UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

Thurgood Marshall U.S. Courthouse 40 Foley Square, New York, NY 10007 Telephone: 212-857-8500

MOTION INFORMATION STATEMENT

Docket Number(s): 22-728 _____ Caption [use short title] _____

Motion for: leave to file an amicus curiae brief in support of no party.

Set forth below precise, complete statement of relief sought:

The Pensmore Foundation seeks leave to file the attached amicus curiae brief in support of no party.

Federal Trade Commission, et al. v. Shkreli

MOVING PARTY: Pensmore Foundation **OPPOSING PARTY:** N/A

☐ Plaintiff ☐ Defendant

☐ Appellant/Petitioner ☐ Appellee/Respondent

X Amicus

MOVING ATTORNEY: Thomas M. Huff **OPPOSING ATTORNEY:** N/A

[name of attorney, with firm, address, phone number and e-mail]

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The defendant-appellant consents to the motion.

The appellee FTC does not oppose the motion.

The State appellees take no position on the motion.

Court- Judge/ Agency appealed from: USDC-SDNY - Hon. Denise L. Cote (20-cv-706-DLC)

Please check appropriate boxes:

Has movant notified opposing counsel (required by Local Rule 27.1):
☑ Yes ☐ No (explain):_____

Opposing counsel's position on motion:
☑ Unopposed ☐ Opposed ☐ Don't Know

Does opposing counsel intend to file a response:
☐ Yes ☑ No ☐ Don't Know

FOR EMERGENCY MOTIONS, MOTIONS FOR STAYS AND INJUCTIONS PENDING APPEAL:

Has this request for relief been made below? ☐ Yes ☐ No

Has this relief been previously sought in this court? ☐ Yes ☐ No

Requested return date and explanation of emergency: _____

Is oral argument on motion requested? ☐ Yes ☑ No (requests for oral argument will not necessarily be granted)

Has argument date of appeal been set? ☐ Yes ☑ No If yes, enter date:_____

Signature of Moving Attorney:

/s/ Thomas M. Huff **Date:** 01/09/2023 Service by: ☑ CM/ECF ☐ Other [Attach proof of service]

22-728

In the United States Court of Appeals for the Second Circuit

FEDERAL TRADE COMMISSION, STATE OF NEW YORK, STATE OF CALIFORNIA, STATE OF OHIO, COMMONWEALTH OF PENNSYLVANIA, STATE OF ILLINOIS, STATE OF NORTH CAROLINA, COMMONWEALTH OF VIRGINIA,

Plaintiffs-Appellees,

v.

MARTIN SHKRELI, individually, as an owner and former director of Phoenixus AG and as a former executive of Vyera Pharmaceuticals, LLC,

Defendant-Appellant.

On Appeal from the United States District Court
for the Southern District of New York
No. 20-cv-706
The Honorable Denise L. Cote

BRIEF OF PENSMORE FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF NO PARTY

[*cover continued on next page*]

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CORPORATE DISCLOSURE STATEMENT

Under Fed. R. App. P. 26.1, the Pensmore Foundation states that it is a nonprofit corporation organized under § 501(c)(3) of the Internal Revenue Code. Pensmore has no parent corporation, does not issue stock, and no publicly held company holds a 10% or greater ownership interest.

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INTEREST OF THE *AMICUS CURIAE*[1]

The Pensmore Foundation is a private § 501(c)(3) nonprofit organization whose mission includes advocating and promoting constitutional principles of limited government. Pensmore believes that this appeal raises important questions concerning the proper scope of a federal court's remedial powers when sitting in equity.

In this case, the district court found the Appellant liable for violations of federal and state antitrust law when he used his influence over a pharmaceutical company that he founded to implement a scheme that restricted sales of product samples to generic drug developers, thereby impeding their ability to conduct FDA-required bioequivalence testing and delaying their entry into the market. Among other remedies, the district court then used Section 13(b) of the FTC Act to impose a lifetime ban on Appellant's participation in the entirety of the pharmaceutical industry. As best Amicus can discover, this is the sole instance in which Section 13(b) has been invoked to impose a plenary industry ban as a remedy for a violation of the Sherman Act. Although Amicus takes no position on the propriety of such an

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[1] Per Fed. R. App. P. 29(a)(4)(E) and Local Rule 29.1(b), counsel for *amicus curiae* states that none of the parties or their counsel authored this brief in whole or in part, and that no person or entity other than *amicus curiae* or its counsel made a monetary contribution to this brief's preparation or submission.

injunction in an extraordinary case backed by appropriate factfinding, it respectfully urges cautious scrutiny under longstanding maxims of equity.

STATEMENT OF THE CASE

The facts of the case are set out in detail in the Appellant's Brief. Amicus wishes to briefly highlights certain salient facts related to its brief.

In 2014, appellant Martin Shkreli, a former hedge fund manager, founded a pharmaceutical company called Turing Pharmaceuticals (now Vyera). In August of 2015, Turing purchased from Impax Laboratories the rights to Daraprim, SPA-48—a tablet formulation of the antiparasitic drug pyrimethamine widely considered by physicians and medical experts to be the "gold standard" for treating the rare and potentially fatal disease toxoplasmosis. *See* SPA-47. At the time of purchase, Daraprim was off patent but had no generic competitors, and had a wholesale acquisition price of $17.60 per tablet. SPA-48.

