No. 18-1807

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

FEDERAL TRADE COMMISSION,
Plaintiff-Appellant,

v.

SHIRE VIROPHARMA INC.,
Defendant-Appellee.

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

BRIEF OF THE FEDERAL TRADE COMMISSION AND APPENDIX VOLUME 1 (PAGES A1-A16)

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INTRODUCTION

This antitrust case involves the abuse of legal processes by Shire ViroPharma Inc. to maintain its monopoly on Vancocin capsules, a drug used to treat a potentially life-threatening gastrointestinal infection. Faced with a threat of generic competition to this lucrative product, ViroPharma inundated the Food and Drug Administration with meritless regulatory and court filings—a total of 46 over six years—knowing that they would delay the agency's approval of a lower-cost generic equivalent. The FDA ultimately rejected ViroPharma's petitions in 2012, but by then the campaign had already succeeded: ViroPharma had delayed generic entry for years and reaped hundreds of millions of dollars in extra profits.

The Federal Trade Commission sued ViroPharma under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), alleging that the company's sham petitioning campaign was an unfair method of competition prohibited by the Act. The FTC sought the same type of relief that has been granted in hundreds of FTC enforcement cases. First, the FTC sought an injunction to prohibit ViroPharma from engaging in similar misconduct in the future with respect to the other branded drugs the company sells. Federal courts routinely grant injunctions where the FTC shows both a past violation of law and a reasonable likelihood that the violation will recur absent an injunction—a standard which is easily satisfied where the company remains in business and has the incentive and opportunity to engage in

future misconduct. Second, the FTC sought equitable monetary relief, such as restitution, to redress the harm to consumers who paid inflated prices for Vancocin capsules due to ViroPharma's illegal maintenance of its monopoly. In keeping with established principles of equity, courts also routinely award restitution and other forms of monetary relief to remedy past violations even without a likelihood of recurrence.

The district court acknowledged that these standards apply when a court is considering whether to *grant* an injunction or other equitable relief. But it dismissed the complaint anyway, holding that the FTC is subject to a stricter *pleading* standard before it can even enter the courthouse. In effect, the court held that no matter how egregious a defendant's past violation, the FTC cannot sue to enforce the FTC Act unless it alleges facts showing that a further violation is not just reasonably likely but imminent. No other court in the 45 years that Section 13(b) has been on the books has ever held that the FTC must allege an imminent violation to state a claim for permanent injunctive relief. Nor has any court ever imposed such a requirement under the analogous provisions of the securities laws, which closely parallel Section 13(b). The district court's order thus threatens to disrupt the FTC's Section 13(b) enforcement program, which is one of the agency's primary tools for combatting unfair and deceptive practices and unfair methods of competition. The FTC appeals the order of dismissal.

JURISDICTION

The district court had subject-matter jurisdiction under 28 U.S.C. §§ 1331, 1337(a), and 1345. Its Memorandum Order dismissing the complaint was entered on March 20, 2018. A3-16.[1] Although the district court granted leave to amend, the FTC elected to stand on its original complaint, rendering the order final for appeal purposes. *See, e.g.*, *Remick v. Manfredy*, 238 F.3d 248, 254 (3d Cir. 2001). The FTC timely filed its notice of appeal on April 11, 2018. A1. This Court has jurisdiction under 28 U.S.C. § 1291.

ISSUES PRESENTED

1. Did the FTC's complaint state a claim for injunctive relief under Section 13(b) when it alleged a past violation of the FTC Act and a reasonable, but not imminent, likelihood of recurrence? *See* A10-14; FTC Opp. to Mot. to Dismiss (ECF No. 22) at 14-26.

2. Did the FTC's complaint state a claim for monetary relief where it alleged that ViroPharma reaped hundreds of millions of dollars from consumers as a result of its unlawful campaign to delay generic competition for Vancocin capsules? *See* A11 n.8; FTC Opp. to Mot. to Dismiss (ECF No. 22) at 26-28.

[1] Citations in the form A_ refer to pages of the Appendix. Citations to pages in the record refer to the ECF page numbers, rather to the document's internal page numbers.

STATEMENT OF RELATED CASES AND PROCEEDINGS

This case has not previously been before this Court. Parties in the following cases brought by or against the FTC have cited the district court's decision: *FTC v. Abbvie, Inc.*, No. 2:14-cv-5151 (E.D. Pa.); *Endo Pharmaceuticals Inc. v. FTC*, No. 2:16-cv-5599 (E.D. Pa.); *FTC v. Next-Gen, Inc.*, 4:18-cv-128 (W.D. Mo.); *FTC v. Hornbeam Special Situations, LLC*, 1:17-cv-3094 (N.D. Ga.); and *FTC v. Roca Labs., Inc.*, No. 8:15-cv-2231 (M.D. Fla.). The FTC is not aware of any other case or proceeding that is in any way related, completed, pending or about to be presented before this Court or any other court or agency.

RELEVANT STATUTES

Relevant statutes are set forth in the addendum.

STATEMENT OF THE CASE

A. ViroPharma's Sham Petitioning Campaign

Companies seeking to market new drugs in the United States must obtain approval from the FDA, which requires them to submit clinical data showing that the drug is safe and effective. *See* 21 U.S.C. § 355(a), (b). Once approved, a new drug may be entitled by statute to a period of market exclusivity, *see id.* § 355(c)(3)(E), or it may be protected from competition by a patent. In either case, the drug manufacturer will have a temporary monopoly on the drug (which is

typically sold as a brand-name product). Once those protections expire, another company can seek approval to market a generic version of the drug.

Congress created a streamlined process for approval of generic drugs. The generic applicant need not make the same showing of safety and efficacy that the brand manufacturer had to make to gain FDA approval. Instead, it need only show that the generic version is "bioequivalent" to the brand drug—*i.e.*, that it contains the same active ingredient with the same rate and extent of absorption as the brand name drug. *Id.* § 355(j); 21 C.F.R. §§ 314.3, 314.96(a)(7). Generic drugs are much less expensive than branded drugs and capture a large share of the market—typically 80% of sales within six months after generic entry. Compl. ¶¶ 28-29 (A30-31). But until the FDA approves a generic application, the brand manufacturer continues to enjoy a monopoly, and can set prices accordingly.

This case involves ViroPharma's attempt to protect a lucrative monopoly on a brand-name product, Vancocin capsules, by unfairly abusing regulatory and judicial processes to keep generics out of the market for as long as possible. Vancocin is the brand name for vancomycin, an oral antibiotic used to treat *Clostridium difficile*-associated diarrhea, a serious and potentially life-threatening gastrointestinal infection. Compl. ¶ 30 (A31). The FDA approved Vancocin capsules in 1986 as a substitute for an oral solution form of the drug (which some patients could not tolerate). Compl. ¶¶ 32, 36 (A31-32). ViroPharma bought the

rights to the drug from the original manufacturer, Eli Lilly & Co., in 2004. Compl. ¶ 37 (A32-33). The drug had no generic equivalent on the market, and ViroPharma took advantage of its newly acquired monopoly to sharply raise prices. Between 2004 and 2011, ViroPharma nearly quadrupled the average wholesale price of Vancocin capsules, causing revenues from the drug to climb from about $40 million in 2003 to almost $300 million in 2011. Compl. ¶¶ 38, 41 (A33). Vancocin capsules were ViroPharma's principal product during that time, accounting for all the company's net revenue from 2004 to 2009 and 53% of net revenue in 2011. *Id.*

The profitability of Vancocin capsules naturally drew the attention of generic companies. Compl. ¶ 42 (A34). The product was vulnerable to generic competition because it was protected neither by a patent nor market exclusivity. *Id.* The only serious barrier to generic competition was an FDA guideline that companies seeking to market a generic demonstrate bioequivalence through *in vivo* clinical endpoint studies—*i.e.*, studies of the drug in sick patients. *Id.* Such studies are expensive and time-consuming. *Id.*

But in February 2006, the FDA revised its guidelines and advised generic manufacturers that they could demonstrate bioequivalence through much cheaper *in vitro* dissolution studies—*i.e.*, studies conducted in the laboratory. Compl. ¶ 47 (A35). This was the type of data originally used to show that Vancocin capsules

were as safe and effective as the oral solution form of the drug. Compl. ¶¶ 34-36 (A32). With the pathway to approval thus eased, several companies submitted applications to market generic versions of Vancocin capsules in 2007. Compl. ¶ 48 (A36).

Beginning in March 2006, ViroPharma embarked on a campaign to obstruct and delay generic competition. Its primary weapon was the "citizen petition"—a request under FDA regulations for the agency to "issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action." 21 C.F.R. § 10.30(b)(3). The FDA must review and respond to every citizen petition it receives. *Id.* § 10.30(e). Because citizen petitions require the FDA to divert time and resources to crafting a response, they are often filed not by ordinary citizens but by branded drug companies as a tactic to delay generic approval. *See* Compl. ¶¶ 20-24 (A28-29). Congress attempted to curb such abuses in 2007, *see* 21 U.S.C. § 355(q), but the FDA has reported that the new law "is not discouraging the submission of petitions that are intended primarily to delay the approval of competing drug products and do not raise valid scientific issues." The FDA expressed concern that branded drug companies are "implementing strategies

to file serial [petitions] in an effort to delay approval of … competing drugs." Compl. ¶ 23 (A29).[2]

ViroPharma was one of the worst abusers of this process. From March 2006 to April 2012, it submitted no fewer than 24 citizen petition filings to the FDA (including amendments and supplements), arguing that the FDA should require applicants for generic Vancocin to submit *in vivo* clinical endpoint studies to demonstrate bioequivalence (even though the FDA had not relied on any such studies when it approved Vancocin). Compl. ¶¶ 49, 54-103 (A36, A438-54). ViroPharma did not submit any clinical data in support of its petitions, although it knew from its own consultants that it needed such data to have any chance of persuading the FDA to revise its bioequivalence guidance. Compl. ¶ 50-51 (A37). But ViroPharma also knew that its petitions were diverting FDA resources and delaying the approval of generic Vancocin capsules. Compl. ¶ 53 (A37-38). Thus, the campaign continued.

ViroPharma engaged in other abusive tactics as well. It submitted 17 public comments regarding the FDA's *in vitro* dissolution guidance for generic Vancocin capsules, another public comment regarding the agency's process for publishing bioequivalence guidelines and a supplemental application asserting (baselessly)

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[2] *See* FDA, *Sixth Annual Report on Delays in Approvals of Applications Related to Citizen Petitions and Petitions for Stay of Agency Action for Fiscal Year 2013*, at 7 (2014) (A204).

that Vancocin capsules should receive an additional three years of regulatory exclusivity. Compl. ¶¶ 49, 96-97 (A36, A52). It also filed three lawsuits against the FDA, two of which were dismissed and one of which ViroPharma ultimately withdrew following a partial grant of summary judgment in favor of the agency. Compl. ¶¶ 49, 108-117 (A36, A54-57). All told, ViroPharma made a total of 46 regulatory and court filings to delay approval for generic Vancocin capsules—by far the most that any company has ever made to the FDA regarding a single drug. Compl. ¶ 1 (A23-24).

ViroPharma's serial petitions lacked any merit. On April 9, 2012, the FDA provided a lengthy and comprehensive rejection of ViroPharma's arguments. Compl. ¶¶ 104-107 (A54). The same day, it approved three applications for generic equivalents to Vancocin capsules, ending ViroPharma's monopoly. Compl. ¶ 107 (A54). But by that point, ViroPharma had already achieved its real goal: it had delayed approval of generics for years and in doing so reaped hundreds of millions of dollars in additional monopoly profits. Compl. ¶ 149 (A65). ViroPharma continues to sell other branded drugs, and thus has the incentive and opportunity to engage in similar misconduct in the future. Compl. ¶¶ 8, 150-51 (A25, A65-66).

B. The FTC's Section 13(b) Enforcement Authority

The FTC is a bipartisan federal agency with a unique dual mission to protect consumers and promote competition. That mandate stems from Section 5 of the FTC Act, which prohibits both "[u]nfair methods of competition" and "unfair or deceptive acts or practices" in or affecting commerce. 15 U.S.C. § 45(a). The Act "empower[s] and direct[s]" the FTC to enforce these prohibitions. *Id.*

The FTC enforces Section 5 through both administrative proceedings before the Commission and lawsuits in federal district court. Lawsuits are governed by Section 13(b) of the FTC Act, which was added to the statute in 1973. Section 13(b) allows the FTC to sue for an injunction "[w]henever the Commission has reason to believe … that any person, partnership, or corporation is violating, or is about to violate, any provision of law enforced by the [FTC]." Under the first part of the statute, which is not at issue here, the FTC may seek a preliminary injunction during the pendency of an administrative hearing before the agency. The FTC typically invokes that aspect of the statute to prevent the closing of corporate mergers that are subject to administrative challenge.

