



## FTC Appeals Dismissal of Antitrust Lawsuit Alleging Abuse of Government Processes to Delay Generic Competition

Jeffrey S. Jacobovitz and Bradford J. Kelley

The Federal Trade Commission (FTC) has appealed a Delaware federal court's recent dismissal of the FTC's suit against Shire ViroPharma Inc. ("ViroPharma") alleging anticompetitive conduct. The appeal, *FTC v. Shire ViroPharma Inc.*,<sup>1</sup> was filed with the U.S. Court of Appeals for the Third Circuit.

On February 7, 2017, the FTC filed its complaint in *FTC v. Shire ViroPharma Inc.*, No. 17-cv-131 (D. Del. Mar. 20, 2018) in the U.S. District Court for the District of Delaware, alleging that ViroPharma engaged in an unfair method of competition in violation of Section 5(a) of the FTC Act. More specifically, the FTC alleged that ViroPharma abused government processes to slow and deter the approval by the U.S. Food and Drug Administration (FDA) of a generic drug to compete with its branded prescription drug, Vancocin HCl Capsules. The complaint alleged that between 2006 and 2012, ViroPharma engaged in an anti-competitive campaign of repetitive and meritless filings with the FDA, along with related litigation, to delay and obstruct the entry of generic competition and therefore maintain its monopoly on Vancocin. The FTC's suit sought a permanent injunction against ViroPharma under Section 13(b) of the FTC Act.

In its motion to dismiss, ViroPharma argued that the FTC must demonstrate that ViroPharma "is violating, or is about to violate" a law enforced by the FTC in order to obtain a permanent injunction pursuant to Section 13(b), and that the FTC failed to do so. ViroPharma also argued that its activities were protected petitioning activity under the *Noerr-Pennington* doctrine, which gives broad immunity from liability to those who petition the government, including administrative agencies and courts, for redress of their grievances, unless it involves sham petitioning.

On March 20, 2018, Judge Richard Andrews granted ViroPharma's motion to dismiss. The court agreed that the FTC failed to make a required showing that ViroPharma was violating (or was about to violate) a law enforced by the FTC. After reviewing Section 13(b)'s statutory language and legislative history, the court held that the relevant provision does not create an independent grant of authority. The court explained that the language "is violating, or is about to violate" is not properly understood to mean that the violation is merely "likely to recur." The court rejected the FTC's argument that its 46-page complaint alleged facts that plausibly suggested that ViroPharma "is about to violate" a law enforced by the FTC, especially in light of the fact that the alleged misconduct ended almost five years before the complaint was even filed. The court held that the FTC's allegations were not barred by the *Noerr-Pennington* doctrine because the issue of whether ViroPharma's activity was in fact a sham constitutes a factual inquiry that could not be resolved at the motion to dismiss stage.

Even though the court granted ViroPharma's motion to dismiss, the court expressly gave FTC leave to amend its complaint. Instead, on April 11, 2018, the FTC filed a notice of appeal to the Third Circuit. The FTC states in its notice of appeal that "[t]he FTC has elected to stand on its original complaint for purposes of taking an appeal from the Memorandum Order [dismissing the case]." The FTC's brief is presently due to be filed by June 5, 2018, and ViroPharma's responsive brief must be filed 30 days thereafter.

The FTC's decision to appeal the ruling rather than amend the complaint shows the perceived significance of the district court's ruling. The decision constituted a loss for the FTC, which is

<sup>1</sup> No. 18-1807 (3d Cir. filed Apr. 11, 2018).

underscored by the fact that the decision has already been cited against the FTC in four other pending cases.<sup>2</sup> For example, in *Endo Pharmaceuticals Inc., et al. v. FTC*, Plaintiffs Watson Laboratories, Inc. and Allergan Finance, LLC filed a notice of supplemental authority in support of their motion for summary judgment on the same day the decision was issued to strengthen their argument that the FTC lacks authority to challenge their wholly past conduct in federal court under Section 13(b) because that statute only authorizes the agency to file suit when a party “is violating, or is about to violate” the law.<sup>3</sup>

The Third Circuit has rendered opinions in a number of noteworthy pharmaceutical antitrust cases in the past.<sup>4</sup> It is also noteworthy that two of the pending cases in which the Delaware federal court’s decision has already been cited against the FTC are in the Third Circuit.<sup>5</sup>

The decision to appeal further suggests that the newly installed FTC Chairman and Commissioners will continue to aggressively target alleged abusers of government processes that might harm competition and consumers, especially as it relates to generic drugs.<sup>6</sup> In a press release issued when the FTC filed its complaint against ViroPharma, former FTC Acting Chairman Maureen K. Ohlhausen stated, “[w]hen we have reason to believe that a branded drug company misuses government processes to unlawfully maintain a monopoly by delaying generic entry, the FTC will act to protect competition.” Indeed, the Commission voted unanimously to file the complaint against ViroPharma in 2017.

Ultimately, this appeal underscores that the FTC will continue to focus on both branded and generic manufacturers. These cases are becoming increasingly frequent in nature and will likely continue with robust enforcement.

If you have any questions regarding antitrust issues, please contact Jeffrey S. Jacobovitz, Chair of Arnall Golden Gregory’s Antitrust and Competition Group. Mr. Jacobovitz is a former attorney in the Bureau of Competition at the FTC. Bradford J. Kelley is an Associate in Arnall Golden Gregory LLP’s Washington, D.C. office.

<sup>2</sup> See *FTC v. Abbvie, Inc.*, No. 2:14-cv-5151 (E.D. Pa.); *Endo Pharmaceuticals Inc., et al. v. FTC*, No. 2:16-cv-5599 (E.D. Pa.); *FTC et al. v. Next-Gen, Inc., et al.*, No. 4:18-cv-128 (W.D. Mo.); and *FTC v. Hornbeam Special Situations, LLC, et al.*, No. 1:17-cv-3094 (N.D. Ga.).

<sup>3</sup> *Endo Pharmaceuticals Inc., et al. v. FTC*, No. 2:16-cv-5599 (E.D. Pa.).

<sup>4</sup> See, e.g., *SigmaPharm, Inc. v. Mut. Pharm. Co.*, 454 F. App’x 64 (3d Cir. 2011); *Ethypharm S.A. France v. Abbott Labs.*, 707 F.3d 223 (3d Cir. 2013).

<sup>5</sup> See *FTC v. Abbvie, Inc.*, No. 2:14-cv-5151 (E.D. Pa.); *Endo Pharmaceuticals Inc., et al. v. FTC*, No. 2:16-cv-5599 (E.D. Pa.).

<sup>6</sup> In April of 2018, the Senate confirmed all five of President Trump’s nominees to serve on the FTC. See Harper Neidig, *Senate confirms full slate of FTC commissioners*, THE HILL, Apr. 26, 2018, <http://thehill.com/policy/technology/385096-senate-confirms-full-slate-of-ftc-commissioners>.

## Authors and Contributors

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**Jeffrey S. Jacobovitz**

Partner, DC Office  
202.677.4056  
jeffrey.jacobovitz@agg.com

**Bradford S. Kelley**

Associate, DC Office  
202.677.4920  
bradford.kelley@agg.com

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