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*,

(Caption continues on inside cover)

On Appeal from the United States District Court
for the Southern District of New York
No. 20-cv-706 (Hon. Denise Cote)

BRIEF OF THE FEDERAL TRADE COMMISSION

Of Counsel:
MARKUS H. MEIER
BRADLEY S. ALBERT
MAREN HANEBERG
NEAL J. PERLMAN
DANIEL W. BUTRYMOWICZ

FEDERAL TRADE COMMISSION
Washington, D.C. 20580

JOEL MARCUS
Deputy General Counsel
BRADLEY DAX GROSSMAN
Attorney
FEDERAL TRADE COMMISSION
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580
(202) 326-2994
bgrossman@ftc.gov

(*Continued from front cover*)

VYERA PHARMACEUTICALS, LLC, PHOENIXUS AG, KEVIN MULLEADY, individually, as an owner and director of Phoenixus AG and as a former executive of Vyera Pharmaceuticals, LLC, *Defendants*.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

RULES

TREATISES

INTRODUCTION

This case involves appellant Martin Shkreli's illegal monopolization of the market for the prescription drug Daraprim, the gold-standard treatment for the life-threatening infection toxoplasmosis. Shkreli (through his company Vyera Pharmaceuticals) bought the rights to Daraprim in 2015 and immediately raised its price by over 4,000%, from $17.60 to $750 per tablet. To maintain sales following the price hike, Shkreli launched a scheme to block generic companies from obtaining the essential inputs they needed to develop competing generic versions of the drug. Shkreli's anticompetitive conduct kept generic rivals off the market for years and allowed him to charge supracompetitive prices for Daraprim. Shkreli and Vyera reaped $64 million in illicit monopoly profits.

The Federal Trade Commission and seven states filed suit against Shkreli for violating federal and state antitrust laws. After a seven-day bench trial, the district court (Cote, J.) found that Shkreli's actions were "heartless," "dangerous," and illegal. The court ordered Shkreli to pay back his company's unlawful profits and, because Shkreli had previously shielded other drugs from competition through similar anticompetitive misconduct, prohibited him from participating in the pharmaceutical industry. On appeal, Shkreli challenges neither the district court's findings of fact nor its legal determination that he violated the antitrust laws. He

disputes only the district court's remedy. This brief addresses the injunction; the State appellees will address the monetary remedy.

The district court acted well within its broad equitable discretion in crafting the prohibition on Shkreli's future participation in the pharmaceutical industry. The court found as fact—and Shkreli does not challenge any of the factual findings—that Shkreli was an egregious, intentional, and recidivist wrongdoer with a high propensity for future violations. His plainly illegal scheme, carried out in part from prison using a contraband phone, exploited the health of vulnerable patients. Nor was this the first time Shkreli had engaged in such predatory conduct. On top of all that, Shkreli showed no remorse, declaring that his only regret was not raising prices even higher. The district court reasonably concluded that he could not be trusted to obey the law, much less a more narrowly tailored injunction, and that the pharmaceutical industry ban was necessary to protect patients and the public from further anticompetitive harm.

JURISDICTION

The FTC agrees with Shkreli's jurisdictional statement.

QUESTIONS PRESENTED

1. Did the district court abuse its discretion when it imposed a permanent injunction against Shkreli's future participation in the pharmaceutical industry?

2. Does the injunction violate Shkreli's First Amendment rights?

3. Do the terms of the injunction satisfy the clarity and specificity requirements of Federal Rule of Civil Procedure 65(d)?

STATEMENT OF THE CASE

Martin Shkreli acquired Daraprim, a life-saving drug with no patent protection but no adequate substitutes, dramatically increased its price, and illegally prevented competitors from introducing rival products at lower prices. The facts found by the district court in its meticulously documented order are not contested on appeal.

A. Generic Drug Competition

Because this case centers on Shkreli's monopolization of a drug market by excluding generic rivals, we begin by describing the legal and economic framework surrounding generic drug competition. Generic drugs are essentially identical to their branded counterparts, SPA-34-37, and generic competition benefits consumers by lowering prices. The first generic typically undercuts the brand-name drug's price by 30 to 40 percent and garners 60 to 70 percent of its sales. SPA-37. Prices fall further with additional generics. SPA-38.

A drug company seeking to sell a generic product must file an Abbreviated New Drug Application with the FDA. SPA-32; *see FTC v. Actavis, Inc.*, 570 U.S. 136, 142 (2013). The application must demonstrate, among other things, that the

generic product uses a suitable source of active pharmaceutical ingredient (API) and is therapeutically equivalent to the brand. SPA-32-37.

A suitable API source is a supplier with a manufacturing process that complies with FDA standards. SPA-32-33. Developing an FDA-compliant process from scratch is expensive and time-consuming, so generic applicants typically use an established API supplier that already has FDA approval for its manufacturing process. SPA-33-34.

A generic applicant must also show that its product "has the same active ingredients as, and is biologically equivalent to, the already-approved brand name drug." *Actavis*, 570 U.S. at 142 (cleaned up). An applicant makes that showing through bioequivalence testing of the generic product against samples of the brand drug. SPA-35. The testing requires access to sufficient quantities of the brand drug, which generic companies ordinarily obtain through drug wholesalers or specialty pharmacies. SPA-35-36.

Most drugs in the United States are sold through what is known as "open distribution" channels, where major distributors sell the product without limitation to retail pharmacies, hospitals, clinics, and nursing homes. SPA-38. A smaller number are sold through "specialty" or "closed" distribution, in which a manufacturer restricts how freely a drug is sold. SPA-38-39. Because specialty distribution results in lower sales, drug companies typically use it only when the

product poses safety concerns; has unique shipping, handling, or storage requirements; or requires ongoing monitoring or skilled administration (*e.g.*, injections). SPA-39-40.

B. Shkreli's Initial Schemes To Forestall Generic Competition

Shkreli's business strategy for more than a decade has been to acquire older drugs without patent protection that treat relatively rare diseases, raise their prices multifold, and prevent competition through restrictive agreements with third parties. Patients are subjected to extreme price-gouging in the meantime.

Shkreli first implemented that approach at Retrophin, which he co-founded in 2011, serving as the CEO and architect of its business strategy. SPA-40. Retrophin acquired two drugs: Chenodal, the sole treatment for a rare, life-threatening cholate excretion disorder, and Thiola, the only drug available to prevent symptoms of a rare kidney stone disorder. SPA-42 & nn.16-17. After acquiring the drugs, Retrophin raised Chenodal's price from $100,000 to $515,000 per year and Thiola's from $4,000 to $80,000 per year. SPA-42. Shkreli sustained these prices by entering agreements to restrict distribution of the drugs and prevent generic companies from acquiring the product samples needed for bioequivalence testing. SPA-41.

Shkreli knew that Chenodal's "unique distribution system does not allow for generics to access product to conduct bioequivalence studies," making FDA

approval "almost impossible," SUPP-95, 105-06, and keeping patients "on our product forever," SUPP-86.[1]

C. Shkreli Repeats And Expands His Anticompetitive Tactics With Daraprim

In 2014, Shkreli left Retrophin and founded Vyera, where he was CEO until December 2015, when he was charged with securities fraud. SPA-42-43, 96. He also served as Chairman of Vyera's parent company, Phoenixus AG, through early 2016.[2] SPA-43. Even after Shkreli left these roles and went to prison, he remained Vyera's largest shareholder and wielded "shadow control." SPA-29, 43, 97-98, 136-37. At Vyera, Shkreli employed the strategy he developed at Retrophin, along with new tactics to prevent generic competition. As the district court found, "[f]rom day one," Shkreli focused Vyera on "acquiring sole-source drugs that were the gold-standard treatment option for life-threatening diseases with a small patient population … with the intent to raise their prices, block generic competition, and reap extraordinary profits." SPA-42-43, 96.

Shkreli first tried to acquire Biltricide, the gold-standard treatment for the "severe parasitic disease" schistosomiasis. SUPP-16, 20. Vyera planned to raise

[1] "SUPP" refers to appellees' Supplemental Appendix.

[2] Vyera changed its name from Turing Pharmaceuticals in 2015 to distance itself from Shkreli in the public mind. SPA-42-43. Unless otherwise specified, we use "Vyera" to refer collectively to Vyera, Turing, and Phoenixus.

the price of a course of treatment from $95 to over $100,000 and close the distribution channels to prevent generic competition. SUPP-20, 26-27. But the deal fell through. SUPP-147.

Shkreli then trained his sights on Daraprim (pyrimethamine). On the market since 1953, Daraprim is the only FDA-approved treatment for toxoplasmosis, a parasitic infection that principally affects immunocompromised patients, including transplant recipients and people with HIV/AIDS. SPA-44-45, 47, 117. The parasites can cause a brain condition called toxoplasma encephalitis, which can kill or cause severe brain damage within 12 to 24 hours after symptoms appear. SPA-45. Doctors thus need immediate access to an effective treatment. *Id.*; SPA-117. Daraprim is both the preferred treatment and an essential diagnostic tool: a response to the drug confirms that the patient had toxoplasmosis and not something else, such as a bacterial infection. SPA-47, 117, 120-21. The only diagnostic alternative for toxoplasma encephalitis is a risky brain biopsy. *Id.* Shkreli and his team decided to acquire Daraprim on the express recognition that it is "the GOLD standard and is essentially unsubstitutable." SUPP-5, 9.

Once Vyera acquired Daraprim, Shkreli immediately raised the price from $17.60 to $750 per tablet. SPA-48, 97. When Vyera's general counsel objected, Shkreli fired him. SPA-97. Vyera's head of research and development called the price increase "the poster child of everything that is considered wrong about the

pharmaceutical industry." SPA-48. Nevertheless, Vyera's gross profit margins soared to 98%. SPA-49.

D. Shkreli's Anticompetitive Plot To Prevent Generic Competition For Daraprim

Shkreli knew that because Daraprim had no patent or regulatory protection, its high price would attract generic entry and undercut his monopoly prices. *See, e.g.*, SUPP-74, 141, 155, 202. He implemented a three-pronged counterstrategy. First, as Shkreli did at Retrophin, he directed Vyera to enter agreements with its distributors to prohibit sales of Daraprim to generic companies. Second, he directed Vyera to agree with pyrimethamine API manufacturers to cut off competitors' access to the necessary ingredient. Third, he directed Vyera to agree with distributors to prevent generic companies from obtaining sales data necessary to assess profitability of a competing drug.