This case involves the separate second part of the statute, referred to as the "second proviso" or "permanent injunction proviso," which states: "*Provided further*, That in proper cases the Commission may seek, and after proper proof, the court may issue, a permanent injunction." *Id.* 15 U.S.C. § 53(b). This proviso

authorizes the Commission to sue for final relief in a district court without invoking its administrative process. *See United States v. JS&A Group, Inc.*, 716 F.2d 451, 456 (7th Cir. 1983); *FTC v. H.N. Singer, Inc.*, 668 F.2d 1107, 1110-11 (9th Cir. 1982). It also authorizes the award of additional equitable remedies, including monetary relief such as restitution. This Court recognized that principle in *FTC v. Magazine Solutions, LLC*, 432 F. App'x 155 (3d Cir. 2011), agreeing with other circuits that "district courts have discretion to grant monetary equitable relief under section 13(b)." *Id.* at 158 n.2. Every other circuit that has considered the issue has reached the same conclusion. *See infra* n.13.

Since Congress enacted Section 13(b), lawsuits seeking permanent injunctions and other equitable relief have become a mainstay of FTC enforcement. The Commission sues to combat a wide variety of unfair or deceptive practices committed by defendants that range from fly-by-night scam artists to household-name corporations. To give just a few recent examples, the FTC has brought Section 13(b) enforcement actions against operators of telemarketing scams, *see FTC v. WV Universal Mgmt., LLC*, 877 F.3d 1234 (11th Cir. 2017), and internet marketing scams, *FTC v. Ross*, 743 F.3d 886 (4th Cir. 2014); companies selling bogus weight-loss products, *FTC v. Bronson Partners*, 654 F.3d 359 (2d Cir. 2011); companies deceptively marketing "unlimited data" plans for smartphones, *FTC v. AT&T Mobility LLC*, 883 F.3d 848 (9th Cir. 2018)

(en banc); and companies that failed to adequately secure sensitive consumer data, *see FTC v. Wyndham Worldwide Corp.*, 799 F.3d 236 (3d Cir. 2015). The FTC also uses Section 13(b) to address antitrust violations like anticompetitive "reverse payment" agreements between drug companies. *See, e.g.*, *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013). Over the years, the FTC has invoked Section 13(b) to return many billions of dollars to American consumers. Just in the one-year period from July 1, 2016 to June 30, 2017, the FTC directly refunded nearly $320 million to consumers and supported programs administered by defendants that delivered more than $6 billion in consumer refunds.[3]

C. The ViroPharma Complaint and the Motion to Dismiss

In 2017, the FTC sued ViroPharma for a permanent injunction and monetary relief under the second proviso of Section 13(b). The complaint alleges that ViroPharma violated the FTC Act's prohibition on unfair methods of competition by willfully maintaining a monopoly on Vancocin capsules through a course of anticompetitive conduct. Compl. ¶ 154 (A66). Consistent with the relief that has been awarded in other Section 13(b) cases, the FTC seeks both an injunction barring ViroPharma from engaging in similar conduct in the future and other equitable relief, such as restitution, necessary to redress the economic harm to

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[3] FTC, *Office of Claims and Refunds Annual Report 2017*, at 1, *available at* https://www.ftc.gov/reports/bureau-consumer-protection-consumer-refunds-program-consumer-refunds-effected-july-2016.

victims of ViroPharma's past violation. A66-67. In support of the request for injunctive relief, the complaint alleges that ViroPharma continues to manufacture and market branded prescription drugs, and that there is a cognizable danger it will obstruct and delay generic competition for those drugs too. Compl. ¶¶ 8, 150-52 (A25, A65-66).

ViroPharma moved to dismiss under Rules 12(b)(1) and 12(b)(6). It argued that because the introductory clause of Section 13(b) authorizes suit when the FTC has reason to believe a company "is violating, or is about to violate" the law, the FTC's enforcement authority is limited to cases involving an "ongoing or imminent" violation of the law. ECF No. 20 at 17-20.[4] Because the misconduct alleged in the complaint occurred between 2006 and 2012 and the complaint does not allege that a further violation is imminent, ViroPharma argued, the FTC lacks authority to bring this case in court and instead can proceed only through its administrative process.

The FTC responded that ViroPharma's position is contrary to a well-established body of judicial decisions stretching back some forty years. ECF No. 22 at 15-19. No court has ever barred the FTC from seeking an injunction and other equitable relief in federal court because the complaint did not allege ongoing

[4] ViroPharma also argued that its petitioning campaign is immune from antitrust challenge under the *Noerr-Pennington* doctrine. ECF No. 20 at 26-35. The district court denied ViroPharma's motion to dismiss on this ground. A14-16.

or imminent misconduct. Instead, courts have consistently held that the FTC may obtain a permanent injunction based on a defendant's past violation if it shows a reasonable likelihood that similar misconduct will recur in the future. Moreover, courts have held that the FTC may obtain equitable monetary relief to redress a defendant's past violation even absent a likelihood of recurrence.

The FTC further showed that the statutory phrase "is … or is about to" relied on by ViroPharma does not compel a different result. The same language appears in closely analogous statutes authorizing the Securities and Exchange Commission to seek an injunction for violations of the securities laws "[w]henever it shall appear to the Commission that any person is engaged or [is] about to engage in acts or practices" constituting a violation of the securities laws. 15 U.S.C. §§ 77t(b), 78u(d)(1).[5] Courts interpreting that language have consistently held that it does not impose an imminence requirement where a defendant has already violated the law, but instead authorizes the SEC to sue, and the court to award relief, where the defendant's past misconduct is likely to recur. *See, e.g.*, *SEC v. Commonwealth Chem. Sec., Inc.*, 574 F.2d 90, 99-100 (2d Cir. 1978). Because the operative language of Section 13(b) is substantively identical to that in the securities laws, the FTC argued, the same interpretation must govern FTC cases.

[5] The second "is" appears in § 78u(d)(1) but not § 77t(b); the difference is immaterial.

The FTC argued that under the proper standard, the complaint states a claim for an injunction because it sufficiently alleges facts showing that ViroPharma's misconduct is likely to recur absent an injunction. It also states a claim for equitable monetary relief, the FTC argued, because it alleges that ViroPharma unjustly enriched itself by hundreds of millions of dollars at the expense of consumers through the unlawful maintenance of its monopoly.

D. The District Court Decision

The district court granted the motion to dismiss, holding that the FTC's complaint failed to allege facts showing the FTC had a right to file suit in the first place.[6] In doing so, the court interpreted Section 13(b) to impose a threshold barrier to suit that required the FTC to plead more facts to get into court than it would have to prove to gain the relief requested. The court determined that "the FTC's ability to bring suit is dependent on its having reason to believe ViroPharma 'is violating, or is about to violate' a law enforced by the FTC, which is a prerequisite to the FTC's ability to bring suit." A9. Although the court did not indicate what it thought that phrase meant, it held that the "plain language" of the words "is violating, or is about to violate" requires more than a likelihood of

[6] The court recited the legal standard for dismissal under Rule 12(b)(1) and 12(b)(6), but did not expressly state which rule it was applying. A4-6. Because the court went on to address the *Noerr-Pennington* issue, however, *see* n.4, *supra*, it must have relied on Rule 12(b)(6), since a dismissal on jurisdictional grounds would have precluded any consideration of the merits.

recurrence. A11. As such, it effectively adopted the "ongoing or imminent" violation standard proposed by ViroPharma. A11-13.

The district court acknowledged that prior Section 13(b) cases "applied a likelihood of recurrence standard," but purported to distinguish some of those cases on the ground that they concerned "whether a district court had properly granted or denied injunctive relief, not whether the FTC had adequately pled, at the motion to dismiss stage, that the defendants were violating or were about to violate the law." A11-12. The district court did not distinguish (or even mention) the cases cited by the FTC explicitly addressing the phrase "is … or is about to" in the SEC statutes and holding that it implemented a likelihood-of-recurrence standard.

The court applied a similar analysis to the FTC's claim for equitable monetary relief. It acknowledged that courts have authority to award monetary equitable relief in FTC cases even absent a likelihood of recurrence. A11 n.8. But it held that this power related to "the court's ability to award a particular remedy," not to "the FTC's authority to bring suit in the first place." *Id.*

Having construed the "is violating, or is about to violate" clause as requiring the FTC to plead more than a likelihood of recurrence to enter the courthouse, the district court concluded that the complaint failed to state a claim. A13-14. It acknowledged the complaint's allegations that ViroPharma continues to market other drugs, that "[a]bsent an injunction, there is a cognizable danger that

ViroPharma will engage in similar misconduct," and that "ViroPharma continues has the incentive and opportunity to engage in similar conduct in the future." *Id.* (quoting Compl. ¶¶ 150-51). But the court found these allegations, without more, insufficient to meet its view of the FTC's pleading standard under Section 13(b).

SUMMARY OF ARGUMENT

1. A court's power to grant injunctive relief survives discontinuance of the defendant's illegal conduct. Courts in Section 13(b) cases therefore have consistently held that injunctive relief is appropriate where the FTC shows a reasonable likelihood that a defendant's past violations will recur absent an injunction. Courts, including this Court, have applied the same standard in cases brought by the SEC under the securities laws, which substantively almost identical to Section 13(b). *See, e.g.*, *SEC v. Bonastia*, 614 F.2d 908, 912 (3d Cir. 1980).

The district court acknowledged that the likelihood of recurrence standard applies when a court is considering whether to *grant* injunctive relief. But it held that the FTC must make a higher threshold showing in its pleadings—in effect, a showing of *imminent* recurrence—before it may even get into court. The court reached that result from its reading of the introductory phrase authorizing the FTC to sue whenever it has "reason to believe" a defendant "is violating, or is about to violate" the law. That interpretation rests on a doubly flawed reading of the statute. First, it fails to give proper effect to the phrase "reason to believe," which

makes clear that the FTC's decision to file suit is discretionary and not subject to judicial review. Thus on a Rule 12(b)(6) motion, a district court does not address whether the FTC has alleged facts sufficient to support its "reason to believe." Rather it should assess only whether the complaint states a claim upon which the *court* could grant relief. The district court, by its own admission, failed to conduct that inquiry, illogically creating a pleading standard higher than the standard for ultimate judgment.

Second, the court adopted an unduly cramped reading of "is violating, or is about to violate." No court has ever read Section 13(b) as the district court did here. Courts reading nearly identical language in the analogous SEC statutes have recognized for years that the phrase "is … or is about to" includes situations where the defendant has already violated the law and is reasonably likely to do so again if not enjoined. Indeed, courts have expressly held that the SEC statutes do not require a showing of imminence. This Court implicitly agreed in *Bonastia.* Given its similarity to the SEC statutes, Section 13(b) must be construed the same way.

Reading Section 13(b) as requiring the FTC to allege ongoing or imminent misconduct as a precondition to bringing suit would significantly limit the statute's effectiveness as an enforcement mechanism. This would undermine Congress's intent in enacting Section 13(b), which was to give the agency an additional enforcement tool to better protect consumers. The district court's reading of the

statute could also interfere with enforcement of many other statutes that authorize government agencies to sue when they determine that a defendant "is … or is about to" violate the law. In addition to the SEC statutes, other laws that use this phraseology include the Foreign Corrupt Practices Act and the Foreign Agents Registration Act. Given the principle that remedial statutes are to be broadly construed, it is not plausible that Congress intended to limit the availability of injunctive relief in all of these statutes to situations where the government can allege ongoing or imminent conduct. The far more plausible reading is that Congress intended these statutes to be read and applied in keeping with traditional equitable principles.

2. Under the proper pleading standard, the complaint states a claim for injunctive relief. *Bonastia* makes clear that likelihood of recurrence must be assessed based on the totality of the circumstances, including whether past violations were isolated or recurrent, whether the defendant has acknowledged its wrongful conduct, and whether the nature of the defendant's business makes it likely that future violations might occur. All of these factors point to a likelihood of recurrence here. The complaint alleges that ViroPharma engaged in a six-year pattern of deliberate and egregious misconduct to preserve a drug monopoly. ViroPharma still has not acknowledged any wrongdoing. And because

ViroPharma is still in the business of selling branded drugs, it has the incentive and opportunity to engage in similar misconduct in the future.