Soon after, Turing—at Shkreli's direction—dramatically raised the wholesale acquisition price of Daraprim from $17.60 per tablet to $750, SPA-48, while simultaneously implementing various distribution restrictions to block its sale to generic drug developers. These actions effectively prevented generic drug developers from obtaining the necessary product samples that they would need to perform regulatory bioequivalence testing and enter the market as generic competitors. *See generally* SPA-50-69.

Shkreli and Turing's actions quickly generated widespread public scorn, with Shkreli in particular dubbed the "most hated man in America."[2] Moreover, as the district court observed, Shkreli "doubled down" in the face of this opprobrium, SPA-141, defending the price increase before public audiences,[3] at times trading brash insults with his critics. In the same timeframe, Shkreli was arrested in December 2015 for unrelated conduct concerning a prior hedge fund; he subsequently resigned as Turing's CEO but remained its largest shareholder.[4] SPA-43.

The Daraprim controversy also attracted the attention of Congress, which launched investigations into Turing and other companies that had adopted similar strategies with off-patent drugs that treated rare diseases. A 2016 Senate Report[5]

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[2] *See* Zoe Thomas & Tim Swift, *Who is Martin Shkreli—'the Most Hated Man in America'?*, BBC NEWS (August 4, 2017), https://www.bbc.com/news/world-us-canada-34331761

[3] In one public comment referenced by the district court, SPA-141, Shkreli told an audience member at the 2015 Forbes Healthcare Summit that if he could go back in time, he "probably would have raised prices higher." *See* Dan Diamond, *Martin Shkreli Admits He Messed Up: He Should've Raised Prices Even Higher*, FORBES (Dec. 3, 2015), https://www.forbes.com/sites/dandiamond/2015/12/03/what-martin-shkreli-says-now-i-shouldve-raised-prices-higher/ ; *see also* Graham W. Bishai, *Protest, False Fire Alarm Disrupt Martin Shkreli's Harvard Speech*, THE HARV. CRIMSON (Feb. 16, 2017), https://www.thecrimson.com/article/2017/2/16/martin-shkreli-protest/

[4] Shkreli was later convicted of three counts of securities fraud in 2017 and sentenced to 84 months in prison; the record reflects that he was incarcerated throughout the district court proceedings in this case. *See* SPA-29.

[5] U.S. SENATE SPECIAL COMM. ON AGING, 114TH CONG., Sudden Price Spikes in Off- Patent Prescription Drugs: The Monopoly Business Model that Harms

(referenced by the appellees in their amended complaint, A-167, ¶¶ 139-140), noted that the "conduct of Turing and others, no matter how disturbing, may be legal," *id*. at 116-17, concluding that caselaw in this Circuit "makes it difficult to bring a successful case against Turing or Mr. Shkreli for failing to deal." *Id*. at 116, n.732 (citing *In re Elevator Antitrust Litig.*, 502 F.3d 47, 54 (2d Cir. 2007)). The report proposed several courses of legislative action. Three years later, on December 20, 2019, Congress enacted the CREATES Act, which now affirmatively obligates branded drug companies to sell drug samples to generic companies to facilitate regulatory bioequivalence testing. *See infra*, 24.

Approximately one month later, the Federal Trade Commission and seven State plaintiffs sued Vyera and its parent corporation—along with then-current CEO Kevin Mulleady and former-CEO Shkreli—in the Southern District of New York on January 27, 2020, asserting that their actions with respect to Daraprim violated the Sherman Act and various state antitrust statutes that mirror federal law. *See* SPA-23; SPA-102. The FTC invoked its jurisdiction under Section 13(b), thereby bypassing its traditional Section 5 administrative process and limiting itself to injunctive relief only. The States similarly proceeded solely in equity, waiving their right to a jury trial and any remedies at law. SPA-8.

Patients, Taxpayers, and the U.S. Health Care System (Dec. 2016), https://www.aging.senate.gov/imo/media/doc/Drug%20Pricing%20Report.pdf [hereinafter, "Senate Report"]

Vyera and Mulleady settled shortly before trial, while Shkreli proceeded. SPA-24. Following a seven-day bench trial, the district court issued an opinion on January 14, 2022, finding Shkreli individually liable for violating "Sections 1 and 2 of the Sherman Act and the parallel violations of state law." SPA-136. Sitting solely in equity, the district court then entered a permanent injunction enjoining Shkreli for life from not only the conduct adjudicated at trial, but also from any participation in any aspect of the pharmaceutical industry, SPA-166-67—expressly banning him even from making any public statements intended to "influence" the "business" of a pharmaceutical company. SPA-159 ("While First Amendment rights deserve of great protection, Shkreli's violations of the antitrust laws have lost for him the right to speak publicly about the pharmaceutical industry when such speech is uttered to influence the management or business of a Pharmaceutical Company."). The district court also entered an equitable disgorgement order of $64.6 million, representing a calculation of profits that Vyera reaped from the charged conduct. SPA-148. The court did not make any apparent findings on what allocation—if any—of these profits Shkreli realized personally. Instead, it ordered him jointly and severally liable for the full amount, to be offset by any payments made by the settling defendants. SPA-148-50.

