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# [***FTC v. Shire ViroPharma, Inc.***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5RXF-HRX1-FGCG-S3FW-00000-00&context=)

United States District Court for the District of Delaware

March 20, 2018, Decided; March 20, 2018, Filed

Civil Action No. 17-131-RGA

**Reporter**

2018 U.S. Dist. LEXIS 45727 \*; 2018-1 Trade Cas. (CCH) P80,316; 2018 WL 1401329

FEDERAL TRADE COMMISSION, Plaintiff, v. SHIRE VIROPHARMA INC., Defendant.

**Core Terms**

permanent injunction, proviso, violating, cases, alleges, motion to dismiss, injunctive relief, bring suit, recurrence, argues, courts, federal court, petitions, applies, district court, sham, factual allegations, injunction, preliminary injunction, petitioning activity, citizen's petition, grant of authority, file suit, defendants', restraining, authorizes, plausibly, temporary, Products, marketed

**Counsel:** **[\*1]**For Federal Trade Commission, Plaintiff: Thomas J. Dillickrath, LEAD ATTORNEY, PRO HAC VICE, Bradley S. Albert, James H. Weingarten, Joseph Mathias, June Im, Meredyth Andrus, Nicholas Leefer, Federal Trade Commission, Washington, DC.

For Shire ViroPharma Inc., Defendant: Colm F. Connolly, LEAD ATTORNEY, Amy Michele Dudash, Morgan Lewis & Bockius LLP, Wilmington, DE; Greta L. Burkholder, John Clayton Everett, Jr., Noah J. Kaufman, Scott A. Stempel, Steven A. Reed, PRO HAC VICE.

**Judges:** Richard G Andrews, United States District Judge.

**Opinion by:** Richard G Andrews

**Opinion**

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)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5GYC-1WP1-6N19-F0YW-00000-00&context=) and [*12(b)(6)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5GYC-1WP1-6N19-F0YW-00000-00&context=). (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*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSD1-NRF4-4254-00000-00&context=), [*15 U.S.C. § 53(b)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSD1-NRF4-4254-00000-00&context=). (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)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSM1-NRF4-44DS-00000-00&context=) of the Act, [*15 U.S.C. § 45(a)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSM1-NRF4-44DS-00000-00&context=), by engaging in an unfair method of competition. (*Id.* ¶ 154).

The action arises**[\*2]** out of ViroPharma's use of the U.S. Food and Drug Administration's ("FDA") citizen petition process.[[1]](#footnote-0)1 (*Id.* ¶ 1). More specifically, the FTC alleges that ViroPharma used the FDA's citizen petition process to maintain its monopoly on Vancocin Capsules.[[2]](#footnote-1)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]](#footnote-2)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)***](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5GYC-1WP1-6N19-F0YW-00000-00&context=)

A court must grant a motion to dismiss pursuant to [*Rule 12(b)(1)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5GYC-1WP1-6N19-F0YW-00000-00&context=) 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)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:55N7-0PB1-F04K-K0CW-00000-00&context=). "In evaluating a [*Rule 12(b)(1)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5GYC-1WP1-6N19-F0YW-00000-00&context=) motion, a court must first determine whether the movant presents a facial or factual attack." *Id.* "In reviewing a facial challenge,**[\*3]** 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)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5GYC-1WP1-6N19-F0YW-00000-00&context=) arguments 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)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5GYC-1WP1-6N19-F0YW-00000-00&context=) motion. . . ." *Id.; see also* [*Baldwin v. Univ. of Pittsburgh Med. Ctr., 636 F.3d 69, 73 (3d Cir. 2011)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:52GY-2KR1-652R-111C-00000-00&context=) ("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)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5GYC-1WP1-6N19-F0YW-00000-00&context=) 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*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:55N7-0PB1-F04K-K0CW-00000-00&context=) (citation omitted).