But even if the complaint did not allege a likelihood of recurrence, dismissal would still have been improper because the FTC also alleged a claim for equitable monetary relief based on the fact that ViroPharma reaped hundreds of millions of dollars from consumers by improperly extending its monopoly and inflating its prices. In keeping with equitable principles, courts in both FTC and SEC cases have consistently held that monetary relief may be awarded to redress past violations even where there is not a sufficient likelihood of recurrence to warrant a prohibitory injunction. For that reason as well, dismissal was improper.

STANDARD OF REVIEW

The Court reviews a dismissal under Rule 12(b)(6) *de novo*.[7] *Phillips v. County of Allegheny*, 515 F.3d 224, 230 (3d Cir. 2008). A complaint will survive a motion to dismiss if it "contain[s] sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal quotation marks omitted). The court must "accept all factual

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[7] As noted above (at n.6), the district court acted under Rule 12(b)(6), but the review standard would not be different if it had acted under Rule 12(b)(1). *See In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 243 (3d Cir. 2012). In any event, dismissal under Rule 12(b)(1) would clearly have been inappropriate. *See FTC v. AT&T Mobility LLC*, 883 F.3d 848, 853 (9th Cir. 2018) (en banc) (challenge based on FTC's authority to bring suit properly evaluated under Rule 12(b)(6), not Rule 12(b)(1)).

allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Phillips*, 515 F.3d at 233 (citation and internal quotation marks omitted). The issue is not whether the plaintiff is likely to prevail at the end of the day; "a well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable, and that a recovery is very remote and unlikely." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007) (internal quotation marks omitted). So long as the allegations are "more than skin-deep, they plausibly pass muster at the motion-to-dismiss stage." *Trzaska v. L'Oreal USA, Inc.*, 865 F.3d 155, 157 (3d Cir. 2017).

ARGUMENT

I. THE DISTRICT COURT SHOULD HAVE APPLIED THE ESTABLISHED LIKELIHOOD-OF-RECURRENCE STANDARD TO ASSESS THE SUFFICIENCY OF THE FTC'S COMPLAINT.

The question before the district court on ViroPharma's motion to dismiss was whether the complaint stated a claim upon which relief can be granted. The Supreme Court ruled long ago that 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." *United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953). Courts in Section 13(b) cases have consistently applied that principle, ordering injunctions when the defendant is no longer

violating the law but is reasonably likely to do so again if not enjoined. *See, e.g.*, *FTC v. Accusearch Inc.*, 570 F.3d 1187, 1201-02 (10th Cir. 2009); *FTC v. USA Fin., LLC*, 415 F. App'x 970, 975 (11th Cir. 2011); *see also FTC v. Evans Prods. Co.*, 775 F.2d 1084, 1087-88 (9th Cir. 1985). Courts apply the same likelihood-of-recurrence test in cases brought by the SEC under the analogous provisions of the securities laws; this Court has endorsed that standard and described it as "well established." *SEC v. Bonastia*, 614 F.2d 908, 912 (3d Cir. 1980).

The district court acknowledged that these standards apply when a court is considering whether to *grant* injunctive relief. But it held that the FTC must make a higher threshold showing in its pleadings—in effect, a showing of *imminent* recurrence—before it may even "bring suit in the first place." A9. This reading of the statute has the perverse result of making it more difficult for the FTC to get into court than to obtain ultimate relief. The court reached that result from its reading of the introductory phrase authorizing the FTC to sue whenever it has "reason to believe" a defendant "is violating, or is about to violate" the law. 15 U.S.C. § 53(b). But as we now show, that interpretation is doubly flawed: the district court failed to properly construe both "reason to believe" and "about to violate," leading to an interpretation that is both illogical and contrary to decades of precedent, and that would seriously undermine the FTC's enforcement efforts.

A. The District Court Erred By Reviewing the FTC's "Reason To Believe" Determination, Rather Than Asking Whether It Could Grant an Injunction.

A basic principle of statutory interpretation is that courts must give effect to every clause and word of a statute where possible. *E.g.*, *Tavarez v. Klingensmith*, 372 F.3d 188, 190 (3d Cir. 2004). In this case, the district court focused primarily on the statutory phrase "is violating or is about to violate." But it went astray by failing to give proper effect to the words "reason to believe," which appear in the very same clause.[8] That led the court to conduct the wrong inquiry, asking whether the FTC had the "ability to bring suit in the first place," rather than asking the relevant question: whether the complaint adequately pled facts that would enable the *court* to grant injunctive relief under established law.

The district court viewed its role as assessing whether the complaint alleged facts to support the FTC's "reason to believe" determination. But Congress uses the words "reason to believe" to indicate that a given determination is committed to agency discretion. A government agency's reason to believe that an infraction has been committed is a quintessential example of a discretionary agency decision

[8] The district court held that the statutory phrase "is violating, or is about to violate" applies equally to actions for preliminary injunctions in aid of administrative proceedings and actions under the permanent injunction proviso of Section 13(b). The FTC does not challenge that aspect of the district court's determination here. The "about to violate" language applies both where the violation has not yet occurred (*e.g.*, when the FTC seeks a preliminary injunction to block a proposed merger) and, as we explain below, where violations have already occurred and are likely to recur absent an injunction.

that is not judicially reviewable. The Ninth Circuit addressed this issue in *Standard Oil Co. v. FTC*, 596 F.2d 1381 (9th Cir. 1979), with respect to the analogous "reason to believe" determination the Commission must make to initiate an administrative proceeding. *See* 15 U.S.C. § 45(b). The court explained that the "reason to believe" determination is committed to agency discretion because "[j]udicial intervention in this legitimate decision making process would serve only to hamper or thwart the FTC's exercise of the power granted to it by Congress." *Standard Oil*, 596 F.2d at 1385; *see also Boise Cascade Corp. v. FTC*, 498 F. Supp. 772, 779 (D. Del. 1980) ("[A]n agency has full discretion in deciding what information is relevant, and what evidence is sufficient for a 'reason to believe' determination.").[9]

Likewise, the Seventh Circuit held in *Board of Trade v. CFTC*, 605 F.2d 1016 (7th Cir. 1979), that a statute authorizing the Commodities Futures Trading Commission to take certain actions "whenever it has reason to believe that an emergency exists" conferred unreviewable discretion on the agency. *Id.* at 1018 (quoting 7 U.S.C. § 12a(9)). Two district courts have specifically addressed Section 13(b) and held that the FTC's determination of its "reason to believe" that a defendant "is violating or about to violate" the law is similarly committed to

[9] The Supreme Court later held that the plaintiff's suit against the FTC should have been dismissed for lack of finality, without reaching the agency discretion issue. *FTC v. Standard Oil Co.*, 449 U.S. 232, 245 & n.13 (1980).

agency discretion and hence effectively unreviewable. *See FTC v. Hornbeam Special Situations, LLC*, No. 1:17-cv-3094, 2018 WL 1870094, at *10 (N.D. Ga. Apr. 16, 2018); *FTC v. Nat'l Urological Grp., Inc.*, No. 1:04-cv-3294, 2006 WL 8431977, at *3 (N.D. Ga. Jan. 9, 2006).

Thus, properly read, Section 13(b) does not entitle a district court to step into the agency's shoes and assess at the threshold whether the FTC has reason to believe that the defendant is violating or is about to violate the law. Nor may it second-guess the agency's determination that it does have such reason. That decision is entrusted to the Commission. The district court's proper function on a Rule 12(b)(6) motion is to determine whether the complaint pleads facts sufficient to state "a claim upon which relief may be granted." Fed. R. Civ. P. 12(b)(6). And as the district court recognized, established case law holds that injunctive relief can be granted if the FTC proves a reasonable likelihood that the defendant's past unlawful conduct will recur absent an injunction. The FTC cannot be required to plead more in its complaint than it will ultimately have to prove to obtain relief on the merits.

The district court's reading of "reason to believe" as imposing a heightened pleading standard on the FTC is therefore illogical on its face. It is "axiomatic" that granting relief on the merits is assessed "under a *much more stringent* standard than a motion to dismiss for failure to state a claim." *Fowler v. UPMC Shadyside*,

578 F.3d 203, 213 (3d Cir. 2009) (emphasis added). The district court's ruling gets that principle backwards, perversely requiring the FTC to allege more facts to state a claim than would be necessary to prove entitlement to an injunction.

Nothing in the statute indicates that Congress intended to impose such an implausible requirement. "A basic tenet of statutory construction is that courts should interpret a law to avoid absurd or bizarre results." *In re Kaiser Aluminum Corp.*, 456 F.3d 328, 338 (3d Cir. 2006). Indeed, at least one court applying the analogous SEC statutes has properly recognized that the standard for pleading a claim for injunctive relief cannot logically be stricter than the standard for issuance of an injunction. In *SEC v. Richie*, No. 5:06-cv-63, 2008 WL 2938678 (C.D. Cal. May 9, 2008), as here, the defendant relied on the phrase "is ... or is about to" in the securities statutes to argue that the complaint should be dismissed because it failed to allege an ongoing or imminent violation. The district correctly noted that it could grant an injunction if there was "a reasonable likelihood of future violations," and that a past violation "may give rise to an inference of future violations." *Id.* at *8-9. It held that interpreting the statute to "creat[e] a higher standard than the reasonable likelihood of future violations standard would be illogical because this would create situations when the S.E.C has made a showing that it could obtain injunctive relief but does not have standing to sue for such relief." *Id.* at *9. That reasoning applies equally here.

B. Where a Defendant Has Already Violated the Law, "Is or Is About To" Encompasses a Reasonable Likelihood of Recurrence.

Even if it were permissible for the district court to review the FTC's "reason to believe" determination, the phrase "is violating, or is about to violate" does not have the narrow meaning ascribed to it by the district court. What the district court viewed as Section 13(b)'s "plain language" requiring imminence has never been read that way by another court. To the contrary, over the past four decades, courts have consistently construed the same phrase as used in the securities laws to require not ongoing or imminent misconduct, but only a past violation and a reasonable likelihood of recurrence absent an injunction. Given the "canon of statutory construction that similar statutes are to be construed similarly," *Lafferty v. St. Riel*, 495 F.3d 72, 81-82 (3d Cir. 2007), Section 13(b) must be construed the same way.

The securities laws utilize language that is substantively almost identical to Section 13(b). In particular, the SEC may sue for an injunction "[w]henever it shall appear to the Commission that any person is engaged or [is] about to engage in acts or practices" constituting a violation of the securities laws. 15 U.S.C. §§ 77t(b), 78u(d)(1) (*see* n.5, *supra*). Numerous cases have directly addressed the meaning of "is … or is about to" in these statutes and have concluded that it is

equivalent to the likelihood of recurrence standard where the defendant has already violated the law but the violation is no longer ongoing.

Judge Friendly's decision for the Second Circuit in *SEC v. Commonwealth Chemical Securities, Inc.*, 574 F.2d 90 (2d Cir. 1978), is the seminal case. Defendants there were sued 15 months after their last violation, and argued that an injunction was improper because they had "voluntarily terminated all connection with [the securities business] long before the injunction issued." *Id.* at 98. The Second Circuit rejected the argument, pointing to the statutory phrase "is engaged or about to engage." The court held that "[e]xcept for the case where the SEC steps in to prevent an ongoing violation, this language seems to require a finding of 'likelihood' or 'propensity' to engage in future violations." *Id.* at 99. Thus, the court determined, the "the ultimate test is whether the defendant's past conduct indicates that there is a *reasonable likelihood* of further violation in the future." *Id.* (citation, brackets, and ellipsis omitted). The court had "no difficulty" in sustaining the injunction against the principal defendants, given their "repeated and persistent" misconduct. *Id.* at 100. *Commonwealth Chemical* thus plainly recognizes that where a defendant has already violated the law, "is … or is about to" does not require a showing of ongoing or imminent violation to justify injunctive relief.

That reading of the clause makes perfect sense, given the well-recognized principle that unlawful "past conduct gives rise to an inference of a reasonable expectation of continued violations." *SEC v. Manor Nursing Ctrs., Inc.*, 458 F.2d 1082, 1100 (2d Cir. 1972); *accord United States v. Local 30, United Slate, Tile & Composition Roofers, Damp & Waterproof Workers Ass'n*, 871 F.2d 401, 409 (3d Cir. 1989). Where a defendant has already engaged in wrongdoing (as the FTC alleges ViroPharma has done here) and is in a position to engage in future wrongdoing if not enjoined, it is reasonable for an enforcement agency like the FTC or SEC to conclude that the defendant is "about to" violate the law, and equally reasonable for a court to issue an injunction against further misconduct. As the Second Circuit recognized, "is … or is about to" easily encompasses those circumstances.

