PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 18-1807

FEDERAL TRADE COMMISSION,
Appellant

v.

SHIRE VIROPHARMA, INC.

On Appeal from the United States District Court
for the District of Delaware
District Court No. 1-17-cv-00131
District Judge: The Honorable Richard G. Andrews

Argued December 11, 2018

Before: SMITH, *Chief Judge*, McKEE, and FISHER,
Circuit Judges

(Filed: February 25, 2019)

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OPINION OF THE COURT

SMITH, *Chief Judge*.

Shire ViroPharma, Inc. ("Shire"),[1] manufactured and marketed the lucrative drug Vancocin, which is indicated to treat a life-threatening gastrointestinal infection. After Shire got wind that manufacturers were considering making generic equivalents to Vancocin, it inundated the United States Food and Drug Administration ("FDA") with allegedly meritless filings to delay approval of those generics. The FDA eventually rejected Shire's filings and approved generic equivalents to Vancocin, but the filings nonetheless resulted in a high cost to consumers—Shire had delayed generic entry for years and reaped hundreds of millions of dollars in profits.

Nearly five years later—and after Shire had divested itself of Vancocin—the Federal Trade Commission ("FTC") filed suit against Shire in the United States District Court for the District of Delaware under Section 13(b) of the Federal Trade Commission Act, 15 U.S.C. § 53(b). The FTC sought a permanent injunction and restitution, alleging that Shire's petitioning was an unfair method of competition prohibited by the Act. Shire moved to dismiss, arguing that the FTC's allegations of long-past petitioning activity failed to satisfy Section 13(b)'s requirement that Shire "is violating" or "is about

[1] Shire ViroPharma, Inc. is the corporate successor to ViroPharma, which it acquired in 2014—after the petitioning activity at issue in this case ceased.

to violate" the law. The District Court agreed and dismissed the case.

On appeal, the FTC urges us to adopt a more expansive view of Section 13(b). According to the FTC, the phrase "is violating, or is about to violate" in Section 13(b) is satisfied by showing a past violation and a reasonable likelihood of recurrent future conduct. We reject the FTC's invitation to stretch Section 13(b) beyond its clear text. The FTC admits that Shire is not currently violating the law. And the complaint fails to allege that Shire is about to violate the law. We will therefore affirm the District Court's judgment.

I.[2]

A.

A company that wishes to manufacture and market a new drug in the United States must submit to the FDA a New Drug Application ("NDA") demonstrating the safety

[2] We derive the facts of this case from the FTC's complaint. In our review of the grant of the motion to dismiss, we take the allegations to be true and construe them in the light most favorable to the FTC. *In re: Tower Air, Inc.*, 416 F.3d 229, 232 n.1 (3d Cir. 2005).

and efficacy of the product.[3] Usually, the NDA filer demonstrates safety and efficacy by using expensive *in vivo* clinical endpoint studies, where researchers provide sick patients with either the proposed drug or a placebo to compare the safety and efficacy of the drug with the placebo. *See Fed. Trade Comm'n v. Actavis, Inc.*, 570 U.S. 136, 142 (2013) (describing the "long, comprehensive, and costly testing process" underlying an NDA). After FDA approval, the manufacturer must seek approval through a supplemental NDA if it wishes to change the drug or its label.

A generic drug manufacturer need not file an NDA because it is essentially copying the approved branded drug. The generic manufacturer must instead file an Abbreviated New Drug Application ("ANDA"), which relies on the approved drug's profile for safety and efficacy. *See id.* ("The Hatch-Waxman process, by allowing the generic to piggy-back on the pioneer's

[3] The regulatory scheme employed by the FDA is governed by the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman"), Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271(e) (1994)), and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

approval efforts, speeds the introduction of low-cost generic drugs to market, thereby furthering drug competition." (internal alteration, quotation marks, and citation omitted)). The generic manufacturer must demonstrate, *inter alia*, that the proposed generic drug is bioequivalent to the referenced branded drug.[4] *See* 21 C.F.R. § 314.3(b) (defining bioequivalence as "the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalences or pharmaceutical alternatives becomes available at the site of drug action . . . .").

B.

Shire develops, manufactures, and markets branded drugs. Until Shire divested itself of the product in 2014,

[4] The FDA has flexibility in determining how a manufacturer must establish bioequivalence. *See, e.g.*, 21 C.F.R. § 320.24(a) (providing that the FDA may require either *in vivo* or *in vitro* studies to demonstrate bioequivalence).

this included Vancocin capsules.[5] Vancocin capsules are an oral antibiotic used to treat *Clostridium-difficile* associated diarrhea, which is a serious, potentially life-threatening gastrointestinal infection. When Vancocin capsules were developed, the NDA did not include *in vivo* clinical endpoint studies because the capsules were an alternative delivery system to Vancocin oral solution, which the FDA already knew to be safe and effective. Instead, the NDA included *in vitro* dissolution data (which measures how quickly the capsules dissolve) and *in vivo* pharmacokinetic data (which compares the absorption of the drug in capsule form versus oral solution form).