1. Restrictions On Distributors' Sale Of Product Samples

Even before Vyera had closed the Daraprim acquisition, Shkreli instructed the company to take Daraprim out of retail distribution, buy back existing inventory, and move to a closed system "as swiftly as possible." SPA-50, 97; SUPP-53. Specifically, Vyera's distribution agreements forbade Daraprim sales to generic companies and tightly limited the amount anyone could acquire so that generic companies could not obtain sufficient product. SPA-52-59; SUPP-119-20. Shkreli's decision to close distribution was not based on patient health or any

requirements for handling the drug, but on preventing generic competition. SPA-52; A-1405-06, 1439, 1928. Shkreli told an investor that because the drug is "in closed distribution there will not be any [generic competition] going forward. … [E]ven if we get 3 years, it is a great payout." SPA-51; SUPP-7.

Shkreli and Vyera took extraordinary steps to ensure that no competitor could get Daraprim. When Vyera learned that an intermediary had obtained five bottles of Daraprim with plans to resell it to the generic company Dr. Reddy's, Vyera's then-CEO, Kevin Mulleady, "frantic[ally]" raced the next day to a Starbucks parking lot in Parsippany, New Jersey, where he met the intermediary and repurchased the bottles for $750,000, double the original price. SPA-58, 77-78; A-2057-58.

Shkreli was so invested in preventing the sale of Daraprim to generic companies that he repeatedly called Vyera executives from prison to instruct them to tighten their grip on supply. SPA-56. When Shkreli learned that generic company Fera sought to buy Daraprim samples, he urged Mulleady not to "sell more than one bottle at a time" so that Fera's CEO is "not getting his hands on

anything." SUPP-58.[3] To maintain control of distribution, Shkreli told another Vyera executive that the company should insist on "meet[ing] … doctors" before agreeing to supply their patients. SUPP-69. Shkreli believed that eliminating generic competition would make Daraprim a "$600 million asset … in perpetuity." *Id.* When the executive reminded Shkreli that Vyera was required to sell Daraprim to hospitals (whose patients needed the drug to survive), Shkreli responded, "that's a shame." *Id.*

2. Agreements To Block Generics From Securing API

At Shkreli's direction, Vyera entered exclusivity agreements with the two leading suppliers of pyrimethamine, Daraprim's API. As discussed at p. 4, generic companies must either use an established API supplier or spend years to create their own manufacturing process. Knowing this, Vyera entered agreements with API suppliers Fukuzyu and RL Fine preventing them from selling pyrimethamine to generic companies for domestic use. SPA-59.

Fukuzyu has long been the main API supplier for Daraprim throughout the world. SPA-60. Fukuzyu had never entered an exclusivity agreement with either

[3] Shkreli's brief misrepresents the extent of his involvement from prison. He claims that he called Mulleady from prison in his capacity as a "longtime friend" and that Mulleady "regularly ignored" Shkreli's "suggestions." Br. 7. The district court found that Shkreli "managed to control his company even from federal prison," SPA-143, a finding that "Shkreli does not appeal," Br. 4 n.3. In a recorded prison call, Shkreli reminded Mulleady of his power to "fir[e] everybody." SPA-101; SUPP-77. Shkreli ultimately did fire Mulleady. SPA-102.

the U.S. or global owners of Daraprim. SPA-60-61, 128. At Shkreli's behest, however, Vyera told Fukuzyu that it needed such an agreement to prevent the sale of "significantly lower" priced generic pyrimethamine, which would reduce Fukuzyu's own profits. SPA-61-63, 97. Fukuzyu accepted the proposal. SPA-128. The sole purpose of the agreement was to cripple generic competition. SPA-63-64, 130-31.

Vyera entered an even more egregious agreement with RL Fine, the second most-viable API supplier. SPA-64-65, 70-71. Shkreli, while imprisoned, learned that generic companies were trying to buy pyrimethamine from RL Fine and texted Mulleady about it from a contraband cell phone. SPA-65-66 & n.27; *see* SUPP-15. Days later, Vyera agreed to pay RL Fine millions not to supply pyrimethamine API to U.S. generics. SPA-66-68, 86, 88, 97, 132. Vyera's corporate board minutes report that the agreement was intended to prevent "the potential market entry by generics manufacturers and distributors," SUPP-51, and it "immediate[ly]" disrupted two generic companies' FDA applications, SPA-129. By October 2019, Vyera had paid RL Fine almost $9.5 million, even though RL Fine never provided any product to Vyera nor sought FDA approval to do so. SPA-68-69, 132. Vyera then paid the company another $750,000 after RL Fine threatened to speak with the FTC. SPA-69.

3. Agreements To Block Reporting Of Commercial Data

Finally, Vyera agreed to pay key distributors a "data blocking" fee not to furnish their sales data to companies that collect, aggregate, and sell market data, so that generic companies would lack accurate or complete information about Daraprim sales when deciding whether to develop a competing product. SPA-115 n.35; SUPP-113-18. Shkreli "believed that … limiting data to generic manufacturers … would limit or impede their ability to assess the size of the market opportunity" for generic pyrimethamine. SUPP-115; *see also* A-1418-19.

E. Anticompetitive Consequences

Shkreli's machinations were highly successful. SPA-69-70. A generic company could ordinarily obtain Daraprim product samples and an API supplier within weeks. SPA-71. Lack of access delayed market entry by Dr. Reddy's for 30 months, SPA-81, and by Fera for roughly two years, SPA-88-89. During this time, Vyera maintained prices "very substantially above the competitive price level." SPA-118, 124.

The exploding price of Daraprim and its cumbersome distribution restrictions jeopardized the health of the immunocompromised patients who urgently needed Daraprim to avoid death or brain damage. Sales of the drug plummeted, SPA-49, and some doctors switched to cheaper, second-tier treatments, A-625-26 ¶¶ 80-81; A-1371:3-22; SUPP-1. The next-best option,

TMP-SMX (Bactrim), is 25-to-50 times less potent than Daraprim, does not reach the brain in sufficient quantities to treat toxoplasmosis infection properly, and is not an option for the 30-35% of HIV-positive patients who are allergic. SPA-120-21. The Infectious Disease Society of America and the HIV Medical Association pleaded with Vyera to reverse course, explaining that hospitals had become "unable to obtain" Daraprim. SUPP-3. They explained that Vyera's extraordinarily high prices were "unjustifiable for the medically vulnerable patient population in need of this medication and unsustainable for the health care system." SUPP-4.

Shkreli was unmoved. He later stated that his only regret was that he should have "raised prices higher … and made more profits for our shareholders." SUPP-90. By that, Shkreli effectively meant himself, for he was the largest shareholder, SPA-43, and had purportedly invested "every penny I have—$25 million" into the company, SUPP-16.

Generics finally entered the market in 2020, predictably causing prices to decline by 27% in just the first several months. SPA-93, 95-96, 118. More generic entry will lead to additional price decreases. SPA-96. Greater affordability has in turn led to increased sales, meaning that more immunocompromised patients are now receiving life-saving treatment. SPA-93-94.

F. The Decision Below

The FTC and the appellee States sued Shkreli, Vyera, and Mulleady for violating Section 5 of the FTC Act, 15 U.S.C. § 45, which prohibits unfair methods of competition, Section 1 of the Sherman Act, 15 U.S.C. § 1, which forbids unreasonable restraints of trade, Section 2 of the Sherman Act, 15 U.S.C. § 2, which prohibits monopolization, and analogous state laws. SPA-101-15.

Vyera and Mulleady settled; Shkreli proceeded to trial. SPA-24. After seven days of testimony, the district court found that the government had met its burden to show that Shkreli committed the charged violations by restricting distributors from selling product samples to generic companies and entering exclusive API supply agreements.[4] SPA-115-16, published at *FTC v. Shkreli*, 581 F. Supp. 3d 579 (S.D.N.Y. 2021).

The court found that Shkreli's actions impeded competition in the market for FDA-approved pyrimethamine by "block[ing] generic competition to Daraprim … for as long as possible," allowing Shkreli and Vyera to maintain their monopoly and astronomical prices. SPA-125, 127-28, 134-35. Shkreli's purported justifications were "pretextual" and unsupported. SPA-126-27, 130-32, 135-36. The court held Shkreli personally liable, since he "conceived of, implemented,

[4] The district court found that the data-blocking agreements did not cause additional delay in generic entry. SPA-115 n.35.

maintained, and controlled Vyera's anticompetitive and monopolistic scheme … even after he entered federal prison." SPA-136. These violations were intentional: Shkreli admittedly sought "to impede generic companies from launching competitive products that would threaten the price of Daraprim." SPA-116, 125, 136-37.

The court ordered Shkreli to disgorge up to $64.6 million in unlawful profits. SPA-144-50. The court also entered a permanent injunction against Shkreli under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), and comparable laws applicable to the appellee States, finding that the public interest justified barring Shkreli from the pharmaceutical industry for life. *See* SPA-137-43. The court acknowledged that such a remedy "must be [imposed] with care and only if equity demands," but stressed that Shkreli's conduct was "egregious, deliberate, repetitive, long-running, and ultimately dangerous." SPA-140.

