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The US Court of Appeals for the Third Circuit Court dismisses a complaint only based on past conduct against a pharmaceutical company *(Shire Viropharma)*

PROCEDURES, PHARMACEUTICAL, BARRIERS TO ENTRY, ADMISSIBILITY (COMPLAINT), COMPETENCE, UNITED STATES OF AMERICA, CONSUMER PROTECTION, PAY-FOR-DELAY

FTC, Complaint against Shire Viropharma, 7 February 2017
US Court of Appeals for the Third Circuit, FTC / Viropharma, No. 18-1807, 25 February 2019

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On February 25, 2019, the Third Circuit held that the Federal Trade Commission cannot bring litigation in federal court based on past conduct, absent factual allegations demonstrating that a defendant "is violating or is about to violate" the laws enforced by the FTC. In doing so, the court affirmed the dismissal of a case brought by the FTC alleging that defendant Shire ViroPharma, Inc. ("Shire") had violated the antitrust laws by engaging in serial, sham petitioning of the United States Food and Drug Administration (FDA). Neither the district court's decision nor the Third Circuit's affirmance relied on the substance of the underlying allegations. Instead, both courts concluded that the FTC had overstepped its statutory authority by bringing the case in the first place. The Third Circuit's decision substantially limits the FTC's ability to litigate in federal court.

Background: The Federal Trade Commission Act

The FTC was established more than a century ago by the FTC Act, which provides the FTC with tools to prevent unfair methods of competition and unfair or deceptive practices. [*1*] Unlike the Department of Justice ("DOJ"), which has broad authority to challenge violations of the antitrust laws in federal court, the FTC's enforcement powers are circumscribed by the FTC Act. The FTC's traditional enforcement tool is its ability to file an administrative complaint initiating proceedings before an Administrative Law Judge. [*2*] In the administrative process, the FTC may obtain cease-and-desist orders and, if such an order is subsequently violated, may seek civil penalties.The FTC's action against Shire was based on another provision in the FTC Act, Section 13(b). [*3*] In summary, Section 13(b) allows the FTC to seek a temporary restraining order or injunction in federal court if the FTC has "reason to believe" that "any person . . . **is violating, or is about to violate**" any of the laws enforced by the FTC. [*4*] Section 13(b) was not part of the original FTC Act, but was subsequently added to allow the FTC "to quickly enjoin ongoing or imminent illegal conduct" while slow-moving administrative proceedings were pending. [*5*] Through Section 13(b), the FTC is accordingly "empower[ed] . . . to speedily address ongoing or

impending illegal conduct, rather than wait for an administrative proceeding to conclude." [*6*] The FTC has been aggressive in making use of Section 13(b), including in its efforts to expand the relief under Section 13(b) to include disgorgement. [*7*]

FTC v. Shire ViroPharma Litigation

In February 2017, the FTC filed a Complaint in federal court alleging that Shire had violated the FTC Act by abusing the FDA's regulatory processes to delay the entry of generic versions of Vancocin Capsules, a branded antibiotic. [*8*] The FTC alleged that Shire had filed multiple "sham" citizen petitions to obstruct and delay the FDA's approval of generic Vancocin Capsules. [*9*]

In the FTC's view, Shire's efforts delayed the approval of generic Vancocin Capsules for several years, until 2012. The FTC's Complaint sought injunctive relief and disgorgement.Shire moved to dismiss the FTC's claims on two grounds. First, Shire argued that the FTC had improperly sought an injunction because the alleged unlawful conduct—delaying the approval of generic Vancocin Capsules from 2010 until 2012—occurred in the past and Shire was accordingly not "violating or about to violate" the law within the meaning of Section 13(b). [*10*]

Second, Shire argued that its conduct was protected by Noerr-Pennington immunity, which generally bars antitrust liability based on petitioning the government. [*11*]While the district judge ultimately found that the FTC had adequately pleaded a "sham" exception to Noerr-Pennington immunity, he dismissed the FTC's claims on the grounds that the FTC had not sufficiently pleaded facts that "plausibly suggest[ed]" that Shire was "about to violate" any law. [*12*]

On appeal, the FTC argued that its Complaint should have been allowed to proceed because they had pleaded a "reasonable likelihood that past violations will recur." [*13*] The FTC also argued that Section 13(b) should be construed broadly and consistently with similar securities laws that authorize the Securities and Exchange Commission to seek injunctions. [*14*]The Third Circuit, however, resoundingly rejected the FTC's arguments. As the court explained, Section 13(b) is "unambiguous; it prohibits existing or impending conduct . . . [and] does not permit the FTC to bring a claim based on long-past conduct without some evidence that the defendant 'is' committing or 'is about to' commit another violation." [*15*] While the FTC cited a "parade of horribles" that would unfold without the ability to bring Section 13(b) cases in federal court for past conduct, the Third Circuit explained that the FTC could—and was required to—bring administrative proceedings instead. [*16*]