Shkreli has now appealed. He does not challenge the lower court's findings of antitrust liability, but focuses solely on the appropriateness of the remedies

imposed. Amicus files this brief to address those same appellate issues, but with a focus on principles of equity.

SUMMARY OF THE ARGUMENT

1. *Courts sitting in equity should exercise caution in issuing broad injunctive relief to remedy violations of previously unsettled questions of antitrust law*. Amicus does not dispute the FTC's important congressional mandate to promote fair competition through enforcement of the federal antitrust laws. But a "key feature" of antitrust law is that it "is developed entirely through adjudication." Rohit Chopra & Lina M. Khan, The Case for "Unfair Methods of Competition" Rulemaking, 87 U. CHI. L. REV. 357, 357 (2020). In rule-of-reason cases, like the one under review here, the Sherman Act often requires courts to reconcile competing legal rules and evaluate novel types of conduct that were not clearly proscribed ex ante. This ambiguity—while perhaps an unavoidable consequence of the adaptive nature of antitrust—can also "deprive[] market participants . . . notice about what the law is" and "thereby undermin[e] due process." *Id*. at 359. Indeed, "the line between *anticompetitive* behavior, which is illegal under federal antitrust law, and *hypercompetitive* behavior, which is not," *FTC v. Qualcomm Inc.*, 969 F.3d 974, 982 (9th Cir. 2020) (emphasis in original) is not always clear. Accordingly, a market actor pursuing what it believes to be a hypercompetitive business model under one legal precedent may later find itself liable for anticompetitive behavior under

another. If the FTC has—as here—pursued its case under Section 13(b), that actor will then be subject to a permanent injunction. *See* 15 U.S.C. § 53(b). In such circumstances, Amicus respectfully submits that the longstanding equitable principle that "injunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs," *Madsen v. Women's Health Ctr., Inc.*, 512 U.S. 753, 765 (1994), merits special emphasis.

The actions of the defendants in this case invoked widespread public outrage—and perhaps rightly so. But courts sitting in equity are confined to remedial purposes, not punitive ones. And here, the record reflects that the anticompetitive conduct that was ultimately found to violate the Sherman Act was hardly a matter of settled illegality when the defendants purchased Daraprim in 2015. To the contrary, subsequent congressional investigations appear to have universally concluded that Turing's "abuses d[id] not clearly violate antitrust law," Senate Report, supra at 116, pointing to a longstanding precedent of this Court to conclude that "[t]he law is far from clear on whether it is an antitrust violation to refuse to deal with potential generic entrants seeking reference listed drugs." *Id*.; *see also id*. at n.732 ("Because Mr. Shkreli undertook his actions with regards to restricted distribution in New York—within the Second Circuit—*In re Elevator Antitrust Litigation* makes it difficult to bring a successful case against Turing or Mr. Shkreli for failing to deal."). Nor does the conduct appear to have been limited

to the defendants: then-FDA Commissioner Scott Gottlieb testified to Congress in 2017 that sample blockades were a growing problem,[6] and reported the year after that the agency had fielded "more than 150 complaints from generic drug developers seeking assistance in obtaining samples from brand companies."[7] These congressional investigations ultimately culminated in Congress' enactment on December 20, 2019, of the CREATES Act, which now affirmatively requires branded drug manufacturers to sell drug samples to generic companies to facilitate regulatory bioequivalence testing, thereby resolving the legal ambiguity going forward. Pub. L. No. 116-94, § 610.

2. *The FTC's power to seek a "permanent injunction" under Section 13(b) is cabined by traditional principles of equity*. As the Supreme Court has repeatedly emphasized, "[s]tatutory references to a remedy grounded in equity must, absent other indication, be deemed to contain the limitations upon its availability that equity typically imposes." *Liu v. SEC*, 140 S. Ct. 1936, 1947

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[6] *See* Wen W. Shen, Cong. Rsch. Serv., LSB10272, The CREATES Act of 2019 and Lowering Drug Prices: Legal Background and Overview 2 (2019), https://crsreports.congress.gov/product/pdf/LSB/LSB10272 [hereinafter, "CRS Report"]

[7] Food and Drug Administration, Statement from FDA Commissioner Scott Gottlieb, M.D., on new agency efforts to shine light on situations where drug makers may be pursuing gaming tactics to delay generic competition (May 17, 2018), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-agency-efforts-shine-light-situations-where-drug [hereinafter, "Gottlieb Statement"]

(2020). A permanent injunction is an equitable remedy and must therefore conform with equity's requirements that it be exclusively forward-looking and non-punitive. By contrast, an injunction issued to punish past conduct, or that is motivated by a desire to achieve general deterrence by sending a message to the pharmaceutical industry at large, does not conform with such principles. Congress has created ample non-equitable alternatives to 13(b) to achieve the goals of punishment and deterrence—including the FTC's traditional administrative process under Section 5 and the Sherman Act's authorization of punitive legal remedies, including treble damages, civil fines, and criminal prosecution.