First, the court determined that a lifetime prohibition was necessary to protect the public against the danger of Shkreli engaging in further anticompetitive schemes in the pharmaceutical industry. SPA-141. His violations were "flagrant and reckless," SPA-143, and repeated at two different companies, SPA-141. The Daraprim violations were "particularly heartless and coercive," the court explained, since patients needed the drug "within hours" to treat a deadly brain infection, yet Shkreli "recklessly disregarded" the health of those patients. *Id.*

Second, the court stressed that Shkreli exploited the FDA's regulatory process for developing new drugs. He "cynically took advantage of the requirements of a regulatory scheme designed to protect the health of a nation by ensuring that its population has access to drugs that are not only effective but also safe." *Id.*

Third, the court found that Shkreli's lack of contrition and repentance made reform unlikely. "[I]n the face of public opprobrium," Shkreli "refused to change course and proclaimed that he should have raised Daraprim's price higher." *Id.* In written testimony, Shkreli "denie[d] responsibility" for virtually every part of the scheme and asserted that he could not be held liable because he did not personally sign or negotiate the contracts. SPA-142.[5]

Fourth, the court determined that a "lifetime ban would not deprive Shkreli of the opportunity to practice a profession or to exercise a lawful skill for which he trained." SPA-141-42. Shkreli holds an undergraduate degree in business administration, has no academic background in pharmaceutical research or development, and had no pharmaceutical industry experience before co-founding Retrophin. *See* SUPP-125; SPA-40.

[5] *See* A-794 ¶¶ 42-43; A-796 ¶ 54; A-797 ¶¶ 57-60; A-798 ¶¶ 63-64; A-799 ¶¶ 71-73; A-800 ¶¶ 75-78; A-801 ¶ 81.

Fifth, the court rejected Shkreli's argument that a lifetime ban would exceed the court's equitable powers, explaining that "[i]f a court sitting in equity is powerless to impose a lifetime industry ban to protect the public against a repetition of the conduct proven at this trial, then the public could rightfully ask whether its wellbeing has been adequately weighed." SPA-143. Shkreli had argued for a narrower injunction that prevented him from "acquiring commercial assets" or engaging in the "day-to-day affairs of commercializing medicine." *Id.* But the district court concluded that such an injunction would not provide "adequate protection" to the public, given that "Shkreli has demonstrated that he can and will adapt to restrictions." *Id.*

Indeed, Shkreli "managed to control his company even from federal prison," including by using a cell phone that he smuggled past prison guards. *Id.*; *see also* SPA-66. The court explained that Shkreli communicated with a single Vyera executive, Mulleady, from prison "over 1,500 times" in under seven months. SPA-101. While incarcerated, Shkreli even orchestrated purges of directors and officers who would not do his bidding. SPA-98-102; A-1212-1213. In 2017, when Vyera's then-CEO resisted Shkreli's orders, Shkreli declared him a "cockroach that needed to be stomped or crushed" and ousted him. SPA-98-99, A-1205-06. Shkreli replaced that CEO with Mulleady, but then removed Mulleady three years later for resisting Shkreli's "meddlesome involvement." SPA-101-02.

G. The Permanent Injunction

The injunction prohibits Shkreli from "directly or indirectly participating in any manner in the pharmaceutical industry." SPA-166. The order provides detailed and precise descriptions of what conduct is permitted and proscribed.

Shkreli may not "[p]articipat[e] in or direct[]" the activities of a Pharmaceutical Company, "whether through compensated or uncompensated employment, consulting, advising, board membership, or otherwise." *Id.* A "Pharmaceutical Company" is "any Entity engaged in the research, Development, manufacture, commercialization, or marketing of any Drug Product or API." SPA-165. A "Drug Product" is "any product that is subject to an FDA Authorization, or any product that is regulated through an over-the-counter drug monograph." SPA-164. API "means any active pharmaceutical ingredient that is used in the manufacture of a Drug Product." *Id.*

The injunction also forbids Shkreli from, *inter alia*, participating in a Pharmaceutical Company's "business decisions"; holding an ownership interest in such a company (except indirectly through a diversified mutual fund or similar vehicle); or "[t]aking any action to directly or indirectly influence or control the management or business" of such a company. SPA-166. A public statement by Shkreli may constitute such "action" only if Shkreli intends it to influence or

control the management or business of a Pharmaceutical Company "or if a reasonable person would conclude that the statement has that effect." *Id.*

Shkreli may, however, accept "Qualified Employment" with a Pharmaceutical Company so long as the company "is not primarily involved in the research, Development, manufacture, commercialization, or marketing of Drug Products or API" and derives less than 10% of its total gross revenues from such activities. SPA-165-66. Shkreli must, however, notify the government of his intent to accept Qualified Employment, SPA-166-67, and must submit verified compliance reports at regular intervals and upon request, SPA-168. Shkreli must also participate in interviews and provide information to determine whether he has complied with the order. SPA-169.

The district court overruled Shkreli's objections that the order was impermissibly vague, overbroad, and contrary to the First Amendment, SPA-152-61, and it denied Shkreli's motion to stay the permanent injunction pending appeal, SUPP-214-29.

SUMMARY OF ARGUMENT

Shkreli does not challenge any of the district court's detailed factual determinations. Those findings prove Shkreli to be a serial recidivist without remorse, whose dangerous, incorrigible misconduct persisted even from prison. Shkreli is, in short, a poster child for the type of defendant who must be seriously

restrained in order to protect society. The district court acted well within its discretion in prohibiting him from any further participation in the pharmaceutical industry, ever.

1. District courts have equitable authority to impose an "absolute and permanent" "quarantine" on a defendant's future participation in an industry where necessary to protect the public. *See United States v. Carson*, 52 F.3d 1173, 1184-85 (2d Cir. 1995). This Court thus affirmed "eternal boardroom banishment" for securities violators where doing so was "necessary" given their "high degree of scienter," record of similar misconduct, and lack of "assurances against future violations." *SEC v. Posner*, 16 F.3d 520, 521-22 (2d Cir. 1994). Those descriptions fit Shkreli to a T, and he does not argue otherwise.

Shkreli is wrong that industry bars are improper in FTC Act cases. Appellate courts consistently uphold such remedies on records similar to the facts here showing systematic, deliberate, or repeated violations, where the trial court determines that a more narrowly-crafted injunction would not suffice. *See, e.g.*, *FTC v. Gill*, 265 F.3d 944, 954 (9th Cir. 2001); *FTC v. Grant Connect, LLC*, 763 F.3d 1094, 1097-98, 1105 (9th Cir. 2014); *FTC v. Pukke*, 53 F.4th 80, 99, 101, 110 (4th Cir. 2022).

2. The district court's unchallenged factual findings show that Shkreli is the archetype of a recalcitrant wrongdoer for whom a permanent industry bar is

appropriate and necessary. His violations—controlled for years from prison—were egregious, deliberate, dangerous, and heartless. He recklessly disregarded the health of immunocompromised patients with a life-threatening disease. Worst of all, he showed no remorse for his actions and is likely to reoffend.

On that record, the district court had no obligation to restrict its remedy to a "narrowly-drawn" injunction that simply forbade Shkreli from repeating specific wrongdoing. The law is clear that the court had discretion to stop Shkreli from taking even "untraveled roads" to his "prohibited goal" of reaping monopoly profits by suppressing drug competition. *See Int'l Salt Co. v. United States*, 332 U.S. 392, 400-01 (1947), *abrogated on other grounds by Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28 (2006). The court's ruling was especially solid given that Shkreli's predatory behavior grew worse over time. His first forays into monopoly profiteering involved blocking generic companies from obtaining product samples. In this case, he added the new anticompetitive tactics of depriving generics of API and critical sales data. The court was not required to give Shkreli the leeway to devise additional schemes for his anticompetitive playbook.

The district court also reasonably decided that a more limited injunction would be too difficult to monitor and enforce given Shkreli's history of inducing others to violate the law. Even prison did not stop him from running his scheme.

And given Shkreli's admitted plan to carry out his schemes "forever," SUPP-86, and "in perpetuity," SUPP-69, the injunction properly lasts just as long.

Similarly, the injunction reasonably applies to all drug research and development and company ownership. Shkreli enticed co-conspirators to join his illegal schemes by promising to involve them in research and development. SPA-156. He used his status as Vyera's largest shareholder to orchestrate the violations even after leaving his officer and director roles. SPA-160-61. The injunction also appropriately forbids Shkreli from involvement with patented, over-the-counter, and generic drugs, because he could easily commit the same or analogous violations in connection with those types of pharmaceuticals.

3. The order's bar on seeking to control or influence a pharmaceutical company's management or business decisions is fully consistent with the First Amendment. The provision targets not speech but *conduct*. The undisputed record showed that Shkreli directed corporate behavior through his verbal commands; the order forbids Shkreli from making similar commands in the future. The restriction is no broader than necessary to protect the public, since Shkreli remains free to engage in public commentary so long as his statements are not intended to influence a pharmaceutical company's business decisions.

4. The permanent injunction complies with the requirements of Rule 65(d). Shkreli's claims to the contrary either mischaracterize the order or ignore specific

guidance provided by the district court. For example, Shkreli claims not to understand the meaning of "pharmaceutical industry," but he raised no objections below to this commonly understood term, which the order supports with specific definitions of "Pharmaceutical Company," "Drug Product," and "API." The injunction is no less understandable than other industry restrictions upheld by this Court. The order's "Qualified Employment" exception answers questions about the types of future employment in which Shkreli may engage.

Shkreli's true grievance is not with the order's supposed imprecision, but its breadth. The district court had no duty, however, to impose a decree "so narrow as to invite easy evasion," as Shkreli has shown himself highly capable. *McComb v. Jacksonville Paper Co.*, 336 U.S. 187, 193 (1949). The court appropriately held that a broad remedy was necessary to give complete protection to patients and the public and ensure that Shkreli is no longer in a position to exploit them.

STANDARD OF REVIEW

District courts have "broad authority in crafting … injunctions," and "appellate review is correspondingly narrow." *Conn. Office of Prot. & Advocacy v. Hartford Bd. of Educ.*, 464 F.3d 229, 245 (2d Cir. 2006) (cleaned up). It is "axiomatic that the contours of an injunction are shaped by the sound discretion of the trial judge and, barring an abuse of that discretion, they will not be altered on appeal." *Merck Eprova AG v. Gnosis S.p.A.*, 760 F.3d 247, 265 (2d Cir. 2014)

(cleaned up). An abuse of discretion occurs if a district court: "(1) bases its decision on an error of law or uses the wrong legal standard; (2) bases its decision on a clearly erroneous factual finding; or (3) reaches a conclusion that, though not necessarily the product of a legal error or a clearly erroneous factual finding, cannot be located within the range of permissible decisions." *EEOC v. KarenKim, Inc.*, 698 F.3d 92, 99-100 (2d Cir. 2012) (cleaned up).