In April 1986, the FDA approved Vancocin capsules. Shire acquired Vancocin capsules in November 2004. From then until 2011, Vancocin capsules were Shire's largest revenue-generating product. Vancocin capsules accounted for all of Shire's net revenue until 2009 and up to 53% of its net revenue in 2011. United

[5] We take judicial notice of this fact—which is not in the complaint—from Shire's Form 8-K filings with the Securities Exchange Commission. Shire plc, *Form 8-K*, 5 (Oct. 24, 2014), https://bit.ly/2SxTOm8; *see Oran v. Stafford*, 226 F.3d 275, 289 (3d Cir. 2000) (taking judicial notice of SEC filings).

States sales for Vancocin capsules grew from $40 million in 2003 to almost $300 million in 2011.

Generic manufacturers, attracted by Vancocin's financial success, wanted to enter the market. Vancocin was vulnerable to generic competition because it lacked both patent protection and regulatory exclusivity. One primary barrier to generic entry remained—the FDA's recommendation that generic manufacturers seeking to demonstrate bioequivalence conduct *in vivo* clinical endpoint studies. Ironically, these tests were more expensive and onerous than the *in vitro* dissolution testing and *in vivo* pharmacokinetic studies that had been used to gain approval of Vancocin capsules in the first place. The FDA apparently realized this inconsistency; in October 2004 it convened a public meeting of the Advisory Committee for Pharmaceutical Science (the "Advisory Committee")[6] to reassess bioequivalence testing for locally-acting gastrointestinal drugs like Vancocin.

Shire became increasingly concerned that the FDA might allow generic manufacturers to demonstrate bioequivalence using *in vitro* data. Shire thus hired a

[6] The Advisory Committee is a body of sixteen independent experts from academia, non-profits, and hospitals. These experts are "knowledgeable in the fields of pharmaceutical sciences, clinical pharmacology, and gastrointestinal diseases." Compl. ¶ 85.

bioequivalence consultant to advise it on the FDA's likely course of action. In November 2005, the consultant confirmed Shire's suspicions, advising Shire that the FDA would likely allow generic manufacturers to submit *in vitro* dissolution data to establish bioequivalence to Vancocin capsules. The consultant counseled Shire to submit a citizen petition "sooner than later" but warned that without supporting clinical data, Shire "could not convince the FDA of its position against use of *in vitro* dissolution testing." Compl. ¶ 45.

Shire's fear came to pass: the FDA indeed changed its position on bioequivalence testing for Vancocin capsules. In February 2006, the FDA advised a generic manufacturer that bioequivalence for Vancocin capsules could be demonstrated by *in vitro* dissolution testing. The FDA also shared this guidance with other generic manufacturers that inquired. In March 2007, the first generic manufacturer submitted its ANDA for Vancocin capsules. Two other generic manufacturers followed suit later that year.

C.

Not surprisingly, Shire wanted to protect its monopoly on the Vancocin market. Among its options was a citizen petition. The First Amendment guarantees individuals the right to petition the government. U.S. Const. amend. I. Consistent with that right, the Administrative Procedure Act permits any "interested

person" to petition a federal agency "for the issuance, amendment, or repeal of a rule." 5 U.S.C. § 553(e); *see also* 21 C.F.R. § 10.30 (FDA regulation governing citizen petitions).

The filing of a citizen petition can substantially delay approval of a generic drug. During the time period at issue here, the FDA automatically suspended ANDA approval if a branded manufacturer filed a citizen petition.[7] The FDA is obligated to respond to every citizen petition within 180 days.[8] *Id.* § 10.30(e)(5); *see also* 21

[7] Although inapplicable to Shire's citizen petition, Congress passed the Food and Drug Administration Amendments Act of 2007 to assuage the FDA's fear that many brand manufacturers' citizen petitions were meritless attempts to delay generic competition. *See* 21 U.S.C. § 355(q). Post-2007, the FDA cannot delay ANDA approval due to a citizen petition unless "a delay is necessary to protect the public health." *Id.* § 355(q)(1)(A)(ii). Under the amendment, the FDA may also deny a citizen petition filed "with the primary purpose of delaying" ANDA approval that "does not on its face raise valid scientific or regulatory issues." *Id.* § 355(q)(1)(E).