**B.** [***Rule 12(b)(6)***](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5GYC-1WP1-6N19-F0YW-00000-00&context=)

In reviewing a motion to dismiss pursuant to [*Rule 12(b)(6)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5GYC-1WP1-6N19-F0YW-00000-00&context=), the Court must accept the complaint's factual allegations as true. *See* [*Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555-56, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4NSN-8840-004C-002M-00000-00&context=). [*Rule 8(a)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5GYC-1WP1-6N19-F0YK-00000-00&context=) requires "a short and plain statement of the claim showing**[\*4]** that the pleader is entitled to relief." [*Id. at 555*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4NSN-8840-004C-002M-00000-00&context=). 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, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4W9Y-4KS0-TXFX-1325-00000-00&context=). 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)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5GYC-1WP1-6N19-F0YW-00000-00&context=) 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)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:7YH1-F2D0-YB0V-F000-00000-00&context=).

**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)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSD1-NRF4-4254-00000-00&context=) of the Act. (D.I. 20 at 17). Second, it argues ViroPharma's alleged conduct is immune from challenge**[\*5]** under the *Noerr-Pennington* doctrine. (*Id.* at 26).

**A.** [***Section 13(b)***](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSD1-NRF4-4254-00000-00&context=)

ViroPharma's first argument raises what appear to be novel questions in regard to the proper interpretation of [*Section 13(b)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSD1-NRF4-4254-00000-00&context=) of the FTC Act. [*Section 13(b)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSD1-NRF4-4254-00000-00&context=) 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**[\*6]** 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)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSD1-NRF4-4254-00000-00&context=) (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)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3YDF-DD40-0038-Y2TM-00000-00&context=) (citations omitted). "The second proviso[[4]](#footnote-3)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))*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-3TG0-003B-G17Y-00000-00&context=); *see also* [*United States v. JS & A Grp., Inc., 716 F.2d 451, 457 (7th Cir. 1983)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4W-YN00-003B-G01C-00000-00&context=) (holding that [*Section 13(b)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSD1-NRF4-4254-00000-00&context=) 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)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSD1-NRF4-4254-00000-00&context=) arguments relates to whether the second proviso constitutes an independent grant of authority for the FTC**[\*7]** to file suit in federal court. More specifically, at issue is whether the language in [*(b)(1)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSD1-NRF4-4254-00000-00&context=), "is violating, or is about to violate," applies to cases where the FTC seeks a permanent injunction pursuant to the second proviso.[[5]](#footnote-4)5

ViroPharma argues the [*(b)(1)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSD1-NRF4-4254-00000-00&context=) language applies. (*See* D.I. 23 at 7). The FTC, on the other hand, suggests that because courts have held that [*(b)(2)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSD1-NRF4-4254-00000-00&context=) does not apply to cases brought under the second proviso, it makes sense that neither would [*(b)(1)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSD1-NRF4-4254-00000-00&context=) apply in such cases. (D.I. 22 at 16 (citing [*JS & A Grp., 716 F.2d at 456*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4W-YN00-003B-G01C-00000-00&context=); [*Singer, 668 F.2d at 1110-11*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-3TG0-003B-G17Y-00000-00&context=); [*Commonwealth Mktg. Grp., 72 F. Supp. 2d at 535-36*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3YDF-DD40-0038-Y2TM-00000-00&context=)); *see also* Tr. at 40:13-23).

I disagree. Although courts have held that [*(b)(2)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSD1-NRF4-4254-00000-00&context=) does not apply when the FTC seeks a permanent injunction pursuant to the second proviso, *e.g.,* [*Singer, 668 F.2d at 1110*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-3TG0-003B-G17Y-00000-00&context=),[[6]](#footnote-5)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)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:47TG-1WB0-0038-X10M-00000-00&context=). Here, [*Section 13(b)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSM1-NRF4-44BK-00000-00&context=) provides that the FTC, in certain circumstances, "may bring suit in a district court of the United States." [*15 U.S.C. § 53(b)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSD1-NRF4-4254-00000-00&context=) (emphasis added). It goes on to state**[\*8]** 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)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4829-3J30-0038-X3Y0-00000-00&context=) (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 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)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSM1-NRF4-44BK-00000-00&context=) 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. . .**[\*9]** a permanent injunction." [*15 U.S.C. § 53(b)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSD1-NRF4-4254-00000-00&context=). 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)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSD1-NRF4-4254-00000-00&context=) was enacted as part of the [*Trans-Alaska Pipeline Act, P.L. 93-153*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5CD7-HSD0-01XN-S2XT-00000-00&context=), but was originally a part of the Senate bill for the [*Federal Trade Improvement Act of 1973, P.L. 93-637*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5CD7-HSF0-01XN-S3SX-00000-00&context=)." [*Singer, 668 F.2d at 1110*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-3TG0-003B-G17Y-00000-00&context=). The Senate Report on that bill explained the intent of [*Section 13(b)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSD1-NRF4-4254-00000-00&context=) 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*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSM1-NRF4-44DS-00000-00&context=) of the [*Federal Trade Commission Act*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GWN1-NRF4-4310-00000-00&context=). The purpose of**[\*10]** 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*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GR01-NRF4-43MY-00000-00&context=), 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*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GR01-NRF4-43MY-00000-00&context=). 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)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSD1-NRF4-4254-00000-00&context=).)