3. Amicus does not endorse the business model of the defendants and takes no position on what—if any—equitable relief should be imposed on Mr. Shkreli in his individual capacity. But whatever relief is ultimately entered, it should satisfy the same traditional principles that bind courts of equity in all cases. Courts sitting in law are free to impose punishments, issue civil fines, condemn egregious conduct, and otherwise fashion punitive remedies that serve general deterrence—but those punishments at law carry the added protection of a jury trial. Courts of equity, by contrast, sit without juries and are confined to remediation. Permitting the FTC's Section 13(b) power to stray beyond traditional principles of equity and morph into a tool of punishment would set a disturbing precedent.

As Justice Holmes famously cautioned, public opinion has a tendency to exert "a kind of hydraulic pressure . . . before which even well settled principles of law will bend." *Northern Securities Co. v. United States*, 193 U.S. 197, 400 (1904) (Holmes, J., dissenting) ("Great cases like hard cases make bad law. For great cases are called great, not by reason of their real importance in shaping the law of the future, but because of some accident of immediate overwhelming interest which appeals to the feelings and distorts the judgment."). The conduct of the defendants may well have been egregious—but punishing egregious behavior is the function of law, not equity. In our system of government, the distinction should be maintained and enforced. This case, like both great and hard cases, should not be allowed to make bad law.

ARGUMENT

I. THE FTC'S POWER TO SEEK A "PERMANENT INJUNCTION" UNDER SECTION 13(b) IS CABINED BY TRADITIONAL PRINCIPLES OF EQUITY.

Section 13(b) of the FTC Act empowers the Commission to seek "in proper cases" a "permanent injunction" against a party it believes is "is violating, or is about to violate" a law falling under its enforcement jurisdiction. 15 U.S.C. § 53(b). Section 13(b) authorizes only injunctive relief and is cabined by traditional principles of equity—principles that Amicus submit have special relevance here.

A. The term "permanent injunction"—as used in Section 13(b)—incorporates its traditional meaning in equity.

As the Supreme Court has repeatedly emphasized, congressional statutes that authorize equitable relief must be cabined by the traditional and historical doctrines that inform those equitable remedies—unless Congress has made a clear statement to the contrary. *See*, *e.g.*, *Liu*, 140 S. Ct. at 1947 ("Statutory references to a remedy grounded in equity must, absent other indication, be deemed to contain the limitations upon its availability that equity typically imposes.") (cleaned up).[8] Accordingly, when Congress uses the term "injunction" in a statute, that term should be construed as "a statutory limitation" to the specific varieties of "injunctive relief" that were "typically available in equity." *GreatWest Life & Annuity Ins. Co. v. Knudson*, 534 U.S. 204, 211, n.1 (2002); *see also Taggart v. Lorenzen*, 139 S. Ct. 1795, 1801 (2019) (statutory references to injunctions "bring with them the 'old soil' that has long governed how courts enforce injunctions" under "traditional principles of equity practice."). The same is true for statutory references to "permanent

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[8] *See generally* Samuel Bray, *The Supreme Court and the New Equity*, 68 VAND. L. REV. 997 (2015) ("In a series of cases over the last decade and a half . . . the Court has consistently reinforced the line between legal and equitable remedies, and it has treated equitable remedies as having distinctive powers and limitations. . . . Faced with many federal statutes authorizing equitable relief, the Court has looked to history and tradition to determine what counts as an equitable remedy and also to determine the circumstances in which equitable relief should be given.").

injunction[s]," which must be read to incorporate "well-established principles of equity." *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 391 (2006).

Operating under this framework, the term "permanent injunction"—as used in Section 13(b)—is equally constrained by its traditional meaning in equity. Nothing in the statute's text conveys that Congress intended to allow permanent injunctions to issue more broadly than those permitted in traditional equity practice.[9] Indeed, the Supreme Court's recent conclusion that Section 13(b) authorizes only "prospective, not retrospective" relief, *AMG Cap. Mgmt., LLC v. FTC*, 141 S. Ct. 1341, 1348 (2021), hinged in part on traditional equitable principles. *See id*. at 1347.

In any event, the Constitution would prohibit any departure from equity because Section 13(b) does not offer the protections of a jury trial. While the Seventh Amendment guarantees defendants the right to a jury "in suits at common law," U.S. CONST. amend. VII., suits in equity are historically exempted from this right. *See Tull v. United States*, 481 U.S. 412, 417 (1987). Thus, courts have universally denied demands for jury trials in Section 13(b) cases. *FTC v. Verity Int'l, Ltd.*, 443 F.3d 48, 67 (2d Cir. 2006) ("The fact that only an equitable remedy is available [under §

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[9] If anything, Section 13(b)'s requirement that the defendant "is" or "is about to violate" the law further limits the FTC's power to only those cases involving ongoing or imminent violations. *See FTC v. Shire Viropharma, Inc.*, 917 F.3d 147, 154-61 (3d Cir. 2019).

13(b)] eviscerates the defendants-appellants' contention that the Seventh Amendment confers a right to a jury trial.").

* * *

In this case, the district court, operating under the rule of reason, *see* SPA-134-135, found that Shkreli violated the Sherman Act when he masterminded Vyera's scheme to block generic competition to Daraprim, and when he continued to exert his influence as the company's largest shareholder to keep the scheme in place after he departed as CEO. SPA-136-137. As a remedy, the district court issued a permanent injunction under Section 13(b) that was not limited to enjoining the conduct found to violate the Sherman Act—instead, it banned him for life from participating in any aspect of the pharmaceutical industry in any way. As best Amicus can discover, this is the sole instance in which Section 13(b) has been invoked to impose a plenary industry ban as a remedy for a violation of antitrust law. Although Amicus takes no position on the propriety of such an injunction in an extraordinary case backed by appropriate factfinding, it respectfully urges cautious scrutiny under two longstanding maxims of injunctive relief in equity.