[8] This time period has since been shortened to 150 days. 21 C.F.R. § 10.30(e)(5).

U.S.C. § 355(q)(1)(F). But the FDA's response need not dispose of the entire petition within that time. The FDA may deny the petition, approve it in whole or in part, provide a tentative response, or delay a decision by modifying or postponing any suggested action. *See* 21 C.F.R. § 10.30(e)(2)(i)–(iv).

From March 2006 to April 2012, Shire submitted a total of forty-three filings to the FDA and instituted three federal court proceedings—all allegedly to delay the approval of generic Vancocin capsules by convincing the FDA to require ANDA applicants to conduct *in vivo* clinical endpoint studies. Shire's filings ranged from a citizen petition and amendments thereto to public comments on other manufacturers' ANDAs. Many of these filings were around the same time Shire suspected the FDA was nearing approval of generic equivalents to Vancocin.

On April 9, 2012, the FDA rejected Shire's citizen petition.[9] The FDA concluded that Shire's scientific challenges to the bioequivalence recommendation "lack[ed] merit" and "were unsupported." Compl. ¶ 104 (internal quotation marks omitted); App. 77–95. On that same day the FDA approved three ANDAs for generic

[9] Shire did not prevail in any of its lawsuits, which were either dismissed or withdrawn.

Vancocin capsules. Shire lost almost 70% of its unit sales for Vancocin capsules within three months.

D.

Nearly five years later, on February 7, 2017, the FTC sued Shire, seeking a permanent injunction and equitable monetary relief under Section 13(b) of the FTC Act. The FTC claimed that Shire's conduct—submitting serial, meritless filings—had harmed consumers and competition because it enabled Shire to maintain and extend its monopoly by delaying the FDA's approval of generic alternatives to Vancocin capsules. *See* 15 U.S.C. § 45(a).

The FTC alleged that, absent an injunction, "there is a cognizable danger" that Shire will "engage in similar conduct causing future harm to competition and consumers." Compl. ¶ 150. It based this assertion on Shire's (1) knowledge that its petitioning campaign would enrich it at the expense of consumers; (2) incentive to engage in similar conduct in the future; and (3) opportunity to engage in similar conduct in the future. As to the third point, the FTC specifically alleged that Shire "marketed and developed drug products," namely Cinryze, "for commercial sale in the United States, and it could do so in the future." *Id.* ¶¶ 8, 151.

Shire moved to dismiss the complaint, arguing that the FTC had failed to plead sufficient facts to invoke its

authority under Section 13(b). Shire also contended that its petitioning activity was immune from antitrust challenge pursuant to the *Noerr-Pennington* doctrine. *See E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 136 (1961); *United Mine Workers of Am. v. Pennington*, 381 U.S. 657, 670 (1965). The FTC responded that Section 13(b) authorized its lawsuit and that Shire had engaged in sham petitioning, which is not protected by *Noerr-Pennington*.

The District Court granted Shire's motion to dismiss, ruling that the FTC had failed to plead sufficient facts to show that Shire "is violating, or is about to violate" the law.[10] The Court flatly rejected the FTC's contention that Shire was about to violate the law merely because it had the incentive and opportunity to engage in similar conduct in the future.

[10] Despite the District Court's grant of Shire's motion to dismiss—which was couched in jurisdictional terms—the Court also reached Shire's *Noerr-Pennington* defense. The Court declined to dismiss the case on these grounds, explaining that the allegations in the complaint were sufficient to invoke the sham petitioning exception—at least at the pleading stage. Because we affirm the District Court's dismissal, Shire's *Noerr-Pennington* defense is not before us on appeal.

The FTC filed this timely appeal.

II.

We begin by addressing whether Section 13(b)'s requirements are jurisdictional. The FTC contends that Section 13(b) is not jurisdictional while Shire argues the opposite. The District Court appears to have assumed—without expressly analyzing the issue—that Section 13(b) does *not* impose a jurisdictional requirement.[11]

The Supreme Court of the United States has instructed us to assume that statutory limitations are nonjurisdictional unless Congress provides otherwise. In *Arbaugh v. Y&H Corp.*, the Court addressed whether Title VII's definition of "employer" (which only includes those having fifteen or more employees) "affects federal-court subject-matter jurisdiction or, instead, delineates a substantive ingredient of a Title VII claim for relief." 546 U.S. 500, 503 (2006). The Court held that it was the latter, cautioning courts against "drive-by jurisdictional rulings"

[11] The District Court's opinion was murky on this point, citing both Rule 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure. At several points the District Court couched its inquiry as jurisdictional, yet still addressed the merits of Shire's *Noerr-Pennington* defense. Regardless of the District Court's conclusion, our review is plenary.

that fail to actually assess "whether the federal court had authority to adjudicate the claim in suit." *Id.* at 511 (citation omitted).