Ordinary principles of statutory construction reinforce this conclusion. It is well-settled that "remedial legislation should be construed broadly to effectuate its purpose." *Long v. Tommy Hilfiger U.S.A., Inc.*, 671 F.3d 371, 375 (3d Cir. 2012); *accord Atchison, T&S.F. Ry. Co. v. Buell*, 480 U.S. 557, 562 (1987); *Roberts v. Fleet Bank*, 342 F.3d 260, 266 (3d Cir. 2003). This is especially true of statutes governing injunctions sought by the government. "When Congress grants district courts jurisdiction to enjoin those violating or about to violate federal statutes, it is authorizing the exercise of 'equity practice with a background of several hundred

years of history.'" *SEC v. Unifund SAL*, 910 F.2d 1028, 1035 (2d Cir. 1990) (quoting *Hecht Co. v. Bowles*, 321 U.S. 321, 329 (1944)). The statutory language must be construed against that background. The Second Circuit reasonably construed "is … or is about to" as consistent with the longstanding rule of equity jurisdiction that an injunction is appropriate when "there exists some cognizable danger of recurrent violation." *W.T. Grant*, 345 U.S. at 633.

Other courts have followed the Second Circuit's lead. For example, in *SEC v. First Financial Group of Texas*, 645 F.2d 429 (5th Cir. 1981), the court held that the SEC may obtain an injunction where it shows "a reasonable likelihood that the defendant is engaged or about to engage in practices that violate the federal securities laws." *Id.* at 434. The court explained that the "[t]he latter showing"— *i.e.*, "about to engage"—"is usually made with proof of past substantive violations that indicate a reasonable likelihood of future substantive violations." *Id.* Numerous other decisions address the phrase "is … or is about to," and they uniformly conclude that this standard is satisfied when the defendant has previously engaged in illegal conduct and there is a reasonable likelihood it will do so again if not enjoined. *See SEC v. Am. Bd. of Trade, Inc.*, 751 F.2d 529, 537 (2d Cir. 1984); *SEC v. Materia*, 745 F.2d 197, 200 (2d Cir. 1984); *SEC v. Zale Corp.*, 650 F.2d 718, 720 (5th Cir. Unit A July 1981); *SEC v. Mize*, 615 F.2d 1046, 1051 (5th Cir. 1980); *SEC v. Caterinicchia*, 613 F.2d 102, 105 (5th Cir. 1980); *SEC v.*

Monarch Fund, 608 F.2d 938 (2d Cir. 1979); *SEC v. Mgmt. Dynamics, Inc.*, 515 F.2d 801, 807 (2d Cir. 1975).

Although the Supreme Court has not addressed the issue as directly, it too has left no doubt that "about to" does not mean "imminently about to." In *Aaron v. SEC*, 446 U.S. 680 (1980), the Court addressed the use of "about to" in the SEC statutes and explained that:

> In cases where the Commission is seeking to enjoin a person '*about* to engage in any acts or practices which … *will* constitute' a violation of [the securities laws], the Commission must establish a sufficient evidentiary predicate to show that such future violation may occur. . . . An important factor in this regard is the degree of intentional wrongdoing evident in a defendant's past conduct.

Id. at 701. Thus, examining the meaning of "about to," the Court concluded that it required only a showing that a future violation "may occur"—not that one was "imminent"—and that such a showing may be based on the defendant's past conduct. The Court cited *Commonwealth Chemical*, thereby signaling agreement with the Second Circuit's analysis. *Id.*

This Court too has endorsed the Second Circuit's reading of the SEC statutes and its eschewal of an imminence standard. In *Bonastia*, the district court had denied an injunction on the ground that the defendant was no longer engaged in any business subject to the securities laws. *Bonastia*, 614 F.2d at 912. But this court reversed, relying on *Commonwealth Chemical* and similar cases to conclude that that the "well established standard" to determine whether an injunction should

issue is "whether there is a reasonable likelihood that the defendant, if not enjoined, will again engage in the illegal conduct." *Id.* The court concluded that the defendant's central role in a five-year fraud scheme amply showed a likelihood of recurrence that mandated issuance of an injunction. *Id.* at 913. Had the Court read "is … or is about to" to mean "imminent," it could not have reached that result.

The First Circuit has likewise held that an injunction under the SEC statutes requires "reasonable likelihood of recidivism, not an imminent threat of it." *SEC v. Sargent*, 329 F.3d 34, 39 (1st Cir. 2003). Almost every other court of appeals has similarly held that the proper test for granting injunctive relief is whether there is a reasonable likelihood that the defendant's past violation will recur absent an injunction. *See SEC v. Ginsburg*, 362 F.3d 1292, 1304 (11th Cir. 2004); *SEC v. Pros Int'l, Inc.*, 994 F.2d 767, 769 (10th Cir. 1993); *SEC v. Steadman*, 967 F.2d 636, 647 (D.C. Cir. 1992); *SEC v. Comserv Corp.*, 908 F.2d 1407, 1412 (8th Cir. 1990); *SEC v. Holschuh*, 694 F.2d 130, 144 (7th Cir. 1982); *SEC v. Murphy*, 626 F.2d 633, 655 (9th Cir. 1980). We are aware of no decision that has ever imposed an imminence standard. Notably, the district court did not address *Commonwealth Chemical* or *Bonastia* (both of which were discussed in the district court briefs). Nor did it distinguish any of the many other cases that have expressly or implicitly read "is … or is about to" as equivalent to the likelihood of recurrence standard.

Given that the SEC statutes are so similar to Section 13(b), it is not surprising that courts have also consistently recognized that "is … or is about to" is equivalent to likelihood of recurrence in the FTC context. The Ninth Circuit explicitly addressed this phrase in *Evans Products*, holding that the "statutory language" of Section 13(b) implemented the "general rule" of equitable jurisdiction that "an injunction will issue only if the wrongs are ongoing *or likely to recur*." *Evans Prods.*, 775 F.2d at 1087 (emphasis added). And other courts, while not explicitly addressing the "about to" language, have nonetheless held that injunctive relief is appropriate based upon a likelihood of recurrence. For example, in *Accusearch,* the defendant had stopped its illegal sale of telephone records several months before the FTC filed suit and did not have immediate plans to resume that practice; the Tenth Circuit held that an injunction was appropriate because the company remained in the information brokerage business and had the capacity to engage in similar misconduct in the future. *Accusearch*, 570 F.3d at 1201-02. Similarly, in *USA Financial*, the Eleventh Circuit affirmed an injunction where one of the defendant telemarketers had ceased its deceptive practices a few months before the FTC filed suit, holding that the defendants' past unwillingness to comply with the law demonstrated a likelihood of recurrence warranting an injunction. *USA Fin.*, 415 F. App'x at 975.[10]

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[10] *See also FTC v. Engage-a-Car Servs., Inc.*, No. 86-cv-3758, 1986 WL 15066

ViroPharma's reading of "is … is about to," which the district court implicitly accepted, would require this Court to conclude that these decisions stretching back four decades simply ignored the plain language of the statute and should have been dismissed at the outset. That cannot possibly be correct. The unbroken line of cases starting with *Commonwealth Chemical*, including this Court's decision in *Bonastia* and the FTC cases like *Evans Products* and *Accusearch*, can be read only as recognizing that where a defendant has already violated the law, "is … or is about to" is equivalent to the reasonable likelihood of recurrence standard.

C. Limiting Section 13(b) to Cases of Ongoing or Imminent Violation Would Undermine the Statute's Effectiveness and Defeat Congress' Law Enforcement Objectives.

As discussed above, a remedial statute like the FTC Act "must be construed with all the liberality necessary to achieve [its] purposes." *Disabled in Action of Penn. v. S.E. Penn. Transp. Auth.*, 635 F.3d 87, 94 (3d Cir. 2011). The district court's misinterpretation of Section 13(b) would thwart the purposes of Section 13(b), limiting its effectiveness as an enforcement tool and undermining the objectives Congress sought to achieve when it enacted the statute. The district court's reading would also potentially undermine the enforcement of the SEC

(D.N.J. Dec. 18, 1986), which rejected an "is … or is about to" argument similar to the one raised here, holding that that "that the facts pleaded by [the FTC] are sufficient to justify a cause of action under § 13(b)" because they support "an inference that defendants' § 5 violations are likely to recur." *Id.* at *5.

statutes and many other federal law enforcement statutes that use the same "is … or is about to" phraseology. Congress could not have intended such a result. The much more plausible interpretation is that Congress used this language in the expectation that it would be construed—as it has been—consistent with the well-established principles of equity jurisdiction.

Congress added Section 13(b) to the FTC Act in 1973 because it determined that the FTC needed additional enforcement tools to adequately protect American consumers. Congress expressed particular concern that under the then-existing regime, which provided for enforcement only through the FTC's administrative process, unfair or deceptive acts or practices "might continue for several years until agency action is completed." S. Rep. No. 93-151, at 30 (1973). It anticipated that "Commission resources will be better utilized, and cases can be disposed of more efficiently" by authorizing the Commission to dispense with the administrative process and instead seek a permanent injunction in district court. *Id.* at 31.

Limiting the FTC's Section 13(b) authority to cases of ongoing or imminent violation would make it easy for wrongdoers to 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. Cases like *Accusearch* and *USA Financial*, where

defendants ceased their challenged practices before the FTC filed suit, illustrate the problem. *See Accusearch*, 570 F.3d at 1192, 1202; *USA Fin.*, 415 F. App'x at 975. By the district court's logic, these cases should have been thrown out at the pleading stage.

The FTC's recent settlements with Volkswagen provide another illustration. As has been widely reported, for years Volkswagen sold cars that it marketed as "Clean Diesel" vehicles meeting the Environmental Protection Agency's emissions standards. In fact, Volkswagen had rigged the vehicles to cheat the emissions test. When Volkswagen was caught in 2015, it stopped the cheating—but by that time American consumers had already paid billions of dollars for more than half a million fraudulently marketed vehicles. The FTC later sued under Section 13(b), and ultimately entered into two consent judgments with Volkswagen pursuant to which the company has already returned over $8 billion to consumers through vehicle buybacks and other programs.[11] The FTC was able to sue under Section 13(b) and obtain this relief because there was clearly a reasonable likelihood of recurrence—Volkswagen remained in the business of selling cars, and could have resumed its illegal practices at any time absent an injunction. But under the district court's reading of the law, the FTC likely could not have sued under Section 13(b)

[11] *See In re Volkswagen "Clean Diesel" Mktg., Sales Practices, and Prods. Liab. Litig.*, No. 3:15-md-2672 (N.D. Cal.), ECF Nos. 2104, 3227.

because Volkswagen was no longer engaged in ongoing misconduct and it is not clear that the FTC could have alleged that another violation was imminent. And the same problem would likely have doomed hundreds of other Section 13(b) actions that the FTC has filed over the years—cases that collectively have recovered many billions of dollars for victimized American consumers.

The district court's reading of Section 13(b) also has the potential to interfere with other agencies' enforcement efforts. The SEC is one obvious example for all the reasons discussed above. But many other federal enforcement statutes also use the "is … or is about to" formulation. For example, the Foreign Corrupt Practices Act authorizes suits for injunctive relief against a U.S. person or business "[w]hen it appears to the Attorney General that [the defendant] is engaged, or about to engage" in bribery of foreign officials. 15 U.S.C. § 78dd-2(d); *see also id.* § 78dd-3(d). By the district court's logic, the government would be powerless to proceed against a person or company who had engaged in past bribery unless it could show that another bribe was imminent.

Similarly, the Foreign Agents Registration Act allows action "[w]henever in the judgment of the Attorney General any person is engaged in or about to engage in any acts which constitute or will constitute" a violation of the Act or its implementing regulations. 22 U.S.C. § 618(f). This provision enables the government to obtain injunctive relief against organizations acting on behalf of

foreign principals that fail to properly register or submit inaccurate or incomplete registration materials. *See, e.g.*, *Attorney General v. Irish Northern Aid Comm.*, 530 F. Supp. 241 (S.D.N.Y. 1981), *aff'd*, 668 F.2d 159 (2d Cir. 1982). But under the district court's interpretation, the government could not take action against an organization that had already violated the Act without showing that it was imminently about to do so again.

Essentially the same phrasing appears in many other federal statutes authorizing the Attorney General or other law enforcement agencies to seek injunctive relief for violations of the law.[12] Congress could not possibly have intended such widely used language to limit the government's power to seek an injunction to cases where it can show a further violation is imminent. It is far more plausible that Congress employed this basic phraseology in the law in the FTC Act, the SEC statutes, and many other places in the U.S. Code on the understanding that it would be construed consistent with the ordinary injunctive relief standard set forth by the Supreme Court in *W.T. Grant* and applied in such cases as *Bonastia*, *Commonwealth Chemical*, *Accusearch*, and *Evans Products*.

