



Recent Third Circuit Case Will Impact FTC Enforcement in the Pharmaceutical Space and Beyond: FTC v. ShireViroPharma, Inc.

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On February 25, 2019, the Third Circuit Court of Appeals issued a significant decision that will likely affect the scope, timing, and venue of future enforcement actions initiated by the U.S. Federal Trade Commission (FTC). In the case of FTC v. ShireViroPharma, Inc. (“Shire” or “Company”),² the Court not only found for the defendant in the particular case at issue, but also made findings that may affect future FTC actions, particularly its holding regarding the “about to violate the law” standard in Section 13(b) of the FTC Act.³ Below, we provide a brief summary of the key holdings and potential implications of the case.

Background

The FTC initially filed a complaint against Shire in U.S. District Court in 2017, alleging that the company had violated the FTC Act by engaging in a variety of anti-competitive behaviors in order to deter or delay market entry of generic competitors to one of its brand-name drugs (Vancocin).^{4, 5} The FTC requested a permanent injunction of the anti-competitive behavior under Section 13(b) of the FTC Act, as well as restitution and disgorgement of the profits gained by delaying the entry of generic products to the market.

The District Court dismissed the case in 2018, finding, among other things, that the FTC had failed to plead sufficient facts to establish that the company “is violating, or is about to violate” the law, as required by Section 13(b). The FTC appealed the dismissal to the Third Circuit Court of Appeals.

The Third Circuit held in favor of Shire. Some notable items addressed by the Third Circuit panel opinion include: (i) the FTC did not bring the case until almost five years after the alleged violations had ceased; (ii) the company no longer owned Vancocin when the case was filed; and (iii) the FTC’s reading of Section 13(b) of the FTC Act was considered overbroad by the Court (e.g., the FTC argued that Section 13(b)’s standard for whether a respondent is “about to violate” is met by past violations coupled with a likelihood of future violations).

Key Findings

Key holdings and observations of the Third Circuit panel include: (i) that Section 13(b) requires the FTC to bring a case only when it can show that a defendant “is violating” or “is about to violate” the law, and that violations that occurred in the past or may potentially occur in the future (or both) are not sufficient, and (ii) that Section 13(b) is only intended for use while an administrative action is pending.

Regarding the timing of the violative acts, the Third Circuit panel agreed with the District Court’s dismissal of the case on the basis that the FTC failed to meet the “about to violate” standard.

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² FTC v. ShireViroPharma, Inc., No. 18-1807, slip op. (3rd Cir. Feb. 25, 2019).

³ 15 U.S.C. § 53(b).

⁴ FTC v. ShireViroPharma, Inc., No. 1-17-cv-00131 (D. Del. 2018).

⁵ The FTC alleged that Shire engaged in unfair competition through numerous abuses of the Food and Drug Administration’s petition and drug approval processes as well as allegedly meritless court filings, all for the purpose of protecting Vancocin from generic drug competition. A discussion of such alleged “gaming” of FDA regulatory processes and other anti-competitive behavior in the pharmaceutical space is beyond the scope of this article.

Among other things, the Court noted that the alleged misconduct had ended nearly five years before the complaint was filed, that the Company no longer owned the product that was the subject of the alleged violations, and that the FTC had not alleged in the complaint that the Company was about to violate the law.

However, the Court did not stop there. Not only did the Court find against FTC with regard to the Shire case, in which the alleged violations were nearly five years in the past, but the Court went on indicate its view that the FTC's "about to violate" argument was an overbroad reading of Section 13(b). For example, in the introduction to the opinion, the Court stated: "We reject the FTC's invitation to stretch Section 13(b) beyond its clear text."⁶ The opinion goes on to affirm that the "about to violate" standard requires more than a past violation and a likelihood of future recurrence. Rather, it requires ongoing or impending illegal conduct.

Regarding what is required to meet the Section 13(b) standard, the Court also noted that the stated legislative purpose of Section 13(b) is to halt unfair and deceptive practices while an administrative proceeding is pending, and the Court suggests bringing 13(b) cases only in that context. The Court suggested that past acts could be addressed through the FTC's administrative proceedings under Section 5 of the FTC Act.

AGG Observations

- The precedent is binding only in the Third Circuit, and we are not aware of how many other jurisdictions, if any, will follow the Third Circuit's approach. We also do not know if the FTC will appeal this ruling or the outcome of any appeal.
- The FTC continues to have an array of administrative proceedings available. However, among other differences between FTC lawsuits and agency administrative proceedings, cases brought under Section 13(b) generally progress faster and offer the potential of significantly greater monetary penalties than those available through administrative penalties. The FTC has taken the position that they are likewise entitled to significant monetary penalties under Section 5.
- As the FTC adjusts to the Court's findings regarding the "about to violate" standard, it is likely to make changes in its investigative and prosecutorial strategy. For example:
 - The agency may conduct and complete investigations more quickly in order to bring related cases sooner.
 - The agency may be more likely to initiate administrative proceedings than it was before the opinion. Among other things, this would allow the FTC to meet the pending administrative proceeding standard described by the Court, and, while the action is pending, the agency could then consider whether the situation also meets the standards for a Section 13(b) case.
 - The agency may be less willing to spend time in discussion and negotiation with companies under investigation before it decides whether or not to initiate an administrative proceeding or file a complaint under Section 13(b).
- Effects on certain FDA regulatory and enforcement actions are possible, given that this case related directly to alleged abuses of FDA regulatory processes and that FDA frequently works with the FTC to identify and address anti-competitive behavior.
- Given that Section 13(b) of the FTC Act is not limited to the pharmaceutical industry, there will likely be downstream effects of this decision on FTC enforcement in other areas.

⁶ Slip op., *supra* note 1, at 5.

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