The Court reviews *de novo* whether the terms of an injunction meet the clarity and specificity requirements of Rule 65(d). *City of New York v. Mickalis Pawn Shop, LLC*, 645 F.3d 114, 143 (2d Cir. 2011).

ARGUMENT

Shkreli challenges (1) the district court's authority to issue an injunction barring him from an industry; (2) the court's fact-based decision to do so here; (3) the restrictions on Shkreli's rights of speech; and (4) the clarity of the injunction. His claims are unfounded.

I. COURTS HAVE EQUITABLE DISCRETION TO IMPOSE LIFETIME INDUSTRY RESTRICTIONS FOR VIOLATIONS OF THE FTC ACT

The Supreme Court established long ago that "once the Government has successfully borne the considerable burden of establishing a violation of law, all doubts as to the remedy are to be resolved in its favor." *United States v. E.I. du Pont de Nemours & Co.*, 366 U.S. 316, 334 (1961). "A Government plaintiff, unlike a private plaintiff, must seek to obtain the relief necessary to protect the

public from further anticompetitive conduct and to redress anticompetitive harm," and it has "legal authority broad enough" to accomplish this goal. *F. Hoffmann-La Roche Ltd. v. Empagran S.A.*, 542 U.S. 155, 170-71 (2004).

When a district court enjoins future conduct, its charge is not merely to "end specific illegal practices," but to prohibit the defendant from taking even "untraveled roads" to the "prohibited goal." *Int'l Salt Co. v. United States*, 332 U.S. 392, 400-01 (1947), *abrogated on other grounds by Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28 (2006); *accord FTC v. Ruberoid Co.*, 343 U.S. 470, 473 (1952); *United States v. Apple, Inc.*, 791 F.3d 290, 339 (2d Cir. 2015). "Acts entirely proper when viewed alone may be prohibited." *United States v. U.S. Gypsum Co.*, 340 U.S. 76, 89 (1950). As the Supreme Court put it in the specific context of the FTC Act, once a defendant is "caught violating the Act," he "must expect some fencing in." *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 395 (1965) (cleaned up).

The permanent injunction in this case is consistent with extensive precedent under the FTC Act and analogous statutes meant to protect the public. There is no merit to Shkreli's claim that district courts lack power to permanently restrict participation in an industry, or that "[s]uch matters are normally the province of [state] licensing boards" for a "narrow class of professionals." Br. 39-40.

A. This Court Has Sustained Injunctions Permanently Barring Wrongdoers From An Industry

This Court has repeatedly affirmed lifetime bans under statutes comparable to the FTC Act. In *SEC v. Posner*, 16 F.3d 520 (2d Cir. 1994), the Court confirmed that district courts have "general equitable power[]" to impose "eternal boardroom banishment" on proven securities-law violators, forbidding them from serving as an officer or director of a public company *in any industry*. *Id.* at 521-22. *Posner* credited district court findings that this remedy was "necessary to protect public investors" given the defendants' "high degree of scienter," track record of violations, and "lack of assurances against future violations." *Id.*[6] Courts in other circuits have relied on *Posner* when imposing similar lifetime bans. *See, e.g.*, *SEC v. First Pac. Bancorp*, 142 F.3d 1186, 1193-95 & n.8 (9th Cir. 1998). *Posner* applies foursquare here given the district court's uncontested findings that Shkreli is a remorseless recidivist whose violations were deliberate. *See supra* pp. 15-16.

Likewise, in the civil RICO case *United States v. Carson*, 52 F.3d 1173 (2d Cir. 1995), this Court upheld, under general equity principles, an "absolute and permanent" "quarantine" on the defendant working for or even joining a labor organization. *Id.* at 1184-85. The Court credited the district court's finding that a

[6] Although the SEC now has explicit statutory authority to seek a director-and-officer ban in district court, *see* 15 U.S.C. §§ 77t(e) & 78u(d)(2), the violations in *Posner* occurred before that authority went into effect, so the ruling rested on common-law equity principles. 16 F.3d at 521.

narrower ban on assuming positions of union leadership would have been ineffectual given the defendant's history of using his organized crime ties to create a "climate of fear" within unions. *Id.* at 1185. The Court had earlier affirmed a lifetime ban on participation in the waste carting industry as a remedy for civil RICO violations involving bribery to maintain control of that industry on Long Island. *United States v. Private Sanitation Industry Ass'n of Nassau/Suffolk, Inc.*, 995 F.2d 375, 377 (2d Cir. 1993).

Shkreli argues that civil RICO cases are inapposite because that statute expressly authorizes courts to "impos[e] reasonable restrictions on the future activities" of violators and bar them "from engaging in the same type of endeavor as the enterprise engaged in." Br. 41, quoting 18 U.S.C. § 1964(a). But *Carson* relied on general principles of equity, supported by precedent upholding permanent injunctions in SEC and CFTC cases under statutes nearly identical to Section 13(b) of the FTC Act. *See Carson*, 52 F.3d at 1184 (discussing, *e.g.*, *SEC v. Manor Nursing Ctrs., Inc.*, 458 F.2d 1082, 1100 (2d Cir. 1972)). *Compare* 15 U.S.C. § 53(b) *with* 15 U.S.C. §§ 77t(b) & 78u(d)(1) *and* 7 U.S.C. § 13a-1(b).

Moreover, the text of civil RICO does not distinguish that statute from the FTC Act or other statutes authorizing injunctions. *All* prohibitory injunctions seek to "restrain acts which are of the same type or class as unlawful acts which the court has found to have been committed or whose commission in the future, unless

enjoined, may fairly be anticipated from the defendant's conduct in the past." *NLRB v. Express Publ'g Co.*, 312 U.S. 426, 435 (1941). *Carson* directly held that under civil RICO, equitable jurisdiction is limited to "preventing and restraining future violations" rather than punishing past violations, 52 F.3d at 1182 (cleaned up), which is the same as under the FTC Act.[7]

Shkreli likewise is wrong to claim that a district court may not "enjoin lawful conduct." *See* Br. 39, 44 (citing *Mickalis Pawn*, 645 F.3d at 144-45). In *Mickalis Pawn*, this Court vacated injunctions that required gun sellers to "adopt[] appropriate prophylactic measures to prevent violation[s] of the firearms laws," 645 F.3d at 142, since, contrary to Rule 65(d), they would have forbidden "unidentified types of sales practices" without explaining what those practices were or why they were related to those found unlawful, 645 F.3d at 145; *see infra* pp. 56-62 (explaining why the injunction here comports with Rule 65(d)). The Court did not forbid district courts from imposing injunctions that applied to lawful conduct when appropriately tailored to the violations at issue.

Moreover, *Mickalis Pawn* did not overrule the many Supreme Court precedents holding that an injunction may restrain otherwise-lawful conduct

[7] Shkreli also claims that civil RICO cases are not analogous because they involve "criminality" and "safeguards such as the right to a jury trial." Br. 41-42. But the ban in *Carson* was imposed following a non-jury trial after the defendant's criminal conviction had been overturned. *See* 52 F.3d at 1178-79.

(discussed at pages 24-25 above), nor did it abrogate (or mention) *Posner*, *Carson*, or *Private Sanitation*, all of which upheld this sort of injunction. Indeed, soon after *Mickalis Pawn*, this Court affirmed an antitrust remedy requiring Apple to give all e-books the "same terms and conditions as other applications" in its App Store, holding that this restriction on otherwise-lawful conduct was needed to prevent "circumvent[ion]" of a narrower injunction. *Apple*, 791 F.3d at 339.

B. Serious, Deliberate, Or Repeated FTC Act Violations Merit Serious Remedies

Lifetime industry prohibitions are a bedrock remedy for FTC Act violations when lesser restrictions will not suffice. Shkreli argues that under the FTC Act, injunctions are "usually" limited to certain "conduct" and do not "necessarily" bar defendants "from an entire category of goods." Br. 42. Although Shkreli claims that "the term 'industry ban' is often a misnomer" in FTC Act cases, *id.*, he overlooks extensive case law upholding precisely that remedy.

For example, the Ninth Circuit affirmed a permanent ban on a defendant "participating in *any aspect of* the credit repair business." *FTC v. Gill*, 265 F.3d 944, 954 (9th Cir. 2001) (emphasis added). *Gill* credited the district court's finding that the defendants posed a "real likelihood of recurring violation" given their "systematic" misdeeds and flouting of a preliminary injunction. *Id.* at 957. The court rejected the defendants' argument that the district court should have enjoined them from repeating their past violations without banning them from the

industry; it found "no basis for disturbing the district court's prudent assessment that giving Defendants another chance might prove to be unwise." *Id.*;[8] *see also FTC v. AMG Capital Mgmt., LLC*, 910 F.3d 417, 422, 428 (9th Cir. 2018) (upholding permanent ban on "engaging in consumer lending"), *rev'd on other grounds*, 141 S. Ct. 1341 (2021).

Indeed, appellate courts in FTC cases have upheld orders permanently banning a defendant from *several* entire industries. The Ninth Circuit, for example, affirmed an order proscribing the defendant from "engaging in … negative-option marketing, continuity programs, preauthorized electronic fund transfers, the use of testimonials, and marketing or selling products related to grants, credit, business opportunities, diet supplements, or nutraceuticals." *FTC v. Grant Connect, LLC,* 763 F.3d 1094, 1097-98 (9th Cir. 2014). The court rebuffed the defendant's contention that the injunction should be limited to his "specific bad acts." *Id.* at 1105. The defendant had "consistently engaged in variations on the same deceptive marketing scheme," and those practices were "easily transferable both to new product lines and to new modes of communications with consumers." *Id.*

[8] Shkreli notes that Congress has provided for administrative debarment before the FDA of pharmaceutical officers convicted of crimes. *See* Br. 40 (citing 21 U.S.C. § 335a(a)-(b)). But nothing in that statute curtails a district court's power to impose injunctive relief for violations of the FTC Act or other federal laws.