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**[\*11]** 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)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSD1-NRF4-4254-00000-00&context=) 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)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSD1-NRF4-4254-00000-00&context=) arguments. That issue relates to the proper interpretation of the language from [*(b)(1)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSD1-NRF4-4254-00000-00&context=), "is about to violate."**[\*12]** 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)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSD1-NRF4-4254-00000-00&context=) 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, 73 S. Ct. 894, 97 L. Ed. 1303 (1953)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-JFW0-003B-S0B2-00000-00&context=)."[[7]](#footnote-6)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]](#footnote-7)8 (*See id.* at 19-22). The FTC cites [*Evans Products Co., 775 F.2d 1084 (9th Cir. 1985)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-CY00-0039-P328-00000-00&context=) and [*F.T.C. v. Accusearch Inc., 570 F.3d 1187 (10th Cir. 2009)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4WNR-04Y0-TXFX-F1V1-00000-00&context=), 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 adequately pled, at the motion to dismiss stage, that the defendants were violating or were about to**[\*13]** violate the law. *See* [*Evans Products, 775 F.2d at 1088*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-CY00-0039-P328-00000-00&context=) (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*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4WNR-04Y0-TXFX-F1V1-00000-00&context=) (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)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSD1-NRF4-4254-00000-00&context=) at the motion to dismiss stage. They are [*F.T.C. v. Engage-A-Car Services, Inc., 1986 U.S. Dist. LEXIS 16357, 1986 WL 15066 (D.N.J. Dec. 18, 1986)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4N-78N0-0039-R13J-00000-00&context=) and [*F.T.C. v. Citigroup Inc., 239 F. Supp. 2d 1302 (N.D. Ga. 2001)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:44XW-2JB0-0038-Y26Y-00000-00&context=).

I think those cases are similarly inapposite. In [*Engage-A-Car,*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4N-78N0-0039-R13J-00000-00&context=) 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 U.S. Dist. LEXIS 16357, 1986 WL 15066, at \*4*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4N-78N0-0039-R13J-00000-00&context=). 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]](#footnote-8)9*See* [*1986 U.S. Dist. LEXIS 16357, [WL] at \*4-5*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4N-78N0-0039-R13J-00000-00&context=). That inquiry included considering whether the complaint alleged facts supporting an inference that the defendants' violations were likely to recur. [*1986 U.S. Dist. LEXIS 16357, [WL] at \*5*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4N-78N0-0039-R13J-00000-00&context=). The court did not appear to consider or interpret the language, "is violating,**[\*14]** or is about to violate."

In [*Citigroup*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:44XW-2JB0-0038-Y26Y-00000-00&context=), 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. Supp. 2d at 1305*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:44XW-2JB0-0038-Y26Y-00000-00&context=). In deciding the defendants' motion, the court characterized the defendants' argument as a [*Rule 12(b)(6)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5GYC-1WP1-6N19-F0YW-00000-00&context=) challenge to the FTC's claim for injunctive relief. [*Id. at 1305-06*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:44XW-2JB0-0038-Y26Y-00000-00&context=). Accordingly, the court referred to the likelihood of recurrence standard. *See* [*id. at 1306*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:44XW-2JB0-0038-Y26Y-00000-00&context=). Like the court in [*Engage-A-Car*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4N-78N0-0039-R13J-00000-00&context=), however, the court in [*Citigroup*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:44XW-2JB0-0038-Y26Y-00000-00&context=) 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**[\*15]** 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**[\*16]** 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)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSD1-NRF4-4254-00000-00&context=).

