DOJ's Investigation Into Generic Pharma Pricing Is Unusual

Law360, New York (November 12, 2014, 5:44 PM ET) -- The United States Department of Justice Antitrust Division recently served two U.S.-based generic pharmaceutical manufacturers — Lannett Co. Inc. and Impax Laboratories Inc. — with criminal grand jury subpoenas. It is reported that the subpoenas request all communications discussing generic pharmaceutical pricing and sales with competitors, and that they are not limited to particular products.[1]

The subpoenas signal a much broader federal investigation into potential Sherman Act violations in the generic pharmaceutical industry — with potential criminal implications for the companies and individuals involved. It is unusual that the DOJ, and not the Federal Trade Commission's Bureau of Competition, is investigating this industry and certainly significant that the DOJ issued criminal grand jury subpoenas to do so.

Others in the pharmaceutical industry should keep apprised of this investigation, consider how to bolster their antitrust compliance, and prepare a potential response to this new approach to investigation.

Significance of a DOJ Investigation in the Pharmaceutical Industry

The FTC and DOJ share authority in investigating potential breaches of the U.S. antitrust laws, but generally split responsibilities by industry. For example, the FTC assumes responsibility for investigations in the pharmaceutical industry (among many others), while the DOJ maintains responsibility for investigations in the financial services, telecommunications and transportation industries (also among many others). The DOJ maintains sole responsibility for prosecuting criminal antitrust violations such as price-fixing, bid-rigging and market allocation. (While the FTC may also investigate, and bring enforcement actions, for such conduct, it does not have criminal enforcement authority.)

This arrangement allows the agencies to develop experience and expertise within particular industries, therefore enabling federal investigations to proceed efficiently and ensuring equitable enforcement for consumers.

A DOJ investigation into the alleged exchange of pricing information in the pharmaceutical industry likely indicates that the agency anticipates uncovering criminal antitrust conduct in the form of price-fixing or customer allocation. The situation presents unique issues for the DOJ's Antitrust Division, which has less experience with the nuances of the pharmaceutical industry, and for the parties under investigation, which may have limited experience with criminal antitrust investigations. While the potential consequences of an antitrust investigation are always significant, the stakes are much higher when the conduct may
Greater Liability and Unique Processes of a Criminal Investigation

As pharmaceutical companies monitor this investigation and consider antitrust compliance programs, they should keep in mind the broader scope of potential liability as well as the procedural differences implicated by a criminal, versus civil, investigation.

First, and perhaps most notably, criminal antitrust investigations may reach beyond the corporate structure and focus on individuals, often leading to severe financial penalties and even jail time for those who participated in or condoned the illegal conduct.[2] Procedurally, the fact that there may be individual exposure adds complexity and costs to defending the investigation, particularly when certain employees require separate counsel.

Second, a company convicted of a criminal antitrust violation (or agreeing to plea to a criminal violation) faces significantly higher fines than typically faced in the civil context[3] and additional requirements, such as submitting to an external compliance monitor.

Finally, companies subject to criminal antitrust investigations frequently endure a slew of “follow-on” private cases, resulting in years of taxing litigation. Documents from criminal investigations, and even the public announcement of a DOJ investigation, may be used by plaintiffs to allege a violation, making prediscovery dismissal more difficult.

A DOJ criminal investigation also introduces governmental processes that may be new to many pharmaceutical companies. The DOJ’s investigational procedures are institutionally distinct from those of the FTC, involving unique elements such as the ”leniency program,” the “attorney proffer,” and “cooperation credit” under the United States Sentencing Guidelines.

A DOJ criminal investigation further raises unique issues for counsel who represent companies under investigation, such as “Upjohn Warnings.” Pharmaceutical companies unfamiliar with this terrain may struggle with preparing the proffer, leveraging cooperation in turn for leniency, juggling different witnesses, and knowing when to invoke constitutional protections. It is imperative that companies facing a criminal antitrust investigation react immediately and strategically to understand their potential defenses or secure an advantageous bargaining position to minimize corporate exposure and save employees from potential jail sentences.

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[3] The Sherman Act provides for a maximum fine of $100,000,000 for an antitrust violation. 15 U.S.C. 1. However, fines are typically much greater, given that Title 18 increases the potential exposure to “twice the gross gain or twice the gross loss.” 18 U.S.C. § 3571(d).