[12] Other examples include laws authorizing the Attorney General to seek injunctions against fraud, *see* 18 U.S.C. § 1345(a), illegal wiretaps, *see id* § 2521, and misuse of the name, seal or insignia of various government agencies. *See* 10 U.S.C. §§ 425(b), 7881(c), 50 U.S.C. §§ 3233(b), 3513(b), 3613(b). The language also appears in statutes authorizing the Federal Energy Regulatory Commission and the Director of the Consumer Financial Protection Bureau to sue for injunctive relief. *See* 15 U.S.C. §§ 717s(a), 1714(a); 16 U.S.C. § 825m(a).

II. UNDER THE CORRECT LEGAL STANDARDS, THE COMPLAINT STATES A CLAIM FOR BOTH INJUNCTIVE RELIEF AND FOR EQUITABLE MONETARY RELIEF.

For all the foregoing reasons, the FTC states a claim for injunctive relief under Section 13(b) based on a defendant's past conduct if it alleges facts plausibly showing "a reasonable likelihood that the defendant, if not enjoined, will again engage in the illegal conduct." *Bonastia*, 614 F.2d at 912. The complaint here easily satisfies that standard. Moreover, even if it did not, dismissal would still have been improper, because the complaint also states a claim for equitable monetary relief.

A. The Complaint States a Claim for Injunctive Relief.

Bonastia identified several factors courts should consider in determining whether a defendant's violation is likely to recur, including "the degree of scienter involved on the part of the defendant, the isolated or recurrent nature of the infraction, the defendant's recognition of the wrongful nature of his conduct, the sincerity of his assurances against future violations, and the likelihood, because of defendant's professional occupation, that future violations might occur." *Id.* "Essentially, a court makes a prediction of the likelihood of future violations based on an assessment of the totality of the circumstances surrounding the particular defendant and the past violations that were committed." *Id.* Other courts have looked to substantially the same factors to assess likelihood of recurrence in cases

under the FTC Act and the SEC statutes. *See, e.g.*, *Accusearch*, 570 F.3d at 1201; *Commonwealth Chem.*, 574 F.2d at 99.

Applying this framework, the FTC's complaint easily clears the bar for alleging a reasonable likelihood of recurrence. First, it alleges not an isolated instance of misconduct, but repeated acts spread over six years, which included 43 baseless regulatory filings and three meritless lawsuits. *See* Compl. ¶ 49 (A36). As in *Bonastia*, where the defendant engaged in fraudulent activities for five years, the "repetitiveness of the violations weighs heavily in favor of the imposition of an injunction." 614 F.2d at 913.

Furthermore, the complaint amply alleges that ViroPharma knew its petitioning campaign had no chance of succeeding on its merits, and that the company's true goal was to obstruct and delay generic competition to Vancocin capsules, thereby preserving ViroPharma's monopoly for as long as possible. *See* Compl. ¶¶ 50-53, 59-61, 67-68, 86-88, 128-29 (A37, A40-41, A42-43, A49-50, A59-60). Such allegations of deliberate misconduct "underscore[] the propriety of injunctive relief." *Bonastia*, 614 F.2d at 913.

Courts also assess "the sincerity of [the defendant's] assurances against future violations." *Id.* at 912. ViroPharma has given no assurances against future violations; to the contrary, it argued before the district court that its petitioning campaign was lawful.

Finally, another important factor is "the likelihood, because of defendant's professional occupation, that future violations might occur." *Id.* In that regard, this case is comparable to *Accusearch*, where the defendant had ceased its illegal sales of telephone records but remained in the information brokerage business—selling other kinds of data—and thus had the "capacity to engage in similar unfair acts or practices in the future." *Accusearch*, 570 F.3d at 1202 (brackets and internal quotation marks omitted). Similarly, in this case, while ViroPharma can do no more to stave off competition for Vancocin capsules, the complaint alleges that ViroPharma remains in the business of developing, manufacturing, and marketing branded drugs, and that it has the incentive and opportunity to obstruct and delay generic competition in the future. Compl. ¶¶ 8, 151 (A25, A65-66).

B. The Complaint States a Claim for Equitable Monetary Relief.

Even if the FTC had not plausibly alleged a likelihood of recurrence, dismissal of the complaint still would have been improper. That is because the FTC also sought equitable monetary relief: restitution to consumers of the hundreds of millions of dollars that ViroPharma reaped from its illegal activities. The law is clear that when a statute authorizes injunctive relief, courts may award equitable monetary relief to an agency like the FTC even if it cannot obtain a forward-looking behavioral injunction. Once again, Section 13(b) must be interpreted as consistent with these background principles of equitable jurisdiction.

The Supreme Court has established that when Congress authorizes a district court to issue an injunction, "[u]nless otherwise provided by statute, all the inherent equitable powers of the District Court are available for the proper and complete exercise of that jurisdiction." *Porter v. Warner Holding Co.*, 328 U.S. 395, 398 (1946). Thus, given authority to issue an injunction, the court may exercise its equitable authority to "accord full justice to all the real parties in interest," including an award of monetary remedies like restitution. *Id.* at 398-99. The Court reaffirmed this principle in *Mitchell v. Robert De Mario, Inc.*, 361 U.S. 288 (1960), explaining that "[w]hen Congress entrusts to an equity court the enforcement of prohibitions contained in a regulatory enactment, it must be taken to have acted cognizant of the historic power of equity to provide complete relief in the light of statutory purposes." *Id.* at 291-92.

In *United States v. Lane-Labs USA, Inc.*, 427 F.3d 219 (3d Cir. 2005), this Court addressed whether a district court could award restitution in a suit for injunctive relief under the Food, Drug and Cosmetic Act. After analyzing *Porter* and *DeMario* in detail, the Court concluded that "a district court sitting in equity may order restitution unless there is a clear statutory limitation on the district court's equitable jurisdiction and powers," so long as it "furthers the purposes of the statute." *Id*. at 225. The Court has also specifically recognized that the FTC may obtain monetary equitable relief in Section 13(b) cases. *FTC v. Magazine*

Solutions, LLC, 432 F. App'x 155, 158 n.2 (3d Cir. 2011); *see also FTC v. Check Investors, Inc.*, 502 F.3d 159, 162 (3d Cir. 2007) (affirming equitable restitution judgment under Section 13(b)). Eight other courts of appeals have considered the issue, and all have reached the same conclusion.[13]

Because the goal of equity is to accord complete justice to all the parties, courts also have the authority to award equitable monetary relief even where a forward-looking injunction would not be appropriate. The Supreme Court so held in *United States v. Moore*, 340 U.S. 616 (1951). In that case, landlords charged rents above the limit imposed by a wartime rent control statute. But a prohibitory injunction was not available because the area was decontrolled "after the violations but before the Government brought suit." *Id.* at 617. Nonetheless, the Court held that the government was entitled to restitution of rent overcharges because "[s]uch a decree clearly enforces compliance with the Act and regulations for the period in which [the landlords] demanded and received excess rentals." *Id.* at 620. This Court recognized the same principle in *CFTC v. American Metals Exch. Corp.*, 991 F.2d 71 (3d Cir. 1993). There, the district court denied an injunction because

[13] *See FTC v. Direct Mktg. Concepts, Inc.*, 624 F.3d 1, 15 (1st Cir. 2010); *FTC v. Bronson Partners, LLC*, 654 F.3d 359, 365 (2d Cir. 2011); *FTC v. Ross*, 743 F.3d 886, 890-92 (4th Cir. 2014); *FTC v. Amy Travel Serv., Inc.*, 875 F.2d 564, 571-72 (7th Cir. 1989); *FTC v. Sec. Rare Coin & Bullion Corp.*, 931 F.2d 1312, 1316 (8th Cir. 1991); *FTC v. Pantron I Corp.*, 33 F.3d 1088, 1102 (9th Cir. 1994); *FTC v. Freecom Commc'ns, Inc.*, 401 F.3d 1192, 1202 n.6 (10th Cir. 2005); *FTC v. Gem Merch. Corp.*, 87 F.3d 466, 470 (11th Cir. 1996).

plaintiffs had not adequately shown a likelihood of recurrence, but nonetheless granted the request for monetary relief in the form of disgorgement. *Id.* at 74. This Court held that the disgorgement remedy was "well-recognized" and that the district court "did not err in imposing" that remedy (though it had erred by failing to hold a hearing to determine the appropriate amount). *Id.* at 76.

Courts have applied the same principle in cases brought by the FTC under Section 13(b). In *Evans Products*, where the defendant's misrepresentations had ceased long before the FTC filed its complaint and the company later filed for bankruptcy, the Ninth Circuit affirmed the denial of injunctive relief on the ground that the FTC had not adequately shown a likelihood of recurrence. *Evans Prods.*, 775 F.2d at 1088. But it then went on to hold that "[c]ourts have inherent equitable powers to grant ancillary relief, other than [an] injunction restraining future violations of the law, when there is no likelihood of recurrence." *Id.* Consequently, it separately considered whether the FTC had demonstrated entitlement to an asset-freeze—a provisional equitable remedy that would prevent assets from being dissipated and thus protect the agency's ability to obtain equitable monetary relief as part of a final judgment.[14]

[14] The district court in the bankruptcy case made the point even more explicitly, holding that "a court may exercise those powers to grant ancillary relief, including rescission and restitution, when the primary injunctive relief is not granted because the alleged violations have ceased and are not likely to recur." *In re Evans Prods. Co.*, 60 B.R. 863, 869 (S.D. Fla. 1986).

The Ninth Circuit addressed this issue again only a few months ago in *FTC v. AT&T Mobility, LLC*, 883 F.3d 848 (9th Cir. 2018) (en banc). There, AT&T argued that an order issued by the Federal Communications Commission stripped the FTC of its authority to enforce the FTC Act against broadband internet providers. The Ninth Circuit disagreed, noting that even if the agency could not obtain a prospective behavioral injunction, "the FTC can still potentially achieve monetary relief for AT&T's past violations." *Id.* at 864.

Commonwealth Chemical also holds that equitable monetary relief may be awarded even absent a likelihood of recurrence. The court there agreed that the SEC had not shown a likelihood of recurrence as to two defendants who had a limited role in the fraud scheme, and thus reversed the injunction as to those defendants. *Commonwealth Chem.*, 574 F.2d at 100-01. But it affirmed the portion of the order requiring those defendants to disgorge their profits from the fraudulent scheme. *Id.* at 103. It explained that "when a violation has been established, a failure of the SEC to show the likelihood of recurrence required to justify an injunction" should not "relieve a defendant found to have violated the securities laws from the obligation to disgorge." *Id.* at 103 n.13.; *see also Unifund SAL*, 910 F.2d at 1041 ("[A]n ancillary remedy may be granted, even in circumstances where the elements required to support a traditional SEC injunction have not been established.").

The reasoning of these decisions squarely applies here. For the reasons set forth above, the FTC's complaint properly states a claim for injunctive relief. But even if it did not, or even if the FTC could not ultimately prove entitlement to an injunction, it would still be entitled to seek equitable monetary relief to redress the harm to consumers who paid inflated prices as a result of ViroPharma's past illegal maintenance of its monopoly on Vancocin capsules. For that reason as well, the district court should not have dismissed the complaint.

CONCLUSION

The judgment of the district court should be reversed and the case remanded.

Respectfully submitted,

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June 19, 2018

COMBINED CERTIFICATIONS

COMPLIANCE WITH TYPE-VOLUME LIMIT, TYPEFACE REQUIREMENTS, AND TYPE-STYLE REQUIREMENTS

1. This brief complies with the type-volume limit of Fed. R. App. P. 37(a)(7)(B) because it contains 11,186 words (excluding the parts of the brief exempted by Fed. R. App. P. 32(f)).
2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 2010, in 14 point Times New Roman.

BAR MEMBERSHIP

All signatories to this brief are attorneys who work for a federal government agency.

IDENTICAL COMPLIANCE OF BRIEFS

I certify that the text of the electronically filed brief is identical to the text of the original copies that were sent on June 19, 2018, to the Clerk of the Court of the United States Court of Appeals for the Third Circuit.

PERFORMANCE OF VIRUS CHECK

I certify that on June 19, 2018, I performed a virus check on the electronically filed copy of this brief using Symantec Endpoint Protection Version 14 (14.0 MP2) build 2415 (14.0.2414.0200) (last updated June 19, 2018). No virus was detected.

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I certify that on June 19, 2018, I filed the foregoing brief via the Court's electronic filing system. All parties will be served by the CM/ECF system.

June 19, 2018

/s/Matthew M. Hoffman
Matthew M. Hoffman

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§ 45. Unfair methods of competition unlawful; prevention by Commission

(a) Declaration of unlawfulness; power to prohibit unfair practices; inapplicability to foreign trade

(1) Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful.

