CLIENT ALERT

ROPES & GRAY

ANTITRUST

April 6, 2006

Pharmaceutical Industry Faces Broad FTC Investigation

The Federal Trade Commission has announced that it will subpoena over 200 pharmaceutical companies as part of an industry-wide probe into anticompetitive practices in the prescription drug industry.

The FTC's probe will include an investigation of the competitive effects of authorized generic drugs in the prescription drug marketplace, including the role of such "authorized generics" in reducing competition from other generic manufacturers. In this regard, the FTC is planning to issue a minimum of 190 subpoenas over the next six months, including 80 subpoenas to research pharmaceutical companies, 100 to independent generic manufacturers, and 10 to manufacturers of authorized generic drugs.

The Hatch-Waxman Act establishes the regulatory framework under which the FDA approves the marketing of generic drugs. In certain circumstances, under the Hatch-Waxman Act, the first generic manufacturer approved by the FDA is entitled to an 180-day exclusivity period for marketing its generic. The Hatch-Waxman Act also allows a research pharmaceutical company to license a generic drug company to manufacture an authorized generic drug. Unlike other generic manufacturers, an authorized generic manufacturer is not prohibited from entering the marketplace during the 180-day exclusivity period enjoyed by the first approved generic manufacturer.

The FTC has expressed concerns that the increase in the use of authorized generics may reduce the economic incentives for generic drug companies to develop generic products. At the same time, the FTC recognizes that authorized generics can reduce consumer costs by stimulating generic competition after generics enter the market. The FTC intends to collect and examine economic evidence from research pharmaceutical companies, including detailed sales information, information relating to patents held and listed by research companies, pricing and cost information (including rebates and discounts) as well as documents (including studies, surveys, analyses and reports) that evaluate, consider, analyze or discuss strategies as to how to respond to generic competition. A summary of the proposed study may be accessed on the FTC's website by clicking here.

Our experience leads us to believe that for most research pharmaceutical companies, the effort required to achieve proper compliance will be considerably more than that projected by the FTC. The lawyers in Ropes & Gray's Antitrust Practice Group are knowledgeable about these issues and we are prepared to represent and assist clients in connection with this investigation while ensuring the most efficient and effective use of company and legal resources.

Contact Information

If you have questions about the FTC's investigation or if your company is contacted by by the FTC, please do not hesitate to call or email your regular Ropes & Gray attorney, or contact one of the attorneys listed below.

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