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Federal Trade Commission Deploys Antitrust Weaponry Against Pharmaceutical Company

In *Federal Trade Commission v. Shire ViroPharma Inc.* (D. Del. Feb. 7, 2017), the FTC has, for the first time, deployed its antitrust weaponry against a pharmaceutical company's alleged practice of using the FDA's citizen-petition process to forestall generic entry.

In 2007, Congress amended § 505 of the Food, Drug, and Cosmetic Act to address a perceived abuse of the FDA's citizen-petition process: some branded-drug manufacturers were filing citizen petitions with the FDA in a purported effort to blunt generic competition. The new § 505(q) provided that the FDA could not delay approval of an Abbreviated New Drug Application ("ANDA") despite a pending citizen petition unless the FDA determined that a delay was necessary to protect public health.

Eight years later, the FDA reported that § 505(q) was not sufficiently discouraging the submission of citizen petitions purportedly aimed at delaying generic entry.

Enter the FTC. Several antitrust challenges have been brought by consumers and generic manufacturers against branded drug companies purportedly using the FDA citizen-petition process to block or delay generic entry—with varying results. But until last week the FTC had not deployed its antitrust weaponry in this arena.

That changed when, on February 7, the FTC filed a complaint in federal court in Delaware against Shire ViroPharma Inc. requesting injunctive and other equitable relief, including disgorgement. The complaint alleges that the financial success of ViroPharma's Vancocin Capsules, an antibiotic, attracted generic manufacturers. But those manufacturers were discouraged from entering the market by the FDA's then-existing requirement that companies seeking to develop generic drugs conduct *in vivo* clinical endpoint studies to establish bioequivalence. In February 2006, however, the FDA advised that it would accept an alternative means of establishing bioequivalence (through *in vitro* dissolution data). Three generic manufacturers submitted ANDAs for Vancocin Capsules in 2007. The FDA approved all three on April 9, 2012, the same day it disposed of ViroPharma's filings.

The FTC asserts in its suit that, until generic drug manufacturers entered the market in April 2012, ViroPharma commanded 100% of the Vancocin Capsules market share. The Complaint further alleges that ViroPharma maintained and extended its "monopoly power" by

submitting 46 filings to the FDA and courts— "the most filings that any firm has ever made to the FDA concerning a single drug product." The FTC argues that the filings constituted "wrongful and exclusionary conduct" because they allegedly harmed competition by delaying the approval process for generics and harmed consumers by denying access to generics at lower prices. The FTC has also questioned the timing of ViroPharma's citizen petitions, some of which were within weeks of the filing of generic manufacturers' ANDAs or other key developments in paving the way for generic entry.

To succeed in its lawsuit, the FTC has several hurdles to overcome in trying to prove that filing citizen petitions violates antitrust laws. Among them are the unique nature of the suit and the fact-intensive nature of the Complaint's allegations. The FTC also must overcome the *Noerr-Pennington* doctrine, a judicial rule immunizing efforts to petition the government even if made for anticompetitive purposes. The FTC must establish that ViroPharma made objectively baseless and improperly motivated filings in an effort to thwart competition by generics. ViroPharma will likely argue that it was exercising its constitutional rights and that it properly submitted citizen petitions, noting that 17 of its submissions were public comments. And as evidence that its citizen petitions were proper, ViroPharma will likely point to the 85-page report that the FDA issued to address the legal, procedural, and scientific issues raised by ViroPharma.

Because the outcome of previous challenges have been varied—and also because determining whether a petition is baseless is a fact-specific inquiry—it is difficult to predict the outcome of FTC's case. But the outcome will undoubtedly have a significant impact on both pharmaceutical and antitrust litigation; accordingly, we will be closely monitoring the suit's progress.

Questions:

If you have any questions about this alert, please contact Jill O'Toole (jotoole@goodwin.com or (860) 251-5909) or Jennifer Brooks Crozier (jcrozier@goodwin.com or (203) 836-2810).

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