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DOJ Investigation Into Generic Pharma: You Could Be Next

Law360, New York (March 30, 2015, 10:19 AM ET) -- The U.S. Department of Justice Antitrust Division's investigation into the generic pharmaceutical industry may be expanding.[1] On March 15, 2015, a third generic manufacturer disclosed that it received a subpoena from the DOJ seeking "documents related to communications with competitors" concerning the supply of certain generic pharmaceuticals.[2] This announcement closely follows the disclosure that the DOJ issued a second subpoena to one of the original subpoena recipients.[3]



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The timing and breadth of these subpoenas suggest that the DOJ's investigation is progressing quickly. Given that DOJ criminal investigations often expand into other product areas due in part to the DOJ's amnesty program, it would be prudent for other generic suppliers in the pharmaceutical industry to prepare for potential similar inquiries from the DOJ. Indeed, the best preparation often involves proactively uncovering and disclosing potentially relevant information to the DOJ, as doing so can lead to immunity from prosecution.

The DOJ designed its "Amnesty Plus" program to encourage companies under investigation to continue cooperating with the government by uncovering more illegal conduct. Under Amnesty Plus, a company under investigation for one cartel offense that discovers and informs the DOJ about another cartel offense may receive immunity for the second offense as well as a reduction in penalties (or a "credit") for the original offense.

Conversely, if the company knows of a separate conspiracy but does not disclose it to the DOJ, it is possible the DOJ will argue for a harsher sentence because the failure to disclose constitutes an aggravating factor. This is referred to as the DOJ's "Penalty Plus" policy, and this policy together with Amnesty Plus forms the DOJ's carrot-and-stick approach to cartel enforcement.[4]

The incentives created by the Amnesty Plus and Penalty Plus programs frequently accelerate DOJ criminal investigations. Take, for instance, the DOJ's investigation into cartels in the automobile parts industry. The DOJ announced its first settlement with a member of an auto parts cartel in 2011, and since then it has become "the largest criminal investigation the Antitrust Division has ever pursued." [5] The DOJ has brought charges against 49 individuals, secured plea agreements with 32 companies, and imposed more than \$2.4 billion in criminal fines, all in large part because those under investigation in one product cartel recognized the benefit of alerting the DOJ to another cartel in a different product.

Attorney General Eric Holder proclaimed, "[A]s we have uncovered each auto part conspiracy, we have continued to find more and more parts that are involved ... We will continue to check

under every hood and kick every tire to make sure we put an end to this illegal and destructive conduct.”[6] This is why generic companies that have not yet received subpoenas may want to consider being proactive and uncover potential anti-competitive conduct before hearing from the DOJ. Furthermore, qualifying leniency applicants may benefit from the “detrebling provisions” of the Antitrust Criminal Penalty Enhancement and Reform Act of 2004[7] in often inevitable follow-on civil cases.

The recent disclosures by generic pharmaceutical companies regarding the DOJ probes suggest that the list of products under investigation could be expanding much like in the auto parts investigation. The most recent disclosure is the first to specify the products at issue in the investigation.

According to the U.S. Securities and Exchange Commission filing, the DOJ has requested information pertaining to two generic products,[8] including an oral tablet treatment for heart conditions and all forms of an antibiotic used to treat various bacterial infections. It is unknown whether the investigation is limited to these two products, or whether this is merely the extent of one company’s exposure. Indeed, the disclosure that the DOJ issued a second subpoena to one of the original recipients broadly states that the DOJ is requesting documents “relating to ... communications or correspondence with competitors regarding the sale of generic prescription medications, and the marketing, sale, or pricing of certain products.”[9] While there is not clarity on which specific products may be at issue with regard to that subpoena, it is clear that the DOJ’s investigation is not limited to a specific ailment or a specific formulation.

In addition, it is noteworthy that all three generic manufacturers receiving subpoenas from the DOJ in the past four months also received subpoenas from Connecticut Attorney General George Jepsen during the summer of 2014. There could very well be a direct connection between Connecticut’s investigation and the DOJ’s investigation.[10] It is not uncommon for the state attorneys general to cooperate with the DOJ in their investigations. Further, the participation of a state attorney general could add significant resources to the overall investigation, which only increases the likelihood that the investigation expands into other product areas and, therefore, to other companies.

Given the expanding scope of the DOJ’s investigation, it appears that the DOJ is committing significant resources to this probe and that additional companies could be drawn into the investigation. Thus, generic pharmaceutical manufacturers (including brand pharmaceutical companies that sell or market authorized generics) may have potential exposure and should quickly ascertain their position and develop a plan to address this investigation. Cooperating quickly and introducing the DOJ to new information could be the difference between complete immunity (or a nominal fine) and substantial penalties, including jail time for executives.[11]

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[1] For information regarding the criminal antitrust investigation process, and the potential

impact this may have on generic manufacturers, please see our WSGR Alert here.

[2] Par Pharmaceutical Companies, Inc. Annual Report (March 13, 2015), available at <https://www.sec.gov/Archives/edgar/data/878088/000087808815000002/prx-20141231x10k.htm>.

[3] Lannett Company, Inc. Quarterly Report (February 6, 2015), available at http://www.sec.gov/Archives/edgar/data/57725/000110465915007227/a14-26533_110q.htm.

[4] Scott D. Hammond, Director of Criminal Enforcement, Antitrust Division, Department of Justice, "Cornerstones of an Effective Leniency Program," Address Before the ICN Workshop on Leniency Programs (November 22-23, 2004), available at <http://www.justice.gov/atr/public/speeches/206611.pdf>.

[5] U.S. Department of Justice, Antitrust Division, Division Update Spring 2012, available at <http://www.justice.gov/atr/public/division-update/2012/criminal-program.html>.

[6] Eric Holder, Attorney General, Speech at Auto Parts Press Conference (September 26, 2013), available at <http://www.justice.gov/iso/opa/ag/speeches/2013/ag-speech-1309261.html>.

[7] Antitrust Criminal Penalty Enhancement and Reform Act of 2004, Pub. L. No. 108-237, §§ 211-214, et seq. (codified at 15 U.S.C. § 1 note as amended by Pub. L. No. 111-190)).

[8] Par Pharmaceuticals reports that the DOJ has requested information concerning "our authorized generic version of Covis's Lanoxin® (digoxin) oral tablets and our generic doxycycline products." Par Pharmaceuticals Annual Report, supra note 2.

[9] Lannett Quarterly Report, supra note 3.

[10] In fact, while Connecticut Attorney General George Jepsen's investigation certainly included digoxin, it is not clear that it also included doxycycline. See Ed Silverman, "Justice Department Probes Generic Companies After Price Hike Reports," *The Wall Street Journal* (November 10, 2014), available at <http://blogs.wsj.com/pharmalot/2014/11/10/justice-department-probes-generic-competition-after-price-hike-reports/>. This appears to be the first time this particular compound has been included, and it is noteworthy that the disclosure did not specify a type or dose of doxycycline, but rather "generic doxycycline products." Par Pharmaceuticals Annual Report, supra note 2.

[11] The Sherman Act provides for a maximum corporate fine of \$100,000,000 or "twice the gross gain or twice the gross loss" for an antitrust violation. 15 U.S.C. § 1; 18 U.S.C. § 3571(d). Individuals are subject to a maximum fine of \$1,000,000 and a maximum jail sentence of 10 years. 15 U.S.C. § 1.

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