Key Takeaways

The FTC's use of Section 13(b) to file antitrust litigation in federal court attacking past conduct had gone largely unchallenged until recently. In antitrust litigation involving the drug Opana ER, filed about a year before the FTC's action against Shire, the parties challenged the agency's statutory authority to do so, first in a motion to dismiss and then in declaratory judgment actions. [*17*] But, for reasons related to the unique procedural posture of that case, the court never reached the merits of the argument. The courts in Shire ViroPharma are, therefore, the first to explicitly reject the FTC's use of Section 13(b) to seek relief in federal court for an alleged antitrust violation that occurred in the past. There are a few key takeaways.First, the Third Circuit's decision is a major blow to the FTC's ability to bring so-called "conduct" cases (as opposed to cases challenging pending mergers) in federal court. The Third Circuit's clear reasoning and straightforward construction of the statute may prove persuasive to other Courts of Appeal should the FTC try to bring a Section 13(b) case for past conduct elsewhere. The FTC relies on Section 13(b) in part because it is a "less onerous enforcement mechanism," [*18*] but also because some courts have permitted the FTC to seek large monetary sums as "ancillary" equitable relief in the form of disgorgement. [*19*]

Forcing the FTC to litigate conduct cases in administrative proceedings for cease-and-desist orders removes a potentially potent tool from the FTC's enforcement toolbox.Second, if the FTC does continue to pursue Section 13(b) cases in federal court based on past conduct, litigants should expect the FTC to be more careful in developing a record during the investigation phase showing an imminent likelihood that an antitrust violation might recur. The Third Circuit chided the FTC's "woefully inadequate" allegations that Shire might be "about to violate" the antitrust laws again. [*20*] As the court noted, the FTC relied on bare allegations that Shire "has the incentive and opportunity to continue to engage in similar conduct in the future" because it "marketed and developed drug products for commercial sale in the United States, and it could do so in the future." [*21*] Such reasoning would apply to any company that remained in business.Third, while the Third Circuit did not weigh in on the merits of the FTC's allegations, we note that the district court rejected defendants' Noerr-Pennington immunity defense. While Shire succeeded in getting the FTC's federal court case dismissed, the FTC preserved its ability to challenge the alleged abuse of FDA procedures as a potential violation of the antitrust laws.

[*1*] 15 U.S.C. § 41.

[*2*] See id. § 45(b).

[*3*] See id. § 53(b).

[*4*] Id. (emphasis added).

[*5*] FTC v. Shire ViroPharma, Inc., No. 18-1807, 2019 WL 908577, at *6 (3d Cir. Feb. 25, 2019).

[*6*] Id.

[*7*] Some courts have been receptive to the FTC's arguments that Section 13(b) permits the FTC to seek monetary relief. See, e.g., FTC v. Ross, 743 F.3d 886, 890-92 (4th Cir. 2014) (Section 13(b) confers power to award "monetary consumer redress, which is a form of equitable relief"); FTC v. Bronson Partners, LLC, 654 F.3d 359, 365 (2d Cir. 2011) ("Section 13(b) permits a court to order ancillary equitable relief, including monetary relief"); FTC v. Freecom Commc'ns, Inc., 401 F.3d 1192, 1202 n.6 (10th Cir. 2005) ("[Section] 13(b)'s grant of authority to provide injunctive relief carries with it the full range of equitable remedies, including the power to grant consumer redress").

[*8*] The FTC's Complaint is available here: *https://www.ftc.gov/system/files/documents/cases/170216viropharma_unredacted_sealed_complaint_.pdf* ↗.

[*9*] Companies may file citizen petitions with the FDA requesting that the FDA take some action, including actions pertaining to the FDA's evaluation of pending generic drug applications.

[*10*] FTC v. Shire ViroPharma Inc., No. 17-131, 2018 WL 1401329, at *3 (D. Del. Mar. 20, 2018).

[*11*] Id. at *7.

[12] Id. at *6.

[13] Shire ViroPharma, 2019 WL 908577, at *7.

[14] Id. at *8-9.

[15] Id. at *7 (internal citations omitted).

[16] Id. at 9.

[17] See FTC v. Endo Pharm. Inc., Case No. 16-1440, Doc. 69 (E.D. Pa.) (Defendants' motion to dismiss FTC's claims based on FTC's failure to allege that defendants were violating or about to violate the law); see also Endo Pharm. Inc. v. FTC, 345 F. Supp. 3d 554, 557 (E.D. Pa. 2018) (explaining that parties had previously argued that "the FTC could not proceed in federal court because the FTC Act does not authorize the Commission to challenge in court only past conduct" and observing that such argument was "anything but frivolous").

[18] Shire ViroPharma, 2019 WL 908577, at *9.

[19] See FTC v. Cephalon, Inc., 100 F. Supp. 3d 433 (E.D. Pa. 2015).

[20] Shire ViroPharma, 2019 WL 908577, at *10.

[21] Id.