1. In equity, injunctive remedies are exclusively preventive, never punitive.

It has been long understood that "[t]he historic injunctive process was designed to deter, not to punish." *Hecht Co. v. Bowles*, 321 U.S. 321, 329 (1944). Unlike courts sitting in law, "[i]t is not the function of courts of equity to administer

punishment." *Bangor Punta Operations, Inc. v. Bangor & A. R. Co.*, 417 U.S. 703, 717 n.14 (1974) (*citing Home Fire Ins. Co. v. Barber*, 67 Neb. 644, 673, 93 N.W. 1024, 1035 (1903)). Instead, "[t]he *sole* function of an action for injunction is to forestall future violations." *United States v. Or. State Med. Soc'y*, 343 U.S. 326, 333 (1952) (emphasis added); *see also* Thomas C. Spelling, A TREATISE ON THE LAW GOVERNING INJUNCTIONS § 21, at 34 (1926) ("To employ [an injunction] for the correction or redress of wrongful acts would be a perversion of the remedy.").

In its opinion below, however, the district court looked almost exclusively to Shkreli's *past* conduct as support for a sweeping industry ban, describing his scheme to block and restrict Daraprim sales to generic drug developers as "egregious" and "deliberate." SPA-140. It may well have been. But it also bears acknowledging that that scheme's arguable legality was contemporaneously recognized by Congress and other market actors. A 2016 Senate report—cited by the plaintiffs in their complaint, A-167, ¶¶ 139-140—expressly acknowledged that "[t]he conduct of Turing and others, no matter how disturbing, may be legal." That conclusion was based in part on this Court's decision in *In re Elevator Antitrust Litig.*, 502 F.3d 47 (2d Cir. 2007), concluding that "[t]he law is far from clear on whether it is an antitrust violation to refuse to deal with potential generic entrants seeking reference listed drugs." *See infra*, at 24-26. Indeed, it was precisely this uncertainty the led Congress to enact the CREATES Act in 2019. *See id.*. Of course, Shkreli did not prevail and now stands

liable for violating the Sherman Act. But the case against him proceeded under the rule of reason, SPA-134-135, and implicated legal questions that had not been clearly decided. Thus, the district court's conclusion that "the risk of recurrence is real" because "Shkreli has not expressed remorse or any awareness that his actions violated the law," SPA-142, is inapposite in an antitrust case—particularly in one of first impression. *See Howard Hess Dental Labs. Inc. v. Dentsply Int'l, Inc.*, 602 F.3d 237, 250-51 (3d Cir. 2010) ("Plaintiffs point to Dentsply's purported unrepentance regarding its past conduct as a basis for injunctive relief. They assert that 'Dentsply still refuses to acknowledge the wrongful nature of its conduct.' The antitrust laws, however, afford no relief on that basis alone. In a nutshell, the various examples of alleged injury the Plaintiffs have brought to our attention are purely speculative and thus are insufficient to justify an award of injunctive relief.") (citations omitted); *see also FTC v. AbbVie Inc.*, 976 F.3d 327, 381 (3d Cir. 2020) (same).

Amicus is not asserting that a court sitting in equity is categorically powerless to issue a plenary industry ban in antitrust law. Rather courts should proceed with caution, as "the principle that injunctions may issue only to prevent threatened future harm, not to punish, applies equally to an injunction's scope." *SEC v. Gentile*, 939 F.3d 549, 560 (3d Cir. 2019) (*citing SEC v. Am. Bd. of Trade, Inc.*, 751 F.2d 529, 542-43 (2d Cir. 1984) (Friendly, J.)). An injunction that permanently removes a market actor from commerce is an extraordinary remedy and should require an

equally extraordinary showing of "threatened future harm" to ensure compliance with the well-established principle that "injunctive relief should be no broader than necessary to cure the effects of the harm caused by the violation, and should not impose unnecessary burdens on lawful activity." *Church & Dwight Co. v. SPD Swiss Precision Diagnostics, GmbH*, 843 F.3d 48, 72 (2d Cir. 2016) (cleaned up). The Supreme Court has cautioned that "with lawyerly inventiveness," virtually any order can be "phrased in terms of an injunction." *Great-West*, 534 U.S. at 211 n.1. But punishment for past behavior is incompatible with the traditional understanding of the term "injunction." The injunction below should be scrutinized for compliance with these principles.