Similarly, the Fourth Circuit recently sustained permanent injunctions barring the defendants "from engaging in any real estate ventures" and "from any involvement in telemarketing." *FTC v. Pukke*, 53 F.4th 80, 99, 101 (4th Cir. 2022). The court "summarily rejected" the argument that these injunctions were "overly broad," stressing that the defendants committed "extensive misrepresentations regarding telemarketing and the sale of real estate intertwined with the promotion of goods and services." *Id.* at 110. The injunctions were thus "appropriately tailored to prevent similar scams in the future." *Id.*; *accord FTC v. Lalonde*, 545 F. Appx. 825, 831, 841 (11th Cir. 2013) (upholding permanent ban "from the mortgage, credit repair, loan modification, and telemarketing businesses" due to "repeated fraudulent and unlawful conduct"); *CFPB v. Nesheiwat*, No. 21-56052, 2022 WL 17958636, at *2-3 (9th Cir. Dec. 27, 2022) (affirming ban on "engaging in debt relief, mortgage loans, and telemarketing services, and obtaining consumer data" as a remedy for "blatant" violations in those industries) (citation omitted).

Likewise, district courts, including within this Circuit, have regularly imposed lifetime industry bans as remedies for systematic, deliberate, or repeated FTC Act violations. *See, e.g.*, *FTC v. Micom Corp.*, No. 96-0472, 1997 WL 226232, at *2, 4 (S.D.N.Y. Mar. 12, 1997) (Sotomayor, J.) (permanent ban on promoting, advertising, or selling services or investment offerings that involve

U.S. government licenses or permits); *FTC v. Five-Star Auto Club, Inc.*, 97 F. Supp. 2d 502, 536-37 (S.D.N.Y. 2000) ("a prohibition on all multi-level marketing is appropriate").

Shkreli gets no help from his charge that industry restrictions are improper "in the antitrust context." Br. 43. Corporate dissolution, which is more drastic than an industry-specific bar, is a traditional remedy for antitrust violations. *See, e.g.*, *E.I. du Pont*, 366 U.S. at 329. And courts have upheld industry bans in antitrust cases. *See Ford Motor Co. v. United States*, 405 U.S. 562, 575-78 (1972) (upholding 10-year ban on Ford's manufacture of spark plugs for an anticompetitive acquisition in that industry); *United States v. AT&T Co.*, 552 F. Supp. 131, 185, 223-24 (D.D.C. 1982) (banning AT&T and local bell operating companies from various industries, "[s]ince under the Sherman Act, it is appropriate to bar a company from a market if the restriction is necessary to permit the development of competition in that market"), *aff'd sub nom. Maryland v. United States*, 460 U.S. 1001 (1983).

Shkreli's sole authority, *Mallet & Co. v. Lacayo*, 16 F.4th 364 (3d Cir. 2021), is not even an antitrust case. There, Mallet sued two ex-employees and their new employer for misappropriation of trade secrets and won a preliminary injunction barring the defendants from competing against Mallet. *Id.* at 376-78. The Third Circuit reversed, holding that appellate review was impossible because

the district court had failed to specify which trade secrets were misappropriated or what conduct was forbidden. *Id.* at 385-89. The appeals court recognized that a "total production ban" *is* sometimes permissible, and held merely that the remedy was "not supported on the present record." *Id.* at 389. *Mallet* also involved protection of a business rival, not the general public, which deserves a greater scope of judicial protection. *See, e.g.*, *Apple*, 791 F.3d at 339.

II. THE DISTRICT COURT PROPERLY EXERCISED ITS DISCRETION WHEN IT BARRED SHKRELI FROM THE PHARMACEUTICAL INDUSTRY

The district court acted comfortably within its discretion when it imposed a lifetime restraint on Shkreli's future participation in the pharmaceutical industry based on the evidence presented at the seven-day bench trial. Shkreli concedes that he should be subject to an injunction, Br. 49, but argues that the court could not properly impose an injunction that ran longer than five years or was broader than his characterization of the specific violations he committed in this case: "attempting to impair generic alternatives to commercially available non-patented drugs." Br. 60-61.

These arguments miss the mark. The district court reasonably held, based on controlling precedent and roughly 70 pages of unchallenged factual findings, that (1) a lifetime industry bar was necessary to protect the public from the risk of egregious, deliberate, and recurrent violations by Shkreli in the pharmaceutical

industry, and (2) a more narrowly-crafted injunction would not provide adequate protection against those risks. Shkreli has not met his "heavy burden" to show abuse of discretion. *Posner*, 16 F.3d at 521 (quotation omitted).

A. The District Court Properly Weighed The Relevant Equitable Considerations

District courts consider the following factors when deciding whether to grant injunctive relief:

> [1] the fact that defendant has been found liable for illegal conduct; [2] the degree of scienter involved; [3] whether the infraction is an "isolated occurrence"; [4] whether defendant continues to maintain that his past conduct was blameless; and [5] whether, because of his professional occupation, the defendant might be in a position where future violations could be anticipated.

SEC v. Commonwealth Chem. Secs., Inc., 574 F.2d 90, 100 (2d Cir. 1978) (citation omitted); *see also SEC v. Frohling*, 851 F.3d 132, 139 (2d Cir. 2016); *SEC v. Universal Major Indus. Corp.*, 546 F.2d 1044, 1048 (2d Cir. 1976).

Applying these factors, the district court found that: (1) Shkreli's violations were not only illegal but egregious and recklessly disregarded the health of immunocompromised patients facing a life-threatening disease; (2) his violations were intentional; (3) he has a long track record of similar conduct; (4) he has shown no contrition and has never taken accountability for his misdeeds; and (5) he is well positioned to reoffend. *See* SPA-138-43. Shkreli challenges none of these facts, *see* Br. 4 n.3, and the district court was justified in finding that they

establish a grave threat of future violations that could be prevented only with a lifetime ban.

1. Shkreli's Violations Were Egregious And Threatened Public Health

The district court found that Shkreli committed "egregious," "long-running," and "ultimately dangerous" antitrust violations. SPA-140. Over the course of several years, Shkreli "heartless[ly]" and "coercive[ly]" exploited immunocompromised patients who needed Daraprim, in some instances to treat a brain infection that could kill them *within hours*; raised the price of the drug to a "scandalous level" (by 4,000%); and deprived them of access to lower-cost generic drugs. SPA-22, 127, 141. In the process, Shkreli "cynically" exploited the FDA's "regulatory scheme designed to protect the health of a nation by ensuring that its population has access to drugs that are not only effective but also safe." SPA-141. Shkreli's egregious conduct proven at trial—coupled with his history of engaging in similar conduct and total lack of remorse—signal that he likely would *never*, as a pharmaceutical executive, place legal or ethical duties above profits.

In the face of egregious misconduct that is likely to recur, a district court has a duty to "ensur[e] that [the wrongdoer] is no longer in a position to continue" his violations. *KarenKim*, 698 F.3d at 94, 100-01 (reversing district court's refusal to enter comprehensive injunctive relief for "egregious acts of sexual harassment"). The district court reasonably concluded that a lifetime prohibition from the

pharmaceutical industry was necessary to ensure that Shkreli is no longer in a position to commit anticompetitive harm at patients' expense. *See* SPA-141-43.

Shkreli calls the lifetime bar "overpowered," claiming that the bribery violations by organized crime figures in *Carson* and *Private Sanitation* were "far more extreme" than his own. Br. 41. But the district court's findings—which he does not appeal (Br. 4 n.3)—that Shkreli's violations were egregious, deliberate, heartless, repetitive, dangerous, and likely to recur, repudiate any such distinction.

2. Shkreli's Violations Were Intentional

In *Posner*, this Court sustained a lifetime ban on serving as an officer or director in *any* industry on a finding that the defendants violated securities laws with a "high degree of scienter." 16 F.3d at 521. The same goes here. The district court found that "Shkreli does not dispute that he intended to block generic competition to Daraprim and strove to do so for as long as possible." SPA-125; *see also* SPA-115-16. He "frankly and repeatedly acknowledged that his goal was to delay entry of a generic competitor with Daraprim for at least three years." SPA-136-37. Shkreli also "recklessly disregarded the health of a particularly

vulnerable population, those with compromised immune systems." SPA-141. Shkreli does not deny that he acted with a culpable mental state.[9]

3. Shkreli's Violations Were Repeated

The lifetime ban is also warranted by Shkreli's track record of similar misconduct. As *Carson* explained when upholding a lifetime ban, "[c]ourts are free to assume that past misconduct is highly suggestive of the likelihood of future violations. When the violation has been founded on systematic wrongdoing, rather than an isolated occurrence, a court should be more willing to enjoin future misconduct." 52 F.3d at 1184 (cleaned up); *accord Posner*, 16 F.3d at 521-22; *Grant Connect*, 763 F.3d at 1105; *Gill*, 265 F.3d at 957.

The district court found, and Shkreli no longer contests, that he has engaged in a long pattern of anticompetitive behavior. He employed his business model for Daraprim with two earlier drugs, Chenodal and Thiola. *See supra* pp. 5-6. The conduct and anticompetitive consequences were similar.

---

[9] *Amicus curiae* Pensmore Foundation acknowledges that Shkreli's conduct "may well have been" "egregious" and "deliberate," but argues that his restrictions on distributors selling product samples to generic companies were "arguabl[y] legal." Pensmore Br. 14, 21-26. Shkreli himself makes no such argument, and an amicus may not expand the issues before the Court. The argument fails anyway. Although a seller generally has a right to *unilaterally* refuse to deal with rivals, a seller may not "destroy [his] dealers' independent discretion through restrictive agreements." *United States v. A. Shrader's Son, Inc.*, 252 U.S. 85, 99 (1920). Moreover, Shkreli also broke the law when he conspired to block competitor access to API, which Pensmore does not challenge.