The Supreme Court reiterated that a plaintiff obtains the "basic statutory grant[]" of subject matter jurisdiction in 28 U.S.C. § 1331 by pleading a colorable claim that arises under the Constitution or the laws of the United States. *Id.* at 513. The plaintiff in *Arbaugh* had invoked federal question jurisdiction by pleading a claim under Title VII. *Id.* The Court held that the fifteen-employee threshold went to the merits of the Title VII claim, explaining that Congress had not clearly delineated it as a jurisdictional requirement. *Id.* at 514–16. The Supreme Court created a "readily administrable bright line"—"when Congress does not rank a statutory limitation on coverage as jurisdictional, courts should treat the restriction as nonjurisdictional in character." *Id.* at 516.

Under the standard announced in *Arbaugh*, Section 13(b)'s "is" or "is about to violate" requirement is nonjurisdictional. Section 13(b) provides, in relevant part:

Whenever the [FTC] has reason to believe—

> (1) that any person, partnership, or corporation *is violating, or is about to violate*, any provision of law enforced by the [FTC,] and
>
> (2) that the enjoining thereof pending the issuance of a complaint by the [FTC] and until such complaint is dismissed by the [FTC] or set aside by the court on review, or until the order of the [FTC] made thereon has become final, would be in the interest of the public—
>
> the [FTC] . . . may bring suit in a district court of the United States to enjoin any such act or practice.

15 U.S.C. § 53(b) (emphasis added).

The FTC's claim arises under a law of the United States—15 U.S.C. § 53(b). It thus falls within the general grant of jurisdiction in § 1331. The District Court also had jurisdiction under 28 U.S.C. §§ 1337(a) and 1345.

Section 13(b) includes no indicia that Congress intended to "rank a statutory limitation . . . as jurisdictional"; as such, we must follow the Supreme Court's "readily administrable bright line" rule and treat the statutory language as nonjurisdictional. *Arbaugh*, 546 U.S. at 516. Whether a person "is violating, or is about to

violate" the law relates to the merits of a Section 13(b) claim, and does not indicate that Congress intended to strip district courts of their authority to resolve the FTC's claim. Because "nothing in [Section 13(b)] displays any intent to withdraw federal jurisdiction . . . we will not presume that the statute means what it neither says nor fairly implies." *Verizon Md. Inc. v. Pub. Serv. Comm'n of Md.*, 535 U.S. 635, 644 (2002).

We conclude that the District Court had jurisdiction pursuant to 28 U.S.C. §§ 1331, 1337(a), and 1345.

III.[12]

A.

The FTC Act declares "[u]nfair methods of competition in or affecting commerce" to be unlawful, 15 U.S.C. § 45(a)(1), and directs the FTC to prevent violations of the Act, *id.* § 45(a)(2). The FTC has multiple instruments in its toolbox to combat unfair methods of competition; among these are administrative proceedings and lawsuits in federal court. *See id.* §§ 45(b), 53(b).

Section 5(b), the FTC's administrative remedy, is its traditional enforcement tool. *See id.* § 45(b). Since its inception, the FTC Act has provided for administrative

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[12] We exercise jurisdiction under 28 U.S.C. § 1291. Because Section 13(b)'s requirements are nonjurisdictional, we consider the dismissal to be under Rule 12(b)(6) of the Federal Rules of Civil Procedure. We exercise plenary review over the District Court's order granting a motion to dismiss for failure to state a claim. *Mariotti v. Mariotti Bldg. Prods., Inc.*, 714 F.3d 761, 765 (3d Cir. 2013). We accept "all well-pleaded allegations in the complaint as true and view[] them in the light most favorable to the plaintiff." *Id.* The movant can obtain relief only if the complaint's allegations, "however true, could not raise a claim of entitlement to relief." *Id.* (alteration and internal quotation marks omitted).

proceedings to remedy unfair methods of competition. Federal Trade Commission Act § 5, 38 Stat. 719 (1914) (current version at 15 U.S.C. § 45(b) (2018)). If the FTC has "reason to believe" that a person, partnership, or corporation "has been or is using" unfair methods of competition, the FTC can issue an administrative complaint "stating its charges in that respect." 15 U.S.C. § 45(b). If after receiving the FTC's complaint the respondent contests the charges, the parties adjudicate in a trial-type proceeding in front of an administrative law judge ("ALJ"). Either party may appeal the ALJ's decision. If the FTC believes the respondent is violating the law, it issues a written report and serves a cease and desist order upon the respondent. *Id.* The respondent has sixty days to seek review "in the appropriate court of appeals."[13] *Id.*

