including product development and litigation costs) relevant to the decisions of generic firms about whether and under what circumstances to seek entry prior to patent expiration; and licensing agreements with authorized generics. According to the FTC, these data will enable the proposed study to make new contributions to the economic literature on the effects of generic drug
entry on prescription drug prices and, in particular, the role of the 180-day period of exclusivity in generic competition prior to patent expiration.

To obtain the relevant data, the Commission proposes to send special orders to approximately 80 brand-name drug manufacturers with products that have first faced generic competition since January 1, 1999; 10 authorized generic drug companies that have marketed authorized generic drugs since January 1, 1999; and 100 independent generic drug companies that have filed an ANDA containing paragraph III and IV certifications since January 1, 1999. The Commission reports that it entered into an agreement with the FDA to obtain information to identify these brand-drug companies and independent generic companies.

The proposed subpoenas are very broad, requiring, for example, that branded drug companies submit all documents created after January 1, 1998 that discussed how to respond to (a) future or current generic competition, (b) the expiration of the patent(s) claiming the identified drug product or its use, (c) whether to license or otherwise market the identified drug product as an authorized generic drug product, and/or (d) whether to refrain from marketing an authorized generic. The proposed information requests are also broad, requiring, among other things, that branded drug companies provide monthly sales figures, net of discounts, rebates, promotions, returns and chargebacks, to all customers, and separately to clinics and long-term care facilities, in units, total prescriptions, and dollars. Detailed cost and pricing information is also required.

The proposed subpoenas to generic companies are similarly onerous, requiring them to provide all documents discussing whether or how to proceed with generic entry, including discussion related to whether to file an ANDA containing a paragraph III or IV certification (regardless of whether the company filed such ANDA), whether or when to launch commercial marketing, and the impact that entry by an authorized generic drug would have on generic entry by an ANDA drug product. Generic companies must also provide detailed sales, cost, and pricing data. Finally, the FTC would require all companies to submit IMS data.

Responding to the proposed document and information requests would be an expensive and time-consuming proposition. The FTC estimates that the labor costs per company should range between $35,000 for companies with one to five drug products (140 hours x $250/hour) and $102,000 for large companies with 40 or more drug products (408 hours x $250/hour). These estimates likely understate, perhaps severely, the actual time, cost, and disruption to the companies that these requests would cause unless narrowed.

The FTC lists the proposed document and information requests in the Federal Register and invites comments on (1) whether the proposed collections of information are necessary for the proper performance of the functions of the FTC, including whether the information will have practical utility; (2) the accuracy of the FTC’s estimate of the burden of the proposed collections of information; (3) ways to limit the number of companies included in the study without undermining the validity and reliability of the study results (e.g., reduce the number of drug products studied by only including those products in an oral solid form, eliminate those generic companies that have filed only one ANDA during the study period, reduce the study time period, etc.); (4) ways to enhance the quality, utility, and clarity of the information to be collected; and (5) ways to minimize the burden of
collecting the information on those who are to respond, including through the use of collection techniques or other form of information technology, e.g., permitting electronic submissions of responses. All comments should be filed on or before June 5, 2006.

In view of the breadth of the proposed subpoenas and information requests, pharmaceutical companies likely to receive them would be well served by responding to the FTC’s invitation to comment. Because of the time it will take for the FTC to review and respond to comments, the proposed subpoenas likely will not issue until later this year.

For further information, please contact:

Richard Liebeskind[bio]
Washington, DC
+1. 202.663.9238
richard.liebeskind@pillsburylaw.com

Steven A. Dahm[bio]
Washington, DC
+1. 202.663.8825
steve.dahm@pillsburylaw.com