Shkreli now appears to concede that this recidivist behavior "persist[ed] for several years," but argues that this supports a "*narrowly*-drawn" injunction because his misconduct all fits within the same "pattern." Br. 38-39 (emphasis added); *see also* Br. 34. Shkreli is wrong on both the law and the facts. As a legal matter, injunctions in public-enforcement actions are not limited to "a simple proscription against the precise conduct previously pursued." *Nat'l Soc. of Prof'l Eng'rs v. United States*, 435 U.S. 679, 698 (1978). Rather, a district court may ban the defendant even from taking "untraveled roads" to the "prohibited goal." *Int'l Salt*, 332 U.S. at 400. Shkreli's "prohibited goal" was to reap monopoly profits by suppressing drug competition at the expense of patients, their families, and those who pay for their treatment. Especially given the egregious and persistent nature of Shkreli's misconduct, the district court was empowered to close all roads to this goal by banning him from involvement with any FDA-regulated drug products.

Indeed, contrary to Shkreli's position, the Daraprim conduct was worse than his prior market exploitations. At Retrophin, Shkreli blocked generic companies from securing product samples. At Vyera, Shkreli additionally prevented generic companies from obtaining the essential ingredient needed to manufacture competing products and obscured the sales data needed to assess the market opportunity for a generic substitute to Daraprim. The district court did not need to wait until Shkreli expanded his anticompetitive repertoire even further.

4. Shkreli Has Failed To Accept Responsibility For His Actions

Shkreli has shown no contrition and provided no assurances against future wrongdoing. As this Court explained when affirming the lifetime director-and-officer ban in *Posner*, the defendants' "lack of assurances against future violations demonstrated that such violations were likely to continue." 16 F.3d at 521-22.

The district court found that "in the face of public opprobrium, Shkreli doubled down. He refused to change course and proclaimed that he should have raised Daraprim's price higher." SPA-141. In written testimony, he expressed no "remorse or any awareness that his actions violated the law" and denied responsibility for all aspects of the scheme even though he conceived of and spearheaded it. SPA-142*; see also supra* p. 16 & n.5 (discussing that testimony). Shkreli challenges none of these findings, which amply confirm his high likelihood of reoffending.

5. Shkreli's Control Of The Violations From Prison Signals That He Would Circumvent A Narrower Injunction

The district court also justified the lifetime ban by citing Shkreli's continued control of the anticompetitive scheme from prison, including through use of a contraband cell phone. *See supra* p. 17. As the court put it, "Shkreli has demonstrated that he can and will adapt to restrictions," thwarting the effectiveness of a narrower injunction. SPA-143.

Indeed, the district court found in a pre-trial order that Shkreli used his contraband phone "to discuss highly relevant company business and … knew in doing so that those communications should have been but would not be preserved. Shkreli's use of the Prison Phone to discuss business development constitutes intentional spoliation and warrants sanctions." SUPP-212. Shkreli's intentional disregard of his legal responsibilities underscores the need for a broad and readily administrable form of injunctive relief.[10]

6. The Lifetime Bar Is Not Unduly Burdensome

Finally, although public equities trump private ones, courts may consider "the adverse effect of an injunction upon defendants." *Manor Nursing*, 458 F.2d at 1102. The district court found that given Shkreli's background as a hedge fund professional with a business degree, SPA-40, the "lifetime ban would not deprive Shkreli of the opportunity to practice a profession or to exercise a lawful skill for which he trained." SPA-141-42. In other words, it is not as though Shkreli is a career pharmaceutical executive with no other prospects. That finding was sound, and Shkreli does not dispute it on appeal.

[10] With this appeal pending, Shkreli announced the formation of a new company, Druglike, a "software platform" that seeks to "disrupt the economics of the drug business" by helping users "profit from drug discovery," including for "rare diseases." *See* SUPP-231. After several months of unfulfilled requests, the government recently obtained additional information from Shkreli about this venture and is investigating whether it violates the injunction.

Before founding Retrophin, Shkreli had no experience working in the pharmaceutical industry. SUPP-125; *see* SPA-40. Even in that sector, Shkreli focused on acquiring drugs without patent protection that were the sole treatment for rare and life-threatening diseases, raising the prices, and blocking generic competition. SPA-40-43. This oft-repeated business model was unlawful, and one "can have no vested interest in a business activity found to be illegal." *United States v. Diapulse Corp. of Am.*, 457 F.2d 25, 29 (2d Cir. 1972) (quotation omitted). Since Shkreli's pharmaceutical experience was tied to the illegitimate business model, a prohibition from future participation in the industry may impose minimal burdens on him.

B. The District Court Properly Concluded That A Narrower Remedy Would Not Protect The Public

The district court properly determined that a more narrowly-crafted injunction would not likely "succeed in providing adequate protection against a repetition of illegal conduct." SPA-143. Shkreli challenges none of the court's factual findings, but he makes various legal claims that the injunction is overbroad, some for the first time on appeal. The arguments all fail. The court appropriately tailored its injunction to provide the public with complete protection from the threat of future violations by Shkreli.

1. The District Court Appropriately Declined To Limit The Injunction To Specific Types Of Conduct

Shkreli argued below that the court could ban him from "[e]xclusive supply agreements, restricted distribution agreements, [and] data blocking agreements," but not from the whole industry. A-2289; *see also* Br. 37-39 (arguing that ban should be limited to "particular kinds of conduct"). Given the egregious, intentional, and dangerous nature of Shkreli's violations, SPA-140, along with his ability to continue orchestrating the scheme from prison, SPA-143, the court found that anything less than an industry restriction would pose a "very real risk" that Shkreli would continue to engage in illegal activities "by working through others employed in the industry, as he has done while incarcerated." SPA-159.

The district court had no duty to issue a narrower, conduct-specific injunction against a defendant who had induced others to violate the antitrust laws, pulling the strings behind the scenes and deliberately spoliating evidence of his involvement. *See supra* pp. 17, 39-40. That record creates a "necessity [for] decrees that are not so narrow as to invite easy evasion." *McComb v. Jacksonville Paper Co.*, 336 U.S. 187, 193 (1949); *see Grant Connect*, 763 F.3d at 1105 (upholding district court's refusal to impose narrow, conduct-specific injunction given defendants' history of recalcitrance); *Gill*, 265 F.3d at 957 (same). Shkreli argues that a broad injunction was unwarranted because a "wider fence" is not "harder to jump." Br. 49. But given Shkreli's history of violating the antitrust

laws, exploiting patients, and evading restrictions, the district court was justified in imposing a "fence" wide enough that Shkreli could not simply walk around it.

An industry-wide restriction is far easier to monitor than conduct-specific prohibitions, especially when it comes to unrepentant recidivists who lack regard for behavioral norms. The government can readily determine, for example, whether Shkreli owns, directs, works for, or consults with a pharmaceutical company. It cannot so easily perceive a behind-the-scenes role in company decision-making. If Shkreli were employed at a drug company engaged in anticompetitive behavior, the government may have no way to ascertain his involvement without extensive investigation. And even then, Shkreli may be able to evade detection by purposefully avoiding a paper trail or by using an off-the-books burner phone as he did in this case. Accordingly, the district court was justified in believing that a conduct-specific injunction would be too difficult to effectively monitor and enforce.[11]

Shkreli complains that the industry bar would prevent him from "being a subject in a clinical trial" or "taking a job as a cashier at Walgreens." Br. 58. But

[11] The government did not, as Shkreli claims, justify the industry bar based on "general deterrence." Br. 37. The government argued that "a conduct-specific injunction that would allow Mr. Shkreli's continued participation in the pharmaceutical industry would be more difficult to monitor and enforce and would not be sufficient to protect consumers" from Shkreli repeating his "reprehensible conduct." A-2240.

any broad injunctive remedy is subject to hypotheticals involving activities that do not seem inherently harmful.[12] For instance, the defendant in *Carson* could have complained that the labor-industry ban prevented him from volunteering for a human-rights group that opposes child labor. If Shkreli can show that the order is burdening his *bona fide* objective of becoming a Walgreens cashier, he can request modification for those limited purposes. But, as the Supreme Court has explained, "it would not be good judicial administration to strike" provisions from an order "to meet a hypothetical situation" when defendants can raise their claims "in evidentiary form" by filing a motion to modify the injunction as the need arises. *Int'l Salt*, 332 U.S. at 401; *accord FTC v. Nat'l Lead Co.*, 352 U.S. 419, 431 (1957). At this point, the district court could properly conclude that the public needs the protection and prophylactic benefits of a broad injunction more than Shkreli needs the hypothetical ability to work at Walgreens. This is especially true given Shkreli's decision not to appeal the district court's factual finding that the injunction would not burden him. *See supra* pp. 16, 40-41.

[12] Shkreli's Walgreens hypothetical would have applied equally in *Grant Connect*, where the Ninth Circuit upheld a ban on (among other things) marketing or selling dietary supplements. *See supra* pp. 30.

2. The District Court Properly Barred Shkreli From Pharmaceutical Research And Development And Company Ownership

Shkreli objects that the injunction should not extend to pharmaceutical research and development or drug company ownership. *See* Br. 45-46, 49-50; SPA-166 (Permanent Injunction, ¶¶ II.A, II.C & II.F). The district court did not abuse its discretion in rejecting these arguments.

The district court found that Shkreli was "wrong to suggest that pharmaceutical research and development activities … were not among the conduct at issue in this case." SPA-156. Shkreli "used the promise that Vyera would engage in research and development activities to recruit Vyera executives and to induce one of the restrictive supply agreements at issue." *Id.* Specifically, Vyera told Fukuzyu that if it agreed not to sell API to generic companies, Vyera would work with Fukuzyu on future research projects. SPA-62. Shkreli also sought to justify his violations by arguing that he needed "supracompetitive profits to fund such research and development work." SPA-156.

On appeal, Shkreli does not challenge these findings or argue that they do not support an industry ban. Instead, Shkreli falsely states that the "district court did not purport to explain" why the ban included research and development. Br. 46. The district court offered such an explanation, SPA-156, and Shkreli has forfeited his right to contest it.