In addition to cease and desist orders, Section 5 provides for limited monetary remedies. If a respondent violates a cease and desist order, the FTC may seek a civil penalty of no more than $10,000 per violation. *Id.* § 45(l). The civil penalty is recoverable in a "civil action brought by the Attorney General." *Id.* The FTC may also file a civil action to recover a penalty for knowing violations of

[13] The appropriate court of appeals is "any circuit where the method of competition . . . was used or where [the respondent] resides or carries on business." 15 U.S.C. § 45(c).

rules "respecting unfair or deceptive acts or practices." *Id.* § 45(m)(1)(A). In these actions the District Court is permitted "to grant mandatory injunctions and such other and further equitable relief" as appropriate to enforce the FTC's final order. *Id.* § 45(l).

Section 13 authorizes the FTC—in certain circumstances—to file suit in federal district court. Unlike Section 5, Section 13 was not part of the original FTC Act. Rather, Section 13(b) was added later in an effort to solve one of the main problems of the FTC's relatively slow-moving administrative regime—the need to quickly enjoin ongoing or imminent illegal conduct. In Section 5 proceedings, the FTC must prevail to obtain a cease and desist order. *See id.* § 45(b). Even if the FTC issues a cease and desist order, it must seek a court's aid in enforcing the order. *Id.* § 45(l) To remedy this shortcoming and allow a quicker response, Congress amended the FTC Act in 1973 to allow the FTC to obtain a temporary restraining order or preliminary injunction in federal court whenever it "has reason to believe" that violations of the FTC Act are occurring or are about to occur. *Id.* § 53(b). Section 13(b) thus empowers the FTC to speedily address ongoing or impending illegal conduct, rather than wait for an administrative proceeding to conclude. *See id.*

B.

The crux of the FTC's claim is that it is entitled to pursue immediate relief in the District Court under Section 13(b), rather than via the administrative remedy set forth in Section 5. We begin with the text of the FTC Act. *See Murphy v. Millennium Radio Grp. LLC*, 650 F.3d 295, 302 (3d Cir. 2011) ("When the statute's language is plain, the sole function of the courts—at least where the disposition required by the [text] is not absurd—is to enforce it according to its terms." (internal quotation marks omitted)). Section 13(b) provides, in relevant part,

> Whenever the [FTC] has reason to believe—
>
> > (1) that any person, partnership, or corporation *is violating, or is about to violate,* any provision of law enforced by [the FTC,] and
> >
> > (2) that the enjoining thereof pending the issuance of a complaint by the [FTC] and until such complaint is dismissed by the [FTC] or set aside by the court on review, or until the order of the [FTC] made thereon has become final, would be in the interest of the public—

> the [FTC] by any of its attorneys designated by it for such purpose may bring suit in a district court of the United States to enjoin any such act or practice. Upon a proper showing that, weighing the equities and considering the [FTC]'s likelihood of ultimate success, such action would be in the public interest, and after notice to the defendant, a temporary restraining order or a preliminary injunction may be granted without bond: *Provided*, *however*, That if a complaint is not filed within such period (not exceeding 20 days) as may be specified by the court after issuance of the temporary restraining order or preliminary injunction, the order or injunction shall be dissolved by the court and be of no further force and effect: *Provided further*, That in proper cases the [FTC] may seek, and after proper proof, the court may issue, a permanent injunction.

15 U.S.C. § 53(b)(1)–(2) (first emphasis added).

Section 13(b) requires that the FTC have reason to believe a wrongdoer "is violating" or "is about to violate" the law. *Id.* § 53(b)(1). We conclude that this language is unambiguous; it prohibits existing or impending conduct. Simply put, Section 13(b) 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.

The plain language of Section 13(b) is reinforced by its history. "Generally, where the text of a statute is unambiguous, the statute should be enforced as written and only the most extraordinary showing of contrary intentions in the legislative history will justify a departure from that language." *Millennium Radio Grp. LLC*, 650 F.3d at 302 (internal quotation marks omitted). When Congress added Section 13(b), the provision was expected to be used for obtaining injunctions against illegal conduct pending completion of FTC administrative hearings. *See* S. Rep. No. 93-151, at 30 (1973) ("The purpose of [Section 13(b)] is to permit the [FTC] to bring an immediate halt to unfair or deceptive acts or practices when . . . [a]t the present time such practices might continue for several years until agency action is completed."). The provision was not designed to address hypothetical conduct or the mere suspicion that such conduct may yet occur. *Cf. id.* (explaining that Section 13(b) is meant to "bring an immediate halt to unfair or deceptive acts or practices. . . ."). Nor was it meant to duplicate Section 5, which already prohibits past conduct.