(2) The Commission is hereby empowered and directed to prevent persons, partnerships, or corporations * * * from using unfair methods of competition in or affecting commerce and unfair or deceptive acts or practices in or affecting commerce.

* * *

(b) Proceeding by Commission; modifying and setting aside orders

Whenever the Commission shall have reason to believe that any such person, partnership, or corporation has been or is using any unfair method of competition or unfair or deceptive act or practice in or affecting commerce, and if it shall appear to the Commission that a proceeding by it in respect thereof would be to the interest of the public, it shall issue and serve upon such person, partnership, or corporation a complaint stating its charges in that respect and containing a notice of a hearing upon a day and at a place therein fixed at least thirty days after the service of said complaint. The person, partnership, or corporation so complained of shall have the right to appear at the place and time so fixed and show cause why an order should not be entered by the Commission requiring such person, partnership, or corporation to cease and desist from the violation of the law so charged in said complaint. Any person, partnership, or corporation may make application, and upon good cause shown may be allowed by the Commission to intervene and appear in said proceeding by counsel or in person. The testimony in any such proceeding shall be reduced to writing and filed in the office of the Commission. If upon such hearing the Commission shall be of the opinion that the method of competition or the act or practice in question is prohibited by this subchapter, it shall make a report in writing in which it shall state its findings as to the facts and shall issue and cause to be served on such person, partnership, or corporation an order requiring such person, partnership, or corporation to cease and desist from using such method of competition or such act or practice. * * *

* * *

§ 53. False advertisements; injunctions and restraining orders

* * *

(b) Temporary restraining orders; preliminary injunctions

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 enforced by the Federal Trade Commission, and

(2) that the enjoining thereof pending the issuance of a complaint by the Commission and until such complaint is dismissed by the Commission or set aside by the court on review, or until the order of the Commission made thereon has become final, would be in the interest of the public—

the Commission 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 Commission'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 Commission may seek, and after proper proof, the court may issue, a permanent injunction. Any suit may be brought where such person, partnership, or corporation resides or transacts business, or wherever venue is proper under section 1391 of title 28. In addition, the court may, if the court determines that the interests of justice require that any other person, partnership, or corporation should be a party in such suit, cause such other person, partnership, or corporation to be added as a party without regard to whether venue is otherwise proper in the district in which the suit is brought. In any suit under this section, process may be served on any person, partnership, or corporation wherever it may be found.

* * *

Securities Act of 1933, 15 U.S.C. § 77a *et seq.*

§ 77t. Injunctions and prosecution of offenses

* * *

(b) Action for injunction or criminal prosecution in district court

Whenever it shall appear to the [Securities and Exchange] Commission that any person is engaged or about to engage in any acts or practices which constitute or will constitute a violation of the provisions of this subchapter, or of any rule or regulation prescribed under authority thereof, the Commission may, in its discretion, bring an action in any district court of the United States, or United States court of any Territory, to enjoin such acts or practices, and upon a proper showing, a permanent or temporary injunction or restraining order shall be granted without bond. * * *

* * *

Securities and Exchange Act of 1934, 15 U.S.C. § 78a *et seq.*

§ 78u. Investigations and actions

* * *

(d) Injunction proceedings; authority of court to prohibit persons from serving as officers and directors; money penalties in civil actions

(1) Whenever it shall appear to the [Securities and Exchange]Commission that any person is engaged or is about to engage in acts or practices constituting a violation of any provision of this chapter, the rules or regulations thereunder, the rules of a national securities exchange or registered securities association of which such person is a member or a person associated with a member, the rules of a registered clearing agency in which such person is a participant, the rules of the Public Company Accounting Oversight Board, of which such person is a registered public accounting firm or a person associated with such a firm, or the rules of the Municipal Securities Rulemaking Board, it may in its discretion bring an action in the proper district court of the United States, the United States District Court for the District of Columbia, or the United States courts of any territory or other place subject to the jurisdiction of the United States, to enjoin such acts or practices, and upon a proper showing a permanent or temporary injunction or restraining order shall be granted without bond. * * *

* * *

Foreign Corrupt Practices Act, 15 U.S.C. § 78dd-1 *et seq.*

§ 78dd–2. Prohibited foreign trade practices by domestic concerns

* * *

(d) Injunctive relief

(1) When it appears to the Attorney General that any domestic concern to which this section applies, or officer, director, employee, agent, or stockholder thereof, is engaged, or about to engage, in any act or practice constituting a violation of subsection (a) or (i) of this section, the Attorney General may, in his discretion, bring a civil action in an appropriate district court of the United States to enjoin such act or practice, and upon a proper showing, a permanent injunction or a temporary restraining order shall be granted without bond.

* * *

§78dd–3. Prohibited foreign trade practices by persons other than issuers or domestic concerns

* * *

(d) Injunctive relief

(1) When it appears to the Attorney General that any person to which this section applies, or officer, director, employee, agent, or stockholder thereof, is engaged, or about to engage, in any act or practice constituting a violation of subsection (a) of this section, the Attorney General may, in his discretion, bring a civil action in an appropriate district court of the United States to enjoin such act or practice, and upon a proper showing, a permanent injunction or a temporary restraining order shall be granted without bond.

* * *

Foreign Agents Registration Act, 22 U.S.C. § 611 *et seq*.

§ 618. Enforcement and penalties

* * *

(f) Injunctive remedy; jurisdiction of district court

Whenever in the judgment of the Attorney General any person is engaged in or about to engage in any acts which constitute or will constitute a violation of any provision of this subchapter, or regulations issued thereunder, or whenever any agent of a foreign principal fails to comply with any of the provisions of this subchapter or the regulations issued thereunder, or otherwise is in violation of the subchapter, the Attorney General may make application to the appropriate United States district court for an order enjoining such acts or enjoining such person from continuing to act as an agent of such foreign principal, or for an order requiring compliance with any appropriate provision of the subchapter or regulation thereunder. The district court shall have jurisdiction and authority to issue a temporary or permanent injunction, restraining order or such other order which it may deem proper.

* * *

United States Code, Title 18

§ 1345. Injunctions against fraud

(a)(1) If a person is—

(A) violating or about to violate this chapter or section 287, 371 (insofar as such violation involves a conspiracy to defraud the United States or any agency thereof), or 1001 of this title;

(B) committing or about to commit a banking law violation (as defined in section 3322(d) of this title); or

(C) committing or about to commit a Federal health care offense;

the Attorney General may commence a civil action in any Federal court to enjoin such violation.

* * *

§ 2521. Injunction against illegal interception

Whenever it shall appear that any person is engaged or is about to engage in any act which constitutes or will constitute a felony violation of this chapter, the Attorney General may initiate a civil action in a district court of the United States to enjoin such violation. The court shall proceed as soon as practicable to the hearing and determination of such an action, and may, at any time before final determination, enter such a restraining order or prohibition, or take such other action, as is warranted to prevent a continuing and substantial injury to the United States or to any person or class of persons for whose protection the action is brought. A proceeding under this section is governed by the Federal Rules of Civil Procedure, except that, if an indictment has been returned against the respondent, discovery is governed by the Federal Rules of Criminal Procedure.

Natural Gas Act of 1938, 15 U.S.C. § 717 *et seq.*

§ 717s. Enforcement of chapter

(a) Action in district court for injunction

Whenever it shall appear to the [Federal Power] Commission that any person is engaged or about to engage in any acts or practices which constitute or will constitute a violation of the provisions of this chapter, or of any rule, regulation, or order thereunder, it may in its discretion bring an action in the proper district court of the United States, or the United States courts of any Territory or other place subject to the jurisdiction of the United States, to enjoin such acts or practices and to enforce compliance with this chapter or any rule, regulation, or order thereunder, and upon a proper showing a permanent or temporary injunction or decree or restraining order shall be granted without bond. The Commission may transmit such evidence as may be available concerning such acts or practices or concerning apparent violations of the Federal antitrust laws to the Attorney General, who, in his discretion, may institute the necessary criminal proceedings.

* * *

Federal Power Act, 16 U.S.C. § 791a *et seq.*

§ 825m. Enforcement provisions

(a) Enjoining and restraining violations

Whenever it shall appear to the [Federal Power] Commission that any person is engaged or about to engage in any acts or practices which constitute or will constitute a violation of the provisions of this chapter, or of any rule, regulation, or order thereunder, it may in its discretion bring an action in the proper District Court of the United States or the United States courts of any Territory or other place subject to the jurisdiction of the United States, to enjoin such acts or practices and to enforce compliance with this chapter or any rule, regulation, or order thereunder, and upon a proper showing a permanent or temporary injunction or decree or restraining order shall be granted without bond. * * *

* * *

Interstate Land Sales Full Disclosure Act, 15 U.S.C. § 1701 *et seq.*

§ 1714. Investigations, injunctions, and prosecution of offenses

(a) Permanent or temporary injunction or restraining order; jurisdiction

Whenever it shall appear to the Director that any person is engaged or about to engage in any acts or practices which constitute or will constitute a violation of the provisions of this chapter, or of any rule or regulation prescribed pursuant thereto, he may, in his discretion, bring an action in any district court of the United States, or the United States District Court for the District of Columbia to enjoin such acts or practices, and, upon a proper showing, a permanent or temporary injunction or restraining order shall be granted without bond. The Director may transmit such evidence as may be available concerning such acts or practices to the Attorney General who may, in his discretion, institute the appropriate criminal proceedings under this chapter.

* * *

United States Code, Title 10

§ 425. Prohibition of unauthorized use of name, initials, or seal: specified intelligence agencies

* * *

(b) AUTHORITY TO ENJOIN VIOLATIONS.—Whenever it appears to the Attorney General that any person is engaged or is about to engage in an act or practice which constitutes or will constitute conduct prohibited by subsection (a), the Attorney General may initiate a civil proceeding in a district court of the United States to enjoin such act or practice. Such court shall proceed as soon as practicable to the hearing and determination of such action and may, at any time before final determination, enter such restraining orders or prohibitions, or take such other actions as is warranted, to prevent injury to the United States or to any person or class of persons for whose protection the action is brought.

§ 7881. Unauthorized use of Marine Corps insignia

* * *

(c) Whenever it appears to the Attorney General of the United States that any person is engaged or is about to engage in an act or practice which constitutes or will constitute conduct prohibited by subsection (b), the Attorney General may initiate a civil proceeding in a district court of the United States to enjoin such act or practice. Such court may, at any time before final determination, enter such restraining orders or prohibitions, or take such other action as is warranted, to prevent injury to the United States or to any person or class of persons for whose protection the action is brought.

United States Code, Title 50

§ 3233. Misuse of the Office of the Director of National Intelligence name, initials, or seal

* * *

(b) Injunction

Whenever it appears to the Attorney General that any person is engaged or is about to engage in an act or practice which constitutes or will constitute conduct prohibited by subsection (a), the Attorney General may initiate a civil proceeding in a district court of the United States to enjoin such act or practice. Such court shall proceed as soon as practicable to the hearing and determination of such action and may, at any time before final determination, enter such restraining orders or prohibitions, or take such other action as is warranted, to prevent injury to the United States or to any person or class of persons for whose protection the action is brought.

§ 3513. Misuse of Agency name, initials, or seal

* * *

(b) Injunction

Whenever it appears to the Attorney General that any person is engaged or is about to engage in an act or practice which constitutes or will constitute conduct prohibited by subsection (a) of this section, the Attorney General may initiate a civil proceeding in a district court of the United States to enjoin such act or practice. Such court shall proceed as soon as practicable to the hearing and determination of such action and may, at any time before final determination, enter such restraining orders or prohibitions, or take such other action as is warranted, to prevent injury to the United States or to any person or class of persons for whose protection the action is brought.

§ 3613. Misuse of Agency name, initials, or seal

* * *

(b) Whenever it appears to the Attorney General that any person is engaged or is about to engage in an act or practice which constitutes or will constitute conduct prohibited by subsection (a), the Attorney General may initiate a civil proceeding in a district court of the United States to enjoin such act or practice. Such court shall proceed as soon as practicable to the hearing and determination of such action and may, at any time before final determination, enter such restraining orders or prohibitions, or take such other action as is warranted, to prevent injury to the United States or to any person or class of persons for whose protection the action is brought.

No. 18-1807

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

FEDERAL TRADE COMMISSION,
Plaintiff-Appellant

v.

SHIRE VIROPHARMA INC.,
Defendant-Appellee.