The district court also acted properly by banning Shkreli from acquiring or owning an interest in a drug company (except through a diversified mutual fund or similar vehicle). SPA-166 (Permanent Injunction, ¶¶ II.C & II.F). Shkreli again attacks these provisions (Br. 49-50) while ignoring the district court's reasoning. As the court found, "Shkreli used his position as the largest Phoenixus [Vyera's parent company] shareholder to exert control over it and Vyera's operations even after he had given up all formal role in the companies' operations." SPA-160-61. He wielded that control to "orchestrate[] [the companies'] violation of the antitrust laws." *Id.* The order's restrictions on ownership thus "arise[] directly from the violations of law found at trial." *Id.*

Shkreli asserts that the court should not have banned him from passive stock ownership, Br. 17, 50 & n.16, but given his history of using others to do his bidding—and threatening or retaliating against them should they refuse, *see supra* p. 17—the court was justified in prohibiting Shkreli even from holding non-voting shares in a pharmaceutical company. Requiring Shkreli to divest his Vyera holdings is also consistent with the public interest in ensuring that Shkreli be "denied future benefits from [his] forbidden conduct." *Gypsum*, 340 U.S. at 89.

3. Shkreli Forfeited The Claim That The District Court Improperly Banned Him From Various Industry "Sectors"

As noted, Shkreli's counsel conceded at trial that if the district court found him liable, it could ban him from exclusive supply agreements and distribution

restrictions. A-2289. On appeal, Shkreli reverses course, arguing for the first time that the district court was powerless to ban him from *any* activities involving various "sector[s]" of the industry, including patented drugs, over-the-counter (OTC) drugs, generic drugs, and drugs with established competitors. Br. 44-49. Shkreli deceptively attacks the district court for "ma[king] no findings" about these objections. Br. 46-47. He raised no such claims below and may not do so now.

Even if these objections had been raised below, they backfire, since they show just how easily Shkreli can adapt the misdeeds proven at trial to other settings in the pharmaceutical industry. *See Grant Connect*, 763 F.3d at 1105 (industry ban proper where violations were "transferable" to "new product lines"). Shkreli claims (for the first time on appeal) that because Daraprim had no patent protection, the district court lacked authority to ban him from activities involving patented drugs. Br. 46. But the mere existence of a patent changes nothing, since that patent "may or may not be valid, and may or may not be infringed." *FTC v. Actavis, Inc.*, 570 U.S. 136, 147 (2013). Shkreli thus could have committed the exact same violations to destroy generic competition even if he had held a (possibly invalid or non-infringed) patent.

Besides, patents do not give their holders carte blanche to commit antitrust violations, as Shkreli seems to assume. Patentholders can unlawfully stifle generic competition in various ways, including by:

- paying generic rivals to drop their challenge to the patents and stay off the market, *see id.* at 153-59;
- pursuing "sham" patent litigation against those rivals, *see In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 694-95 (2d Cir. 2009); and
- engaging in "product-hopping," *i.e.*, "withdrawing a successful drug from the market and introducing a reformulated version of that drug" for the purpose of "impeding generic competition," *see New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 659 (2d Cir. 2015).

The district court was entitled to believe that Shkreli poses a substantial threat of such violations given his propensity for anticompetitive conduct, his willingness to exploit the FDA's regulatory scheme and pay off industry members to maintain his monopoly, and his disregard for patients and the medical system.

Next, Shkreli argues for the first time that the district court should not have banned him from OTC drugs, Br. 47, but he fails to explain why he would pose any lower risk of committing antitrust violations in that setting. Drugmakers can violate the antitrust laws by harming generic competition for OTC drugs just as

they can for prescription drugs.[13] Moreover, OTC drugs require active pharmaceutical ingredients just as prescription ones do, which means that Shkreli could replicate the Daraprim scheme in that arena, too.

Shkreli also claims for the first time that the district court should not have banned him from working for a generic company, or for any drug company with "established" rivals. Br. 47, 49. But this Court has held that generic companies can harm competition by entering exclusive-supply agreements to block rivals from obtaining essential ingredients, just as Shkreli did here. *See Geneva Pharms. Tech. Corp. v. Barr Labs., Inc.*, 386 F.3d 485, 504-10 (2d Cir. 2004). Generic companies may also, for example, collude with a brand-name company to split the brand's monopoly profits rather than competing, *see Impax Labs., Inc. v. FTC*, 994 F.3d 484, 489, 493-500 (5th Cir. 2021), or engage in price-fixing, *see In re Generic Pharms. Pricing Antitrust Litig.*, 394 F. Supp. 3d 509, 529 (E.D. Pa. 2019). All these sorts of violations may occur in a market with rivals that are established rather than incipient. The district court had reason to believe that

[13] *See, e.g.*, *URL Pharma, Inc. v. Reckitt Benckiser, Inc.*, No. 15-505, 2015 WL 5042911 at *7-9 (E.D. Pa. Aug. 25, 2015) (plaintiff sufficiently pleaded unlawful monopolization by alleging that manufacturer of OTC Mucinex induced generic rival to delay entry by promising to furnish supply for a licensed generic and then reneging on that commitment).

Shkreli posed a threat to such markets given his history of conspiring with or paying off market participants in order to sustain artificially high monopoly prices.

4. The District Court Properly Imposed The Injunction For Shkreli's Lifetime

Shkreli calls the lifetime duration of the injunction an abuse of discretion, Br. 54-56, but challenges none of the district court's factual findings underlying it. *See* SPA-140-43. Although Shkreli argues that the district court was legally required to place a "time limit" on injunctive relief, Br. 54, this Court and others have routinely upheld permanent restrictions after applying the same factors that the district court considered here. *See supra* pp. 26-32.

Shkreli asserts (Br. 39, 55) that the Eighth Circuit required a time limit for injunctive relief in *ES Development, Inc. v. RWM Enterprises, Inc.*, 939 F.2d 547 (8th Cir. 1991), but the factbound reasoning in that case is inapposite. Several car dealers violated the Sherman Act by orchestrating a coordinated campaign to oppose the development of an auto mall that would have housed competing dealerships. *Id.* at 556-57. The Eighth Circuit upheld the district court's decision to ban the dealers from communicating with their respective manufacturers regarding the mall, but held that the injunction should have had a reasonable time limit, such as three years. *Id.* at 557-59. The decision has little pertinence here because the violation involved a discrete set of events targeted at a specific and time-limited construction project. In that situation, the court explained, "the

continuing effects of the conspiracy are certain to recede with time." *Id.* at 558; *accord EEOC v. AutoZone, Inc.*, 707 F.3d 824, 841-44 (7th Cir. 2013) (requiring district court to put a "reasonable time limit" on a follow-the-law injunction whose perpetual scope was disproportionate to a violation committed against a single employee).

The district court here, in sharp contrast, found that the threat Shkreli poses to drug markets and patients is perpetual, SPA-141, and he provides no good ground to second guess that judgment. Shkreli spent his pharmaceutical career scheming to deprive patients of essential generic drugs and pocket outsized monopoly profits. Shkreli directly admitted that he sought to victimize patients this way "forever," SUPP-86, and "in perpetuity," SUPP-69. Beyond that, he has shown no remorse for his conduct. Just as Shkreli planned to perpetuate his monopolistic pricing schemes "forever," the district court properly determined that this is how long the injunction must last.

III. THE INJUNCTION DOES NOT INFRINGE SHKRELI'S FIRST AMENDMENT RIGHTS

The injunction prohibits Shkreli from "[t]aking any *action* to directly or indirectly influence or control the management or business of any Pharmaceutical Company" and clarifies that Shkreli's "public statements about a Pharmaceutical Company" constitute such action if he "intended the statement" to influence or control such a company "or if a reasonable person would conclude that the

statement has that effect." SPA-159-60, 166 (¶ II.D) (emphasis added). Shkreli contends that this protective measure is an impermissible restriction on his right to free speech. *See* Br. 50-54. But the provision targets Shkreli's *conduct*—controlling or influencing a drug company's business decisions—and makes clear that Shkreli cannot sidestep the order's requirements by telling others to engage in actions that he is barred from performing directly. Because this provision is necessary to protect the public from the risk of Shkreli repeating his antitrust misconduct by directing or encouraging others to violate the law—just as he did with Daraprim from prison—this provision passes First Amendment muster.

Virtually every antitrust violation has an "expressive component," since the participants use speech to collude or carry out boycotts. *See FTC v. Superior Court Trial Lawyers Ass'n*, 493 U.S. 411, 431 (1990). Even so, the First Amendment poses no obstacle to complete injunctive relief for antitrust violations, provided that the injunction "represents a reasonable method of eliminating the consequences of illegal conduct." *Prof'l Eng'rs*, 435 U.S. at 698. An industry restriction—or any injunction proscribing future conduct—would be toothless if a defendant could bypass it by telling or encouraging others to engage in the prohibited actions. This Court thus rejected a First Amendment challenge to an order banning the defendant from involving herself in corporate "management or operations," including by speaking with officers, directors, employees, and agents

to "express[] her opinions" on how the company "is being run." *Peregrine Myanmar, Ltd. v. Segal*, 89 F.3d 41, 52 (2d Cir. 1996). Here, the injunction's restriction on Shkreli using speech to control or influence drug-company business decisions functions to prevent evasion and is no broader than necessary to do so. Shkreli remains free to engage in scientific, economic, political, or other commentary so long as his statements are not calibrated to sway a pharmaceutical company's business decisions.

The need for this provision is especially acute since Shkreli controlled the Daraprim violations for years from prison, *exclusively* by telling others what to do. The First Amendment offered Shkreli no protection then, since "it has never been deemed an abridgement of freedom of speech or press to make a course of conduct illegal merely because the conduct was in part initiated, evidenced, or carried out by means of language, either spoken, written, or printed." *Giboney v. Empire Storage & Ice Co.*, 336 U.S. 490, 402 (1949). "[T]he First Amendment provides no defense to persons who have used otherwise protected speech or expressive conduct to force or aid others to act in violation of a valid conduct-regulating statute." *Jews for Jesus, Inc. v. Jewish Community Relations Council of N.Y., Inc.*, 968 F.2d 286, 296 (2d Cir. 1992). Likewise, the First Amendment gives Shkreli no shelter from an injunction remedying such violations by barring him from using words to direct the actions of a pharmaceutical company in the future.