C.

The FTC's arguments to the contrary are unconvincing. The FTC contends that relief under Section 13(b) is appropriate when it shows a reasonable likelihood

that past violations will recur. In other words, "when a defendant has already violated the law but the illegal conduct has ceased, injunctive relief should be granted if 'there exists some cognizable danger of recurrent violation.'" Br. of Appellant 21 (quoting *United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953)).

The FTC borrows its "likelihood of recurrence" standard from the common law standard for an award of injunctive relief. A party can generally obtain injunctive relief for past conduct that is likely to recur; the wrongdoer cannot avoid an injunction by voluntarily ceasing its illegal conduct. *W.T. Grant Co.*, 345 U.S. at 632. Although injunctive relief can survive discontinuance of the illegal conduct, "the moving party must satisfy the court that relief is needed. The necessary determination is that there exists some cognizable danger of recurrent violation, something more than the mere possibility which serves to keep the case alive." *Id.* at 633.

The FTC insists that other courts have "consistently" applied the likelihood of recurrence standard in Section 13(b) cases. Br. of Appellant 21–22. This is true, and unsurprising, given that Section 13(b) explicitly authorizes the FTC to obtain injunctions. But none of the cases cited by the FTC considers the issue presented here—the meaning of Section 13(b)'s threshold requirement that a party "is" violating or "is about to" violate the law.

The FTC relies heavily on *Federal Trade Commission v. Evans Products Co.*, 775 F.2d 1084, 1087 (9th Cir. 1985). There, the United States Court of Appeals for the Ninth Circuit upheld the denial of an injunction under Section 13(b), ruling that "an injunction will issue only if the wrongs are ongoing or likely to recur." *Id.* The FTC sued a home seller at least two years after it had stopped making allegedly illegal misrepresentations. *Id.* at 1085–88. The district court denied the FTC's motion for an injunction; the Ninth Circuit affirmed, ruling that

the seller's conduct had completely ceased and was not likely to recur.[14] *Id.*

In another case cited by the FTC, *Federal Trade Commission v. Accusearch Inc.*, the United States Court of Appeals for the Tenth Circuit upheld a Section 13(b) injunction prohibiting the operator of a website that sold illegally-acquired personal data from engaging in future misconduct. 570 F.3d 1187, 1191 (10th Cir. 2009). The Tenth Circuit did not even quote—let alone analyze—Section 13(b)'s "about to violate" language because it was

[14] Although the result in *Evans Products Co.* cuts against the FTC, the Commission tries to rely on portions of the Ninth Circuit's reasoning. The Ninth Circuit, however, did not interpret "about to violate." *See Fed. Trade Comm'n v. Evans Prods. Co.*, 775 F.2d 1084, 1086 (9th Cir. 1985). Instead, it gave *Chevron* deference to the FTC's interpretation of a different part of Section 13(b)—the so-called permanent injunction proviso. *See id.* The FTC claimed that the permanent injunction proviso was a standalone cause of action that authorized it to obtain a permanent injunction against violations of any provision of law it enforced. *See id.* Here, however, the FTC has expressly disclaimed reliance on the permanent injunction proviso, *see* Br. of Appellant 23 n.8, making the FTC's arguments relying on *Evans Products Co.* at best inapposite and at worst misleading.

clear that the website operator had the capacity and motivation to engage in similar conduct in the future. *See id.* at 1202. The Tenth Circuit did not address whether the FTC had properly filed suit under Section 13(b).

The FTC next protests that our interpretation of "is about to violate" would make it harder to get in the courthouse door than to win injunctive relief.[15] The FTC contends that the likelihood of recurrence standard—which applies when a court is considering whether to grant or deny injunctive relief—*must* be the sole standard to plead a Section 13(b) claim. But the FTC cannot overcome Congress's plain language in Section 13(b), which requires the FTC to plead, at the time it files suit, that a violation "is" occurring or "is about to" occur. 15 U.S.C. § 53(b). Furthermore, the FTC ignores that the "about to violate" and "likelihood of recurrence" standards coexist. The "about to violate" pleading requirement—

[15] The FTC argues that the District Court erred by imposing a "higher" pleading threshold of "*imminent* recurrence." Br. of Appellant 22. The FTC is wrong. The District Court never imposed an imminence requirement. In fact, it didn't even use the word "imminent" in its opinion. The Court held that the factual allegations in the FTC's complaint failed to "plausibly suggest [Shire] is 'about to violate' any law enforced by the FTC, particularly when the alleged misconduct ceased almost five years before filing of the complaint." Op. 12.

which is applied right out of the gate—is not inconsistent with the likelihood of recurrence standard, which a court uses to determine the FTC's entitlement to an injunction.