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

APPENDIX
Volume 1 of 2 (pages A1-A16)

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FEDERAL TRADE COMMISSION, Plaintiff, v. SHIRE VIROPHARMA INC., Defendant.	Civil Action No. 17-cv-00131-RGA

NOTICE OF APPEAL

On March 20, 2018, the Court issued a Memorandum Order (D.I. 51) granting Defendant's motion to dismiss the complaint and granting the Federal Trade Commission leave to amend the complaint within a reasonable time. The FTC has elected to stand on its original complaint for purposes of taking an appeal from the Memorandum Order. *See, e.g.*, *Remick v. Manfredy*, 238 F.3d 248, 254 (3d Cir. 2001). Accordingly, notice is hereby given that the FTC (the sole plaintiff herein) appeals the Memorandum Order to the United States Court of Appeals for the Third Circuit.

Dated: April 11, 2018

Respectfully Submitted,

/s/ Thomas J. Dillickrath

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FEDERAL TRADE COMMISSION, Plaintiff, v. SHIRE VIROPHARMA INC., Defendant.	Civil Action No. 17-131-RGA

MEMORANDUM ORDER

Presently before the Court is Defendant Shire ViroPharma Inc.'s motion to dismiss pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). (D.I. 19). The matter has been fully briefed. (D.I. 20, 22, 23). The Court heard oral argument on February 2, 2018. (D.I. 45) ("Tr.").

I. BACKGROUND

On February 7, 2017, the Federal Trade Commission ("FTC") filed this action against ViroPharma pursuant to Section 13(b) of the FTC Act, 15 U.S.C. § 53(b). (D.I. 2). ViroPharma is a Delaware corporation that develops, manufactures, and markets branded pharmaceuticals. (*Id.* ¶ 8). The complaint contains one count, alleging that ViroPharma violated Section 5(a) of the Act, 15 U.S.C. § 45(a), by engaging in an unfair method of competition. (*Id.* ¶ 154).

The action arises out of ViroPharma's use of the U.S. Food and Drug Administration's ("FDA") citizen petition process.[1] (*Id.* ¶ 1). More specifically, the FTC alleges that ViroPharma

[1] "A citizen petition is a request that the FDA issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action." (D.I. 2 ¶ 18 (quoting 21 C.F.R. § 10.30(b)(3))).

used the FDA's citizen petition process to maintain its monopoly on Vancocin Capsules.[2] (*Id.*). The FTC maintains that ViroPharma's meritless petitioning activity "harmed competition and consumer welfare by obstructing and delaying the FDA approval process for a generic version of Vancocin." (*Id.* ¶ 144).

The complaint alleges that ViroPharma "inundated the FDA with regulatory and court filings—forty-six in all." (*Id.* ¶ 1). The filings occurred between March 2006 and April 2012.[3] (*Id.* ¶ 49). They are listed at paragraph 118 of the complaint. The filings include twenty-four citizen petition filings, eighteen public comments, a Supplemental New Drug Application, and three lawsuits. (*Id.*).

The FTC seeks a permanent injunction and other equitable relief.

II. LEGAL STANDARDS

A. Rule 12(b)(1)

A court must grant a motion to dismiss pursuant to Rule 12(b)(1) if it lacks subject matter jurisdiction to hear a claim. *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 243 (3d Cir. 2012). "In evaluating a Rule 12(b)(1) motion, a court must first determine whether the movant presents a facial or factual attack." *Id.* "In reviewing a facial challenge, which contests the sufficiency of the pleadings, the court must only consider the allegations of the complaint and documents referenced therein and attached thereto, in the light most favorable to the plaintiff." *Id.* In this case, ViroPharma's Rule 12(b)(1) arguments

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[2] Vancocin is a drug used to treat gastrointestinal infection. (D.I. 2 ¶¶ 1, 30).

[3] Specifically, ViroPharma made its initial citizen petition filing on March 17, 2006. (D.I. 2 ¶ 118). ViroPharma made its final filing, the last of three lawsuits against the FDA, on April 13, 2012. (*Id.*).

constitute a "facial attack" because ViroPharma contends the complaint lacks sufficient factual allegations to establish jurisdiction. *See id.*

"In evaluating whether a complaint adequately pleads the elements of standing, courts apply the standard of reviewing a complaint pursuant to a Rule 12(b)(6) motion . . . ." *Id.*; *see also Baldwin v. Univ. of Pittsburgh Med. Ctr.*, 636 F.3d 69, 73 (3d Cir. 2011) ("A dismissal for lack of statutory standing is effectively the same as a dismissal for failure to state a claim."). That standard is set forth below. "With respect to 12(b)(1) motions in particular, [however,] [t]he plaintiff must assert facts that affirmatively and plausibly suggest that the pleader has the right he claims (here, the right to jurisdiction), rather than facts that are merely consistent with such a right." *In re Schering*, 678 F.3d at 244 (citation omitted).

B. Rule 12(b)(6)

In reviewing a motion to dismiss pursuant to Rule 12(b)(6), the Court must accept the complaint's factual allegations as true. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555–56 (2007). Rule 8(a) requires "a short and plain statement of the claim showing that the pleader is entitled to relief." *Id.* at 555. The factual allegations do not have to be detailed, but they must provide more than labels, conclusions, or a "formulaic recitation" of the claim elements. *Id.* ("Factual allegations must be enough to raise a right to relief above the speculative level . . . on the assumption that all the allegations in the complaint are true (even if doubtful in fact).").

Moreover, there must be sufficient factual matter to state a facially plausible claim to relief. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The facial plausibility standard is satisfied when the complaint's factual content "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* "In deciding a Rule 12(b)(6) motion, a court must consider only the complaint, exhibits attached to the complaint, matters of public record, as

well as undisputedly authentic documents if the complainant's claims are based upon these documents." *Mayer v. Belichick,* 605 F.3d 223, 230 (3d Cir. 2010).

III. DISCUSSION

ViroPharma makes two principal arguments in its motion to dismiss. First, it argues the FTC has failed to plead the facts necessary to invoke its authority under Section 13(b) of the Act. (D.I. 20 at 17). Second, it argues ViroPharma's alleged conduct is immune from challenge under the *Noerr-Pennington* doctrine. (*Id.* at 26).

A. Section 13(b)

ViroPharma's first argument raises what appear to be novel questions in regard to the proper interpretation of Section 13(b) of the FTC Act. Section 13(b) provides in relevant part:

> (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 enforced by the Federal Trade Commission, and
>
> (2) that the enjoining thereof pending the issuance of a complaint by the Commission and until such complaint is dismissed by the Commission or set aside by the court on review, or until the order of the Commission made thereon has become final, would be in the interest of the public—
>
> the Commission 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 Commission'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 Commission may seek, and after proper proof, the court may issue, a permanent injunction.*

15 U.S.C. § 53(b) (2012) (emphasis added).

"The first proviso authorizes the FTC to seek, and district courts to grant, preliminary relief in aid of administrative proceedings." *F.T.C. v. Commonwealth Mktg. Grp., Inc.*, 72 F. Supp. 2d 530, 535 (W.D. Pa. 1999) (citations omitted). "The second proviso[4] authorizes the FTC to seek, and district courts to grant, permanent injunctions without the FTC's initiating the administrative proceedings prerequisite to a grant of relief under the first proviso." *Id.* (citing *F.T.C. v. H.N. Singer, Inc.*, 668 F.2d 1107, 1110 (9th Cir. 1982)); *see also United States v. JS & A Grp., Inc.*, 716 F.2d 451, 457 (7th Cir. 1983) (holding that Section 13(b) authorizes the FTC to seek permanent injunctive relief "irrespective of whether a Commission proceeding regarding the alleged violations is pending or contemplated"). There is no dispute the FTC brought the present action pursuant to the second proviso.

The first issue raised by the parties' 13(b) arguments relates to whether the second proviso constitutes an independent grant of authority for the FTC to file suit in federal court. More specifically, at issue is whether the language in (b)(1), "is violating, or is about to violate," applies to cases where the FTC seeks a permanent injunction pursuant to the second proviso.[5]

ViroPharma argues the (b)(1) language applies. (*See* D.I. 23 at 7). The FTC, on the other hand, suggests that because courts have held that (b)(2) does not apply to cases brought under the second proviso, it makes sense that neither would (b)(1) apply in such cases. (D.I. 22 at 16

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[4] I refer to this proviso as either the "second proviso" or the "permanent injunction proviso."

[5] The only case of which I am aware to touch on this issue, which the FTC cited in the briefing, is *F.T.C. v. Virginia Homes Manufacturing Corp.*, 509 F. Supp. 51 (D. Md. 1981). In that case, the court noted, "A careful reading of s 13(b) lends some credence to th[e] view" that the "'is . . . or is about to' language is not directed at the district court's power to grant permanent injunctions." *Id.* at 56. The court ultimately did not decide, however, whether that language is properly understood to apply to cases brought under the permanent injunction proviso because the FTC had alleged an ongoing violation of law. *Id.* at 56–57. The FTC has not done so here.

(citing *JS & A Grp.*, 716 F.2d at 456; *Singer*, 668 F.2d at 1110–11; *Commonwealth Mktg. Grp.*, 72 F. Supp. 2d at 535–36); *see also* Tr. at 40:13–23).

I disagree. Although courts have held that (b)(2) does not apply when the FTC seeks a permanent injunction pursuant to the second proviso, *e.g.*, *Singer*, 668 F.2d at 1110,[6] I do not think that means the second proviso serves as a stand-alone grant of authority for the FTC to file suit in federal court whenever it seeks permanent injunctive relief. In my opinion, the FTC's interpretation is belied by the plain language of the statute.

"[T]he starting point for interpreting a statute is the language of the statute itself." *Mitchell v. Horn*, 318 F.3d 523, 535 (3d Cir. 2003). Here, Section 13(b) provides that the FTC, in certain circumstances, "*may bring suit* in a district court of the United States." 15 U.S.C. § 53(b) (emphasis added). It goes on to state that "in proper cases the Commission *may seek* . . . a permanent injunction." *Id.* (emphasis added). "It is a well-established canon of statutory interpretation that the use of different words or terms within a statute demonstrates that Congress intended to convey a different meaning for those words." *S.E.C. v. McCarthy*, 322 F.3d 650, 656 (9th Cir. 2003) (citations omitted). Accordingly, "may bring suit" ought not to have the same meaning as "may seek." I think the statutory language is unambiguous in that "may bring suit" refers to the FTC's authority to file suit in federal court, whereas "may seek" refers to the FTC's authority, once it is properly in federal court, to seek a particular remedy, that is, a permanent injunction. Thus, I agree with ViroPharma that if Congress intended for the permanent

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[6] In so doing, one court explained, "Preliminary relief and a permanent injunction are entirely different animals, and here Congress clearly intended that each be governed by a separate statutory provision." *JS & A Grp.*, 716 F.2d at 456. That reasoning would seem to suggest that neither does (b)(1) apply to cases brought under the second proviso. For the reasons explained here, however, I do not think such an interpretation would be a proper reading of the statute.

injunction proviso to be an independent grant of authority, it would have used the language "may bring suit," rather than "may seek."

More generally, I do not think the second proviso seems like a grant of authority to bring suit. First and foremost, Section 13(b) grants the FTC authority to file suit to seek a temporary restraining order or a preliminary injunction. It later states, "*Provided further*, That in proper cases the Commission may seek . . . a permanent injunction." 15 U.S.C. § 53(b). In my opinion, the structure of the statute suggests that the permanent injunction proviso is subject to the language that precedes it. In other words, the way the second proviso follows from the first, demonstrates that the second proviso applies to cases already in federal court pursuant to the first proviso.

Accordingly, I think the FTC's ability to seek a permanent injunction in this case is dependent on its having reason to believe ViroPharma "is violating, or is about to violate" a law enforced by the FTC, which is a prerequisite to the FTC's ability to bring suit in the first place.

The limited legislative history supports this conclusion. "Section 13(b) was enacted as part of the Trans-Alaska Pipeline Act, P.L. 93-153, but was originally a part of the Senate bill for the Federal Trade Improvement Act of 1973, P.L. 93-637." *Singer*, 668 F.2d at 1110. The Senate Report on that bill explained the intent of Section 13(b) as follows:

> This section would permit the Commission to obtain either a preliminary or permanent injunction through court procedures initiated by its own attorneys against any act or practice which is unfair or deceptive to a consumer, and thus prohibited by section 5 of the Federal Trade Commission Act. The purpose of section 210 is to permit the Commission to bring an immediate halt to unfair or deceptive acts or practices when to do so would be in the public interest. At the present time such practices might continue for several years until agency action is completed. Victimization of American consumers should not be so shielded.