**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)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5HC4-0FF1-F04K-K061-00000-00&context=) (citing [*Cal. Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508, 510, 92 S. Ct. 609, 30 L. Ed. 2d 642 (1972))*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-DB70-003B-S53W-00000-00&context=). "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**[\*17]** 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, 81 S. Ct. 523, 5 L. Ed. 2d 464 (1961)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-HKX0-003B-S43T-00000-00&context=); *see also* [*City of Columbia v. Omni Outdoor Advert., Inc., 499 U.S. 365, 380, 111 S. Ct. 1344, 113 L. Ed. 2d 382 (1991)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S65-KV00-003B-R2J0-00000-00&context=).

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*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5HC4-0FF1-F04K-K061-00000-00&context=). When a series of petitions is at issue, the standard from [*California Motor*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-DB70-003B-S53W-00000-00&context=) 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, 113 S. Ct. 1920, 123 L. Ed. 2d 611 (1993)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3RJ6-FCR0-003B-R0M3-00000-00&context=), 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**[\*18]** 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)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5G8M-Y1V1-F04D-W00V-00000-00&context=). 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*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5G8M-Y1V1-F04D-W00V-00000-00&context=) (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 U.S. Dist. LEXIS 16928, 2014 WL 573358, at \*3 (D. Del. Feb. 11, 2014)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5BGW-HNS1-F04D-019M-00000-00&context=) (concluding resolution of *Noerr-Pennington* immunity**[\*19]** "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.

/s/ Richard G Andrews

United States District Judge

**End of Document**

1. 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)*](https://advance.lexis.com/api/document?collection=administrative-codes&id=urn:contentItem:5PRW-JB40-008G-Y27Y-00000-00&context=))). [↑](#footnote-ref-0)
2. 2Vancocin is a drug used to treat gastrointestinal infection. (D.I. ¶¶ 1, 30). [↑](#footnote-ref-1)
3. 3Specifically, 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.*). [↑](#footnote-ref-2)
4. 4I refer to this proviso as either the "second proviso" or the "permanent injunction proviso." [↑](#footnote-ref-3)
5. 5The 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)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4N-V0F0-0039-S1YS-00000-00&context=). In that case, the court noted, "A careful reading of s [*13(b)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSD1-NRF4-4254-00000-00&context=) 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*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4N-V0F0-0039-S1YS-00000-00&context=). 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*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4N-V0F0-0039-S1YS-00000-00&context=). The FTC has not done so here. [↑](#footnote-ref-4)
6. 6In 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*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4W-YN00-003B-G01C-00000-00&context=). That reasoning would seem to suggest that neither does [*(b)(1)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSD1-NRF4-4254-00000-00&context=) 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. [↑](#footnote-ref-5)
7. 7The FTC cites [*S.E.C. v. Richie, 2006 U.S. Dist. LEXIS 45853, 2008 WL 2938678 (C.D. Cal. May 9, 2008)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4KBX-6WS0-TVSH-31VP-00000-00&context=), 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, 2006 U.S. Dist. LEXIS 45853, 2008 WL 2938678, at \*9))*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4KBX-6WS0-TVSH-31VP-00000-00&context=). 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. [↑](#footnote-ref-6)
8. 8Alternatively, 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)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSD1-NRF4-4254-00000-00&context=) carries with it the full range of equitable remedies," [*F.T.C. v. Bronson Partners LLC, 654 F.3d 359, 365 (2d Cir. 2011)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:830F-H7R1-652R-01J5-00000-00&context=) (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. [↑](#footnote-ref-7)
9. 9I note the court in [*Engage-A-Car*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4N-78N0-0039-R13J-00000-00&context=) 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)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSD1-NRF4-4254-00000-00&context=)." [*1986 U.S. Dist. LEXIS 16357, 1986 WL 15066, at \*1*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4N-78N0-0039-R13J-00000-00&context=). 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. [↑](#footnote-ref-8)