2. In equity, injunctive remedies cannot be ordered for the purpose of general deterrence.

Because injunctions in equity are exclusively non-punitive in nature, they should also not issue for purposes of general deterrence. "Just as it is error to issue an injunction for punishment's sake, it is error to broaden the scope of an injunction because of moral desert or to make an example of the defendant." *SEC v. Gentile*, 939 F.3d 549, 560 (3d Cir. 2019). Indeed, "[d]eterrence . . . has traditionally been viewed as a goal of punishment," *United States v. Bajakajian*, 524 U.S. 321, 329 (1998), and punishment is antithetical to equity. Thus, "[r]etribution and deterrence are not legitimate nonpunitive governmental objectives." *Bell v. Wolfish*, 441 U.S. 520, 539, n. 20 (1979); *accord Kokesh v. SEC*, 137 S. Ct. 1635, 1643 (2017). Of

course, injunctive relief can—and indeed must—serve the preventive aim of deterring the *violator* from repeating the conduct that the court has judged illegal. *See Gentile*, 939 F.3d at 563 (distinguishing general and specific deterrence). But "general deterrence," by contrast—*i.e.*, that sought to influence the behavior of the general public—is not a "proper consideration" for the issuance of an injunction. *Id.* at 560 (citing *Arthur Lipper Corp. v. SEC*, 547 F.2d 171, 180 n.6 (2d Cir. 1976) (Friendly, J.)).

Here, the appellees appear to concede that their demand for a plenary industry ban against Shkreli was motivated in part by a desire to send a broader message of deterrence to the pharmaceutical industry, arguing to the court in their closing statement that "[b]anning Shkreli from the pharmaceutical industry would also send a powerful signal to corporate executives in the pharmaceutical industry that they cannot engage in illegal schemes to reap monopoly profits at the expense of vulnerable patients." A-2240. Indeed, shortly after prevailing, the FTC issued public statements warning other pharmaceutical executives that they too should expect severe personal consequences for violations of antitrust law:

- "The federal court's decision to ban Shkreli for life from the pharmaceutical industry is a victory for Americans and should signal to corporate executives that they may be held personally liable for antitrust violations that they direct and may be banned for life from certain industries."[10]

[10] Federal Trade Commission, Prepared Statement Before the United States Senate Committee on the Judiciary Subcommittee on Antitrust, Competition Policy

- "Judge Cote's decision to ban Shkreli for life from the pharmaceutical industry is a significant victory for American consumers. This precedent-setting relief should be a warning to corporate executives everywhere that they may be held individually responsible for the anticompetitive conduct they direct or control."[11]

Though made out of court, these public statements betray a concerning sentiment that the FTC is using its equitable powers under Section 13(b) for more than simple remediation. This is beyond what the statute authorizes.

3. Congress has empowered the government with non-equitable alternatives to seek punishment and deterrence.

Amicus emphasizes that none of these limitations in equity render the government powerless to seek punishment and deterrence in its enforcement of the antitrust laws. Although remedies in equity do not permit punishment, remedies in law do—and Congress has created several mechanisms to accomplish exactly that. Legal liability under the Sherman Act, for example, can include treble damages in civil cases, 15 U.S.C. § 15(a), and fines of up to $100 million in felony criminal prosecutions. 15 U.S.C. § 2.

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and Consumer Rights, "Oversight of the Enforcement of the Antitrust Laws" (Sept. 20, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/P210100SenateAntitrustTestimony09202022.pdf

[11] Press Release, Federal Trade Commission, Statement of Chair Lina M. Khan on the Ruling by Judge Denise L. Cote Federal Trade Commission et al v. Vyera Pharmaceuticals, LLC et al. (Jan. 14, 2022), https://www.ftc.gov/news-events/news/press-releases/2022/01/statement-chair-lina-m-khan-ruling-judge-denise-l-cote-federal-trade-commission-et-al-v-vyera

It is undisputed that the FTC has the power to pursue more comprehensive relief through its traditional administrative process under Section 5, which empowers the Commission to use its subject-matter expertise to investigate anticompetitive conduct via agency adjudication and seek an appropriate cease-and-desist order from an Administrative Law Judge. FTC Act § 5(b), 15 U.S.C. § 45(b). That final order then gives the Commission the power to seek civil penalties for future violations, *see* FTC Act § 5(l); 15 U.S.C. § 45(l), and various forms of consumer redress. *See* FTC Act § 19, 15 U.S.C. § 57. But when, as here, the FTC opts to bypass its traditional administrative process and proceed directly to federal court under Section 13(b), it limits itself to equitable relief.

II. COURTS SITTING IN EQUITY SHOULD EXERCISE CAUTION IN ISSUING BROAD INJUNCTIVE RELIEF TO REMEDY VIOLATIONS OF PREVIOUSLY UNSETTLED QUESTIONS OF ANTITRUST LAW.

The Supreme Court has "repeatedly emphasized the importance of clear rules in antitrust law." *Pac. Bell Tel. Co. v. linkLine Communs., Inc.*, 555 U.S. 438, 452 (2009). While lauding the Sherman Act as the "Magna Carta of free enterprise," *United States v. Topco Assocs.*, 405 U.S. 596, 610 (1972), the Court has nonetheless cautioned that adjudicating exclusionary conduct under Section 2 "can be difficult because the means of illicit exclusion, like the means of legitimate competition, are myriad." *Verizon Communs., Inc. v. Trinko*, 540 U.S. 398, 414 (2004) (citations and quotations omitted). Such ambiguity—though perhaps an unavoidable feature of the

adaptive nature of antitrust—can implicate significant public policy concerns. The rule of law is undermined, not advanced, if market actors face legal liability for conduct that was not clearly proscribed *ex ante*. *See* Chopra & Khan, supra at 359 ("The dearth of clear standards and rules in antitrust means that market actors face uncertainty and cannot internalize legal norms into their business decisions. Moreover, ambiguity deprives market participants and the public of notice about what the law is, thereby undermining due process—a fundamental principle in our legal system.").

