Arnall Golden Gregory LLP

Client Alert

Contact Attorneys Regarding This Matter:

Jeffrey S. Jacobovitz
202.677.4056 - direct
jeffrey.jacobovitz@agg.com

Alan G. Minsk
404.873.8690 - direct
alan.minsk@agg.com

The FTC Sides with Generics on Innovator Sample Drug Availability

In a recent case[1] in the United States District Court for the District of New Jersey, the Federal Trade Commission (FTC) has sided with generic manufacturers regarding access to samples of medicines from innovator drug companies by filing an *amicus* (or Friend-of-the-Court) brief. The original lawsuit, filed by an innovator drug company, seeks declaratory relief that it is under no duty to supply prospective Abbreviated New Drug Application applicants with its brand name drug products for the purposes of bioequivalence testing and ANDA submissions.[2]

The FTC argues in its brief that innovator drug manufacturers that withhold samples from generic drugmakers are stifling competition. The brand company, in this preemptive lawsuit, has alleged that its generic drug competitors sent threatening letters asserting that the brand name drug manufacturer was obligated to provide samples. The innovator further alleged that it is prevented from providing samples under Risk Evaluation and Mitigation Strategy (REMS) stipulations, which relate, in very general terms, to specific plans to help mitigate potential risks asserted with the use of a particular drug.[3]

The FTC argued that the Hatch-Waxman Act, which provides, among other things, the generic drug approval pathway, would be undermined if generic drugmakers are unable to access samples of brand products. The FTC further noted that an innovator's refusal to sell to its potential competitors may, under certain circumstances, violate the antitrust laws. This type of exclusionary conduct could violate Section 1 and Section 2 of the Sherman Act.

This isn't the first time the FTC has jumped into the innovator-generic drug company competition fray. The FTC has become very aggressive in challenging pharmaceutical industry settlements of patent infringement litigation under the Hatch-Waxman Act. The settlement agreement provisions that have been subject to these lawsuits are referred to as "reverse payments" or "pay for delay" agreements. The federal courts are split their opinions on the legality of these agreements, and this issue is currently before the United

1 *Actelion Pharmaceuticals Ltd. v. Apotex Inc*. No. 1:12-cv-05743 (3rd Cir. March 11, 2013).
2 The brief can be found at: http://www.ftc.gov/os/2013/03/130311actelionamicusbrief.pdf
3 AGG has prepared a Bulletin on REMS, which can be accessed here: http://www.agg.com/FDA-Publishes-Draft-Guidance-on-Medication-Guides-in-Risk-Evaluation-and-Mitigation-Strategies-04-06-2011/

Arnall Golden Gregory LLP
Attorneys at Law

171 17th Street NW
Suite 2100
Atlanta, GA 30363-1031

Two South Biscayne Boulevard
One Biscayne Tower 2690
Miami, FL 33131

1775 Pennsylvania Avenue NW
Suite 1000
Washington DC 20006

www.agg.com

States Supreme Court.[4]

This most recent filing by the FTC is significant, because it is indicative of the careful scrutiny the agency undertakes in its Hatch-Waxman enforcement and its apparent preferences to protect generic drug market entry. This is also consistent with the current Department of Justice's enforcement in this area. *See* Department of Justice *amicus curiae* filing in *Schering-Plough Corp.* (2005)

4 Oral arguments of the issue were held before the Supreme Court on March 25, 2013 (*Federal Trade Commission v. Actavis, Inc.*, No. 12-416). AGG recently prepared a Bulletin on this topic, which can be accessed at: http://www.agg.com/Pay-for-Delay-Update--Supreme-Court-Enters-the-Fray-12-19-20121/.