> Section 210 authorizes the granting of a temporary restraining order or a preliminary injunction without bond pending the issuance of a complaint by the Commission under section 5, and until such complaint is dismissed by the Commission or set aside by the court on review, or until the order of the Commission made thereon has become final within the meaning of section 5. The test the Commission would have to meet in order to secure this injunctive relief is similar to the test it must already meet when attempting to secure an injunction against false advertising of food, drugs, devices, or cosmetics. (See 15 USC 53(a).)
>
> Provision is also made in section 210 for the Commission to seek and, after a hearing, for a court to grant a permanent injunction. This will allow the Commission to seek a permanent injunction when a court is reluctant to grant a temporary injunction because it cannot be assured of a early hearing on the merits. Since a permanent injunction could only be granted after such a hearing, this will assure the court of the ability to set a definite hearing date. Furthermore, the Commission will have the ability, in the routine fraud case, to merely seek a permanent injunction in those situations in which it does not desire to further expand upon the prohibitions of the Federal Trade Commission Act through the issuance of a cease-and-desist order. Commission resources will be better utilized, and cases can be disposed of more efficiently.

S. Rep. 93-151, at 30–31 (1973). The Senate Report indicates that Congress intended for Section 13(b) to address violations requiring quick or immediate action by a federal district court. Thus, that the FTC must, to seek permanent injunctive relief, have reason to believe ViroPharma "is violating, or is about to violate" a law enforced by the FTC, is further supported by the legislative history.

Having concluded that the permanent injunction proviso is not an independent grant of authority for the FTC to bring suit, I now move on to the second issue raised by the parties' 13(b) arguments. That issue relates to the proper interpretation of the language from (b)(1), "is about to violate." There does not appear to be any dispute that the FTC has not alleged that ViroPharma "is violating" a law enforced by the FTC.

In opposing ViroPharma's motion to dismiss, the FTC argues that "is about to violate" is properly understood to mean that a past violation of law is "likely to recur" or "there exists some cognizable danger of recurrent violation." (*See* D.I. 22 at 16). More specifically, the FTC maintains, "Courts have consistently treated the 'is violating, or is about to violate' language in Section 13(b) as equivalent to the general standard for awarding injunctive relief set forth by the Supreme Court in *United States v. W.T. Grant Co.*, 345 U.S. 629 (1953)."[7] (*Id.*). Accordingly, argues the FTC, this Court should apply that standard and find the complaint adequately alleges that ViroPharma's misconduct is likely to recur.[8] (*See id.* at 19–22). The FTC cites *Evans Products Co.*, 775 F.2d 1084 (9th Cir. 1985) and *F.T.C. v. Accusearch Inc.*, 570 F.3d 1187 (10th Cir. 2009), among others.

In my opinion, the FTC's reliance on those cases is misplaced. While the courts in *Evans Products* and *Accusearch* applied a likelihood of recurrence standard, they did so in deciding whether a district court had properly granted or denied injunctive relief, not whether the FTC had

[7] The FTC cites *S.E.C. v. Richie*, 2008 WL 2938678 (C.D. Cal. May 9, 2008), for the proposition that to not interpret "is violating, or is about to violate" as equivalent to the permanent injunction standard "would be illogical because this would create situations when the [agency] has made a showing that it can obtain injunctive relief but does not have standing to sue for such relief." (D.I. 22 at 18 (quoting *Richie*, 2008 WL 2938678, at *9)). While I appreciate the argument, I see no reason why I should ignore the plain language of the statute, which authorizes the FTC to file suit in federal court only if it has reason to believe a corporation "is violating, or is about to violate" a provision of law enforced by the FTC.

[8] Alternatively, the FTC argues that, even absent a likelihood of recurrence, the FTC may bring suit in federal court to obtain monetary equitable relief, such as restitution and disgorgement. (D.I. 22 at 26). While "courts have consistently held that the unqualified grant of statutory authority to issue an injunction under [S]ection 13(b) carries with it the full range of equitable remedies," *F.T.C. v. Bronson Partners LLC*, 654 F.3d 359, 365 (2d Cir. 2011) (citations omitted) (alteration in original), I agree with ViroPharma that the FTC confuses the court's ability to award a particular remedy in the absence of a likelihood of recurrence with the FTC's authority to bring suit in the first place. All the cases to which the FTC cites to support its position relate to the court's ability to award other equitable remedies absent a likelihood of recurrence, not to whether the FTC is properly in federal court.

adequately pled, at the motion to dismiss stage, that the defendants were violating or were about to violate the law. *See Evans Products*, 775 F.2d at 1088 (upholding district court's denial of FTC's motion for preliminary injunction where there was no finding of likelihood of recurrence); *Accusearch*, 570 F.3d at 1201–02 (referring to likelihood of recurrence standard in reviewing district court's decision to grant FTC's motion for permanent injunction).

The FTC also cites two district court cases involving 13(b) at the motion to dismiss stage. They are *F.T.C. v. Engage-A-Car Services, Inc.*, 1986 WL 15066 (D.N.J. Dec. 18, 1986) and *F.T.C. v. Citigroup Inc.*, 239 F. Supp. 2d 1302 (N.D. Ga. 2001).

I think those cases are similarly inapposite. In *Engage-A-Car*, the defendants moved to dismiss on the basis that the FTC's complaint was "technically deficient in its failure to plead that violations are ongoing or likely to recur . . . [and that] the Commission [could not] meet the legal standard for demonstrating likelihood of recurrence." 1986 WL 15066, at *4. Accordingly, the court addressed whether the complaint alleged facts sufficient to support an inference that the FTC was entitled to the injunctive relief it sought.[9] *See id.* at *4–5. That inquiry included considering whether the complaint alleged facts supporting an inference that the defendants' violations were likely to recur. *Id.* at *5. The court did not appear to consider or interpret the language, "is violating, or is about to violate."

In *Citigroup,* the defendants moved to dismiss for lack of subject matter jurisdiction, alleging the complaint "fail[ed] to assert the FTC's entitlement to injunctive relief." 239 F.

[9] I note the court in *Engage-A-Car* initially framed the defendants' argument as follows: "[T]he FTC has failed to allege [either defendant] is violating or is about to violate any law enforced by the FTC in accordance with Section 13(b)." 1986 WL 15066, at *1. As explained above, however, the court went on to discuss and address the defendants' argument in more detail. That discussion shows the defendants challenged the complaint on the basis that it did not allege facts sufficient to justify the relief sought by the FTC.

Supp. 2d at 1305. In deciding the defendants' motion, the court characterized the defendants' argument as a Rule 12(b)(6) challenge to the FTC's claim for injunctive relief. *Id.* at 1305–06. Accordingly, the court referred to the likelihood of recurrence standard. *See id.* at 1306. Like the court in *Engage-A-Car*, however, the court in *Citigroup* did not appear to consider or interpret the language from (b)(1), "is violating or is about to violate." Thus, I do not think the cases to which the FTC cites stand for the proposition that "is violating or is about to violate" is equivalent to the standard courts apply in deciding whether an injunction should issue.

Having rejected the FTC's arguments in regard to the likelihood of recurrence standard, I now consider whether the complaint alleges facts that plausibly suggest ViroPharma "is about to violate" a law enforced by the FTC.

In my opinion, it does not. While the forty-five-page complaint contains specific factual allegations in regard to ViroPharma's conduct from March 2006 to April 2012, it contains nothing by way of facts that plausibly suggest ViroPharma "is about to violate" any law. The complaint maintains, "ViroPharma is engaged in the business of, among other things, developing, manufacturing, and marketing branded drug products, including *inter alia*, Cinryze." (D.I. 2 ¶ 8). At oral argument, the FTC argued that "ViroPharma is perfectly positioned to commit [] future violations. . . . They have a blockbuster drug in the pipeline . . . that's being marketed already called Cinryze." (Tr. at 45:1–5). The FTC represented that while it did not think Cinryze is "ripe for generic entry at this point," it is "a drug that is the same type of significance as Vancocin was." (*Id.* at 45:6–8). None of those facts are alleged in the complaint, however. Other than noting ViroPharma markets drugs including Cinryze, the complaint states only in a conclusory fashion, "Absent an injunction, there is a cognizable danger that ViroPharma will engage in similar conduct . . . ." (D.I. 2 ¶ 150). It alleges further that

"ViroPharma has the incentive and opportunity to continue to engage in similar conduct in the future. At all relevant times, ViroPharma marketed and developed drug products for commercial sale in the United States, and it could do so in the future." (*Id.* ¶ 151). I do not think these allegations, without more, plausibly suggest ViroPharma is "about to violate" any law enforced by the FTC, particularly when the alleged misconduct ceased almost five years before filing of the complaint. Thus, having accepted the complaint's factual allegations as true and having viewed those allegations in the light most favorable to the FTC, I find the complaint fails to adequately plead facts allowing for the reasonable inference that ViroPharma is "about to violate" a law enforced by the FTC pursuant to Section 13(b).

B. *Noerr-Pennington*

ViroPharma further argues for dismissal on the basis that the petitioning conduct at issue is immune from challenge under the *Noerr-Pennington* doctrine. (D.I. 20 at 26).

"*Noerr-Pennington* provides broad immunity from liability to those who petition the government, including administrative agencies and courts, for redress of their grievances." *Hanover 3201 Realty, LLC v. Village Supermarkets, Inc.*, 806 F.3d 162, 178 (3d Cir. 2015) (citing *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510 (1972)). "Although *Noerr-Pennington* is a powerful shield, it is not absolute." *Id.* The so-called "sham exception" applies where petitioning is "a mere sham to cover what is actually nothing more than an attempt to interfere directly with business relationships of a competitor." *Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961); *see also City of Columbia v. Omni Outdoor Advert., Inc.*, 499 U.S. 365, 380 (1991).

In deciding whether petitioning activity falls under the sham exception, courts apply two different standards depending on whether there is a single petition or a series of petitions at issue.

See Hanover 3201, 806 F.3d at 180. When a series of petitions is at issue, the standard from *California Motor* applies. *Id.* "Th[at] inquiry asks whether a series of petitions were filed with or without regard to merit and for the purpose of using the governmental process (as opposed to the outcome of that process) to harm a market rival and restrain trade." *Id.* When there is only one alleged sham petition, on the other hand, the standard from *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.*, 508 U.S. 49 (1993), applies. *Id.* That standard involves two parts, the first of which requires a showing that the petition was objectively baseless. *See id.*

In this case, the parties dispute whether the activity at issue constitutes one petition or a series of petitions. The FTC argues that ViroPharma's filings constitute a series of petitions. (D.I. 22 at 30). Accordingly, the FTC maintains that *California Motor* applies, and the complaint adequately alleges ViroPharma's petitioning activity was a sham under that standard. (*Id.* at 30, 33). Alternatively, the FTC argues that even if *Professional Real Estate* were to apply, the complaint adequately alleges that ViroPharma's petitioning activity was objectively baseless. (*Id.* at 35). By contrast, ViroPharma argues there is only one petition at issue. (D.I. 20 at 29). Accordingly, it maintains *Professional Real Estate* applies, and the complaint fails to adequately plead ViroPharma's conduct was a sham under that standard. (*Id.* at 29–30). According to ViroPharma, the complaint is inadequate even if *California Motor* were to apply. (*Id.* at 30).

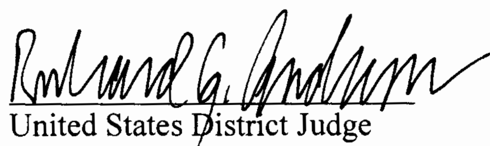
I think the allegations in the complaint, taken as true, are sufficient at this stage to overcome ViroPharma's "presumptive antitrust immunity under the *Noerr-Pennington* doctrine." *See Otsuka Pharm. Co. v. Torrent Pharms. Ltd.*, 118 F. Supp. 3d 646, 656 (D.N.J. 2015). I agree with the FTC that whether ViroPharma's activity was in fact a sham under either standard is a factual inquiry, which cannot be resolved at the motion to dismiss stage. *See id.* at 657 (denying

motion to dismiss where determinations in regard to baselessness of petitioning "require[d] inquiry into issues of fact, which [could not] be resolved in the context of a motion to dismiss, and prior to discovery"); *S3 Graphics Co. v. ATI Techs. ULC*, 2014 WL 573358, at *3 (D. Del. Feb. 11, 2014) (concluding resolution of *Noerr-Pennington* immunity "not proper before discovery"). Thus, I will not dismiss the FTC's complaint on the basis that ViroPharma's petitioning activity is immune under *Noerr-Pennington*.

IV. CONCLUSION

For the reasons stated above, ViroPharma's motion to dismiss (D.I. 19) is **GRANTED**. The FTC has leave to amend its complaint within a reasonable time.

It is **SO ORDERED** this 20 day of March 2018.



United States District Judge