Moreover, because "the line between *anticompetitive* behavior, which is illegal under federal antitrust law, and *hypercompetitive* behavior, which is not," *Qualcomm Inc.*, 969 F.3d at 982 (emphasis in original) is not always clear, a firm pursuing what it believes to be a hypercompetitive business model under one legal precedent may later find itself liable for anticompetitive under another. In such circumstances, Amicus respectfully submits that federal courts sitting in equity should—consistent with the maxim that equity does not punish—exercise special caution in tailoring injunctive relief consistent with the longstanding equitable principle that "injunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs." *Madsen*, 512 U.S. at 765.

A. Contemporaneous case law evinced widespread uncertainty on the extent to which the Sherman Act required branded drug companies to make drug samples available to generic developers.

Here, the contemporaneous caselaw suggests that the defendant's business strategy of refusing to sell product samples of Daraprim—however widely condemned—was hardly a matter of settled illegality under Section 2 when defendants purchased Daraprim in 2015. The Supreme Court has long held that a market actor—even one with monopoly power—generally has no affirmative duty to deal or cooperate with competitors. *United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919). A limited exception to this principle emerged in *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985), which upheld Section 2 liability against a large ski resort that had unilaterally terminated a longstanding, profitable business relationship with a smaller neighboring resort, after finding that the larger firm's willingness to sacrifice profit evinced an anticompetitive intent to harm its smaller rival. *Id*. at 608. But more recently the Court has emphasized that it is "very cautious in recognizing such exceptions," *Trinko*, 540 U.S. at 408, describing *Aspen Skiing* as "at or near the boundary of § 2 liability," *id*. at 409, and declining to recognize a broader duty to cooperate when the plaintiff had not pleaded the defendant's termination of a prior course of dealing under circumstances suggestive of anticompetitive malice. *Id*.

Applying *Trinko*, the Courts of Appeals have yet to clearly answer whether the existence of a prior course of dealing is an affirmative pleading requirement or merely an important factor that guides the analysis. But two decisions of this Court have strongly suggested the former, declaring that "the *sole* exception to the broad right of a firm to refuse to deal with its competitors" applies "*only* when a monopolist seeks to terminate a prior (voluntary) course of dealing with a competitor." *In re Adderall XR Antitrust Litig.*, 754 F.3d 128, 134 (2d Cir. 2014) (emphasis added) (internal quotations omitted) (*citing In re Elevator Antitrust Litig.*, 502 F.3d at 52, 53).

Operating under this framework, courts have similarly struggled to answer whether a branded drug company's refusal to sell product samples to a generic developer faces antitrust liability without the existence of a prior dealing between the companies. *See* CRS Report, *supra* at 3 (noting that most such cases have terminated in settlements). A handful of district courts within the Third Circuit had permitted such claims to survive motions to dismiss or summary judgment, but none appear to have reached final judgment.[12]

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[12] *See Mylan Pharmaceuticals v. Celgene Corp.*, No. 2:14-cv-2094, Dkt. No. 56 (D.N.J., June 17, 2014) (dismissing Section 1 claim while allowing Section 2 claim to proceed); *see also id*. at 16 (noting that this Circuit's decision in *In Re Elevator Antitrust Litig*. "weigh[ed] 'prior course of dealing' more heavily" than the Third Circuit); *Mylan II* (D.N.J., Oct. 3, 2018) (denying defendant's motion for summary judgment in part, allowing Section 2 claim to proceed to trial); *Actelion Pharm. Ltd. v. Apotex, Inc.*, No. 12-5743, Dkt. No. 90 (D.N.J. Oct. 21, 2013) (denying motion

The ongoing ambiguity is also revealed in a 2014 *amicus curiae* brief[13] that the FTC filed with the district court in *Mylan Pharmaceuticals v. Celgene Corp.*, No. 2:14-cv-2094 (D.N.J.), a private antitrust case involving conduct similar to that at issue here. As the FTC explains in its brief, Mylan, a generic, had sued Celgene under the Sherman Act, claiming it had "implemented distribution restrictions that prevent[ed Mylan] from purchasing samples of Celgene's brand products through customary distribution channels, and that Celgene refuse[d] to sell it the products directly, thereby precluding it from meeting Food and Drug Administration (FDA) requirements for developing generic versions of these drugs." *Id.* at 1. Although noting that the case "highlight[ed] a troubling phenomenon," the FTC reported that it was still "monitor[ing] legal and regulatory developments" and "[t]o date, [had] not filed any law enforcement actions challenging conduct in this area." *Id.* at 2. While opining that Mylan's claims against Celgene under the Sherman Act were "plausible," *id.* at 8-12, the FTC did not take an ultimate legal position in support of either party. The FTC also expressly observed that this Court's *In re Elevator*

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for judgment on the pleadings); *Lannett Co., Inc. v. Celgene Corp.*, No. 8-3920, Dkt. No. 42 (E.D. Pa. Mar. 30, 2011) (denying motion to dismiss).