The FTC also places much weight on cases interpreting the Securities Act of 1933 and the Securities Exchange Act of 1934. These Acts permit the Securities Exchange Commission to seek injunctive relief in federal court when a defendant "is engaged" or is "about to engage" in a violation of securities laws. 15 U.S.C. §§ 77t(b) and 78u(d)(1). We reject the FTC's invitation to import the interpretation of "is" or "is about to" contained in cases interpreting the securities laws. We "look to other statutes pertaining to the same subject matter which contain similar terms" only if "the ordinary meaning of a statute and the statute's legislative history fail to provide sufficient guidance to a term's meaning." *Liberty Lincoln-Mercury, Inc. v. Ford Motor Co.*, 171 F.3d 818, 823 (3d Cir. 1999). Here, the plain language of Section 13(b) answers the question for us—"is about to violate" means something more than a past violation and a likelihood of recurrence. If we were in doubt, the structure and history of the FTC Act support our interpretation. Moreover, the statutory scheme—the addition of Section 13(b) to cure a shortcoming of Section 5(b)—is not similar to the securities laws, which have always permitted suits for injunctions. *See also* Amicus Br. of Washington Legal Foundation 9 ("While several other statutes include language similar to the FTC's 'about to violate' language,

none of those statutes include agency-litigating authority that even remotely resembles the overall structure and history of the FTC Act.").

Finally, the FTC trots out the old adage that a remedial statute like the FTC Act should be construed broadly. Because Section 13(b)'s "is" or "is about to" requirement allegedly conflicts with the remedial purpose of the FTC Act, the FTC says we should disregard the plain meaning of that language. Of course, none of the authority the FTC cites stands for the broad proposition that we can *ignore* clear statutory language if it does not promote a remedial interpretation. *See Touche Ross & Co. v. Redington*, 442 U.S. 560, 578 (1979) (explaining that "generalized references" to "remedial purposes" of a statute will "not justify reading a provision more broadly than its language and the statutory scheme reasonably permit" (internal quotation marks omitted)).

The FTC points to a parade of horribles that it predicts will result if we uphold the District Court's decision.[16] *See, e.g.*, Br. of Appellant 35 ("Limiting the FTC's Section 13(b) authority to cases of ongoing or imminent violation would make it easy for wrongdoers to

[16] The FTC also claims that the District Court's interpretation could interfere with other statutes that contain similar language. Given the unique history and structure of the FTC Act, we consider this fear unfounded.

evade Congress' purposes in creating the regime. As soon as a potential defendant got wind that the FTC was investigating its activities, it could simply stop those activities and render itself immune from suit in federal court unless the FTC could allege and prove an imminent re-violation."). But there is no reason to believe that our decision today unnecessarily restricts the FTC's ability to address wrongdoing. Section 5 authorizes administrative proceedings based on past violations. And, of course, if the FTC believes that a wrongdoer is "about to violate" the law during the pendency of an administrative proceeding, it could then come to court and obtain an injunction under Section 13(b).

The FTC's understandable preference for litigating under Section 13(b), rather than in an administrative proceeding, does not justify its expansion of the statutory language. If the FTC wants to recover for a past violation—where an entity "has been" violating the law—it must use Section 5(b). 15 U.S.C. § 45(b). If the FTC instead chooses to use Section 13(b), it must plead that a violation of the law "is" occurring or "is about to" occur. *Id.* § 53(b). Here, the FTC wants to use the most advantageous aspects of each statutory provision—to punish Shire for a past violation using the less onerous enforcement mechanism. But the FTC's attempt to squeeze Shire's conduct into the "about to violate" category distorts Section 13(b) beyond its intended purpose. Section 13(b) cannot accommodate the FTC's

interpretation—that "about to violate" means only that a violation could recur at some future point.

In short, we reject the FTC's contention that Section 13(b)'s "is violating" or "is about to violate" language can be satisfied by showing a violation in the distant past and a vague and generalized likelihood of recurrent conduct.[17] Instead, "is" or "is about to violate" means what it says—the FTC must make a showing that a defendant is violating or is about to violate the law.