[13] Federal Trade Commission's Brief as Amicus Curiae [Dkt. No. 26-3], *Mylan Pharmaceuticals v. Celgene Corp.*, No. 2:14-cv-2094 (D.N.J., June 17, 2014), available at: https://www.ftc.gov/system/files/documents/amicus_briefs/mylan-pharmaceuticals-inc.v.celgene-corporation/140617celgeneamicusbrief.pdf [hereinafter "FTC 2014 Amicus"]

Antitrust Litig. decision had, unlike other circuits, "interpreted *Trinko* to *require* a prior course of dealing." *Id*. at 11, n.39 (emphasis added).

B. The legislative history of the 2019 CREATES Act further confirms widespread legal ambiguity surrounding the conduct at issue.

On December 20, 2019—approximately one month before the appellees brought this case—Congress enacted the CREATES Act, Pub. L. No. 116-94, § 610, to resolve the widespread legal ambiguity surrounding the conduct at issue here. Section 610 now gives generic developers a private right of action to sue a branded drug "license holder" if that branded company fails to provide "sufficient quantities" of RLD product samples under "commercially reasonable, market-based terms" within "31 days" upon written request. *Id*. The Act further authorizes both injunctive relief (to compel the production of RLD samples) and legal monetary relief for unreasonable delay (in an amount "sufficient to deter the license holder from failing to provide eligible product developers with sufficient quantities of a covered product on commercially reasonable, market-based terms"), as well as awards of attorney fees and costs. *Id*. Accordingly, Shkreli and Vyera can no longer point to this Court's decisions in *In re Elevator Antitrust Litig.*, 502 F.3d at 54, and *In re Adderall XR Antitrust Litig.*, 754 F.3d at 134, as a justification to refuse RLD sales of Daraprim to generics developers.

Moreover, the extensive legislative history behind the CREATES Act further confirms the widespread ambiguity concerning the legality of RLD sample blockades by branded drug companies. Two reports are particularly revealing.

The 2016 Senate Report: In a report that Plaintiffs reference in their amended complaint, A-167, ¶¶ 139-140, a Senate Special Committee on Aging released its findings and recommendations from an investigation launched into "dramatic price increases on several off-patent drugs, including Daraprim." *Id.*; *see also* Senate Report, *supra* at 4. Among its findings, the Committee reported:

- "There are no regulations (outside of REMS) that substantially limit how a company distributes its drugs. Companies are generally free to choose from the varied distribution channels offered by the market, and may voluntarily opt for restricted distribution." *Id*. at 114.
- "Some have suggested that abuses of restricted distribution and REMS appear anticompetitive and therefor violate antitrust laws. Further analysis, however, suggests that such abuses do not clearly violate antitrust law and that relying on litigation would not remedy the situation. Legislation and other remedies are needed. The law is far from clear on whether it is an antitrust violation to refuse to deal with potential generic entrants seeking reference listed drugs. . . . regardless of how the legal question is ultimately decided, it may be a question for the Supreme Court and will take years to resolve." *Id*. at 116-17.
- "The conduct of Turing and others, no matter how disturbing, may be legal. Mr. Shkreli and other unscrupulous drug CEOs know this and may have pursued this aspect of the business model precisely because they have precedent supporting the legality of what appears, on the surface, to be anticompetitive conduct. Similarly, brand name manufactures have a strong case that it is legal for them to refuse to admit a potential generic entrant into their single shared REMS system." *Id*. at 116-17.

2019 Congressional Research Service Report: In its legal background report to the CREATES Act, the non-partisan Congressional Research Service reported that this legal ambiguity continued to exist in 2019:

- "The existing statutory and regulatory framework offers little legal recourse to generic product developers who have been denied access to or experience long delays in obtaining samples . . . [T]here are no statutes or regulations that specifically prohibit a company from imposing voluntary distribution restrictions on its products." CRS Report, *supra* at 2.
- "A generic product developer's ability to obtain relief for sample denial under antitrust law is currently uncertain. Under longstanding antitrust precedents, a company—even a monopolist—generally does not have a duty to deal with its competitors. A refusal to deal, however, could be an antitrust violation if it constitutes a willful effort to maintain monopoly power via anticompetitive means, but the case law has not provided a clear standard for this exception to the general rule. Moreover, some courts have held that a refusal to deal is only anticompetitive if the monopolist seeks to terminate a prior course of dealing with the competitor [*citing In re Elevator Antitrust Litig.*, 502 F.3d 47, 54 (2d Cir. 2007)]. . . . This difference in interpretive approach can be dispositive—because a generic product developer often would have no prior course of dealing with the brand manufacturer, the generic product developer would have no antitrust recourse before a court that has adopted or chooses to adopt the former approach." *Id*. at 3.

CONCLUSION

The district court's injunction below should be carefully scrutinized for compliance with the traditional principles of equitable practice that control all injunctions that issue under Section 13(b).

Respectfully submitted,

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RULE 32 CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) and Local Rules 32.1 and 29.1(c) because it contains 6,388 words, excluding the parts exempted by Fed. R. App. P. 32.

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements to Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally-spaced Times New Roman font size 14.

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CERTIFICATE OF SERVICE

I certify that on January 9, 2023, I will file the foregoing document on this Court's CM/ECF system, which will then serve it by electronic notification on all counsel of record. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

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