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[17] The FTC also asserts that Section 13(b)'s "reason to believe" language confers upon it unreviewable discretion to file suit. *See* 15 U.S.C. § 53(b) ("*Whenever the Commission has reason to believe*—(1) that any person, partnership, or corporation is violating, or is about to violate, any provision of law. . .[the FTC] may bring suit in a district court of the United States to enjoin any such act or practice." (emphasis added)). We decline to consider this argument because the FTC failed to raise it in the District Court. *Garza v. Citigroup Inc.*, 881 F.3d 277, 284 (3d Cir. 2018) ("It is well established that arguments not raised before the District Court are waived on appeal." (internal citation omitted)). Even if this argument were not waived, we would find it unpersuasive. Here, there is no evidence to support the FTC's "reason to believe" Shire is violating or is about to violate the law.

D.

Here, the FTC never initiated Section 5 proceedings against Shire.[18] Instead, the FTC waited until five years after Shire had stopped its allegedly illegal conduct before seeking an injunction under Section 13(b). Viewed under the correct standard, the FTC's complaint fails to allege that Shire "is violating" or "is about to violate" the law. The FTC does not contest that Shire is not currently violating the law. Indeed, Shire divested itself of Vancocin in 2014, two years after generic competition entered the market.

Instead, the FTC relies on Section 13(b)'s "is about to violate" language. The few factual allegations in the FTC's forty-five page complaint that suggest Shire "is about to violate" the law are woefully inadequate to state a claim under Section 13(b). The FTC alleges generally that Shire "is engaged in the business of, among other things, developing, manufacturing, and marketing branded drug products, including *inter alia*, Cinryze." Compl. ¶ 8. As to the likelihood that Shire will engage in illegal

[18] At oral argument in the District Court, the FTC explained that it "generally" pursues administrative proceedings and a preliminary injunction simultaneously. App. 381. It is unclear why the FTC did not use that strategy here, particularly when Shire's allegedly illegal conduct ceased long before the FTC filed suit.

behavior, the FTC alleges, "[a]bsent an injunction, there is a cognizable danger that [Shire] will engage in similar conduct causing future harm to competition and consumers. [Shire] knowingly carried out its anticompetitive and meritless petitioning campaign to preserve its monopoly profits. It did so conscious of the fact that this conduct would greatly enrich it at the expense of consumers." *Id.* ¶ 150. Without mentioning Cinryze by name, the FTC alleges that Shire "has the incentive and opportunity to continue to engage in similar conduct in the future. At all relevant times, [Shire] marketed and developed drug products for commercial sale in the United States, and it could do so in the future. Consequently, [Shire] has the incentive to obstruct or delay competition to these or other products." *Id.* ¶ 151.

The District Court concluded that these vague allegations failed to "plausibly suggest [Shire] is 'about to violate' any law enforced by the FTC, particularly when the alleged misconduct ceased almost five years before filing of the complaint." Op. 12. We agree. Taking the factual allegations in the complaint as true, Shire stopped its sham petitioning campaign in 2012 when the FDA approved generic equivalents to Vancocin. The complaint contains no allegations that Shire engaged in sham petitioning in the five-year gap between the 2012 cessation in petitioning and the 2017 lawsuit. The complaint also lacks specific allegations that Shire is "about to violate"

the law by petitioning as to Cinryze, the only other drug mentioned.

At oral argument in the District Court, the FTC provided more support for its argument that Shire "is about to violate" the law. The FTC explained that Shire is "perfectly positioned" to commit violations in the future because it is already marketing a "blockbuster drug" that is in the pipeline. *Id.* at 11. That drug, Cinryze, is not ripe for generic entry but has "the same type of significance as Vancocin . . . ." *Id.* We need not consider whether these allegations might satisfy the pleading standard. None of these facts—other than that Shire markets Cinryze—are pleaded in the complaint, which the FTC chose not to amend. Based upon the pleading before us, we conclude that the FTC has failed to plead that Shire is "about to violate" any law.

In this case, given the paucity of allegations in the complaint, the FTC fails to state a claim under any reasonable definition of "about to violate." Whatever the outer reach of "about to violate" may be, the facts in this case do not approach it.[19] We therefore leave for another

[19] We also reject the FTC's standalone claim for equitable monetary relief. Assuming that such relief is available under Section 13(b), the FTC must still meet the "is" or "is about to" requirement.

day the exact confines of Section 13(b)'s "about to violate" language.

IV.

Under Section 13(b) of the FTC Act, the FTC must plead that Shire "is" violating or "is about to" violate the law. But Shire indisputably is not currently violating the law, nor is it alleged to be poised to do so anytime in the foreseeable future. The FTC thus fails to state a claim upon which relief can be granted. We will affirm the District Court's judgment.

The FTC's improper use of Section 13(b) to pursue long-past petitioning has the potential to discourage lawful petitioning activity by interested citizens—activity that is protected by the First Amendment. Because we affirm the District Court's judgment dismissing the complaint, we need not address the issue further but suggest that the FTC be mindful of such First Amendment concerns.