Shkreli complains that the injunction could stop him "from publishing an op-ed about best industry practices or tweeting disapproval of a distributor's marketing strategy." Br. 52. But, as the district court held, "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." SPA-159. Because Shkreli violated the antitrust laws, the district court was empowered to "curtail the exercise of liberties that [Shkreli] might otherwise enjoy, [but] that is a necessary and … unavoidable consequence of the violation." *Prof'l Eng'rs*, 435 U.S. at 697. "Just as an injunction against price fixing abridges the freedom of businessmen to talk to one another about prices," an injunction against participation in the pharmaceutical industry will curtail Shkreli's "range of expression" when he makes statements seeking to influence or control a drug company. *See id.*

Shkreli tries to distinguish *Professional Engineers* by asserting that the Supreme Court held that the injunction at issue (which forbade the defendant from stating or implying that competitive bidding is unethical) did not "block legitimate paths of expression." Br. 54 (discussing 435 U.S. at 698). Shkreli misstates the Court's holding. The Court did *not* deny that the injunction could potentially block legitimate expression, but held that "the burden is upon the proved transgressor" to come forward with a proposal to modify the decree to allow it to make specific

statements "more closely confined to [a] legitimate objective." *Id.* at 698-99 (cleaned up). In other words, the mere possibility that the order might proscribe legitimate speech was not a basis to vacate the order.[14] The same is true here.

Likewise, outside the antitrust realm, this Court has recognized that district courts may limit conduct otherwise protected by the First Amendment when remedying a statutory violation. In *Carson*, the Court rejected a First Amendment freedom-of-association challenge to a lifetime ban on participation in labor unions given the compelling interest in ridding unions of corruption. *See* 52 F.3d at 1185.

The injunction's bar on participating in a pharmaceutical company's business decisions is not, as Shkreli claims, a "prior restraint." Br. 51. "Not all injunctions that may incidentally affect expression … are 'prior restraints.'" *Madsen v. Women's Health Ctr., Inc.*, 512 U.S. 753, 764 n.2 (1994). Again, the provision targets *conduct* and recognizes that Shkreli may seek to direct corporate behavior through words (which is how he committed antitrust violations in the past) as well as through deeds. "[T]he injunction was issued not because of the content of [Shkreli's] expression … but because of [his] prior unlawful conduct."

[14] In a footnote, *Professional Engineers* rejected the defendants' argument that the injunction would prohibit them from "opposing repeal of statutes," holding that the "injunction contains no such prohibition." 435 U.S. at 698 n.27. Shkreli quotes the "no such prohibition" language out of context to falsely depict the Court as holding that the injunction did not prohibit *any* legitimate paths of expression. *See* Br. 54.

Id. Moreover, as noted, Shkreli remains free to speak his mind "in any one of several different ways," *id.*, and can even make statements about pharmaceuticals, so long as a reasonable person would not interpret the message as seeking to influence a drug company's business decisions.[15]

For these reasons, the injunction "burden[s] no more speech than necessary to serve a significant government interest" in protecting the public from future antitrust violations by Shkreli or those under his power. *See id.* at 765. It therefore comports with the First Amendment.

IV. THE INJUNCTION IS SUFFICIENTLY CLEAR AND SPECIFIC

Shkreli argues that the injunction is vague and indefinite and thereby violates Rule 65(d). Br. 56-60. The argument mischaracterizes the order.

Rule 65(d) requires that "[e]very order granting an injunction … must: (A) state the reasons why it was issued; (B) state its terms specifically; and (C) describe in reasonable detail … the act or acts restrained or required." To comply with this rule, "an injunction must be specific and definite enough to apprise those within its scope of the conduct that is being proscribed." *S.C. Johnson & Son, Inc. v. Clorox Co.*, 241 F.3d 232, 240-41 (2d Cir. 2001) (cleaned

[15] Shkreli's reliance on *Metropolitan Opera Ass'n v. Local 100, Hotel Employees & Restaurant Employees International Union*, 239 F.3d 172 (2d Cir. 2001), is misplaced. *See* Br. 52. There, this Court did not decide whether the injunction was a prior restraint; it vacated the injunction as impermissibly vague. 239 F.3d at 178-79.

up). The purpose of this rule is "to prevent uncertainty and confusion on the part of those to whom the injunction is directed, and to be sure that the appellate court knows precisely what it is reviewing." *Id.* (cleaned up).

Even so, an order does not violate Rule 65(d) merely because it is broad, since "the scope of an injunction … may be broad but at the same time be drafted in a manner that is not vague, but that is specific and precise. There is no inherent inconsistency between the two characteristics." 11A Charles Alan Wright & Arthur R. Miller, FEDERAL PRACTICE & PROCEDURE § 2955 (3d ed. Supp. 2022) ("[T]he court simply may determine that the only way to prevent a statutory violation and thereby accomplish the purpose of the legislation is by entering a broad decree."); *see also Diapulse*, 457 F.2d at 29 ("The injunction may sweep broadly in its prohibition if that is necessary to enjoin future violations which appear likely to occur."). A court satisfies Rule 65(d) when its order cannot "be drawn more narrowly without unduly complicating its enforcement and impairing its effectiveness." *Peregrine Myanmar*, 89 F.3d at 52.

a. Shkreli objects (Br. 56) that the meaning of "pharmaceutical industry" under the injunction is "vague[]" and "ambigu[ous],"*see* SPA-166 (¶ II), but he raised no such objection below. *See* D. Ct. ECF 867-2 at 9. And rightfully so: Pharmaceuticals are a commonly understood term, and if that were not enough, the order provides specific definitions of "Pharmaceutical Company," "Drug Product,"

and "API." *See* SPA-164-65. Shkreli is not, however, barred from involvement with companies that make products, like dietary supplements, that are not regulated by the FDA as drugs.

Because pharmaceuticals have a specific regulatory definition, the order's ban on "directly or indirectly participating in any manner in the pharmaceutical industry" (SPA-166) is even more precise than other industry bans upheld by this Court. In *Carson*, the Court sustained a ban on "participating[16] in any way in the affairs of or having any dealing, directly or indirectly, with … any labor organization." 52 F.3d at 1184 n.10. And in *Private Sanitation*, the Court upheld a ban on "participating directly or indirectly in the carting industry." 995 F.2d at 376. The injunction here is no less understandable.

b. Shkreli argues (Br. 56-57) that the injunction is somehow vague because it contains a limited exception allowing him to obtain "Qualified Employment" with an entity meeting the definition of "Pharmaceutical Company" if that company is "not *primarily* involved in the research, Development, manufacture, commercialization, or marketing" of drugs and derives less than 10% of its gross revenues from these endeavors. Br. 56, discussing SPA-165 (¶ I.N) (emphasis

[16] Shkreli suggests the word "participating" is vague, Br. 56, but this is a term "that the ordinary person exercising ordinary common sense can sufficiently understand and comply with." *U.S. Civil Serv. Comm'n v. Nat'l Ass'n of Letter Carriers, AFL-CIO*, 413 U.S. 548, 577 (1973).

added). As the district court explained, this provision could allow Shkreli to accept employment with a university or advertising agency that does pharmaceutical work as a minority of its business (so long as Shkreli is not personally involved in such work). SPA-157-58. Under the order, Shkreli must give the government advance notice of his intent to accept Qualified Employment and, if the government does not object within 20 working days, it is barred from seeking to hold Shkreli in contempt based on that employment. SPA-166-67 (¶ II.G). And, as the district court stressed, "Shkreli of course may apply for relief should the plaintiffs unreasonably object to his employment." SPA-158.

Far from being vague, this provision makes the order more precise and reduces its burden on Shkreli. He complains that the order is unclear about whether he can "work[] for an advertising company whose clients include pharmaceutical companies," Br. 58, but, as noted, the district court adopted the Qualified Employment exception to answer that very question.

c. Shkreli asserts that the order "might prohibit him from discussing pharmaceuticals with a friend in the industry." Br. 57. The injunction makes plain that such conversations are off-limits when they amount to "[p]articipating in the formulation, determination, or direction of any business decisions" of a pharmaceutical company. SPA-166 (¶ II.B). As the district court explained, "[t]his language is sufficiently clear to give Shkreli the notice he requires of the

terms of the injunction and is also necessary to control the very real risk that he will continue to participate in the industry by working through others in the industry, as he has done while incarcerated." SPA-159.

Shkreli likewise objects that the order is vague about whether he can "lobby[] for or against any federal or state policy that could affect the bottom line of a pharmaceutical company." Br. 59. Not so. The order forbids Shkreli from working on behalf of a pharmaceutical company or (as discussed in Point III) from making "public statements about a Pharmaceutical Company" if he "intended" those statements to influence or control such a company "or if a reasonable person would conclude that the statement has that effect." SPA-166 (¶¶ II.A & II.D). Shkreli therefore may not engage in lobbying to support or oppose a pharmaceutical company's business activities. He may engage in advocacy on a general healthcare policy issue without either working for or making "public statements about a Pharmaceutical Company." Those outcomes are perfectly clear on the face of the injunction.

Shkreli likewise objects to the order's use of a reasonable-person standard to determine whether Shkreli made statements for the purpose of influencing or controlling a pharmaceutical company. Br. 59. But it is not vague to determine liability based on how an objectively reasonable listener would interpret Shkreli's statements; the law does this all the time. *See, e.g.*, *FTC v. Moses*, 913 F.3d 297,

306 (2d Cir. 2019) (even without "intent to deceive," defendants may face FTC Act liability for "representations or practices [that] were likely to mislead consumers acting reasonably") (citation omitted).

d. Shkreli complains that the order is vague because its guidance about practices that do and do not constitute participation in the pharmaceutical industry is "illustrative" rather than "exhaustive," since it is prefaced by the words "including by." Br. 57, discussing SPA-166 (¶ II). This was by design. *See* SPA-158 (explaining that the words "including by" are "necessary to protect the public" and ensure "the effectiveness of the injunction"). Given Shkreli's long history of evading legal restrictions, the district court was justified in ensuring that Shkreli does not circumvent the order by participating in the pharmaceutical industry in ways outside the enumerated list of examples. "Rule 65(d) does not require the district court to predict exactly what [Shkreli] will think of next." *S.C. Johnson*, 241 F.3d at 241 (cleaned up). The district court was entitled to frame the injunction without "specifically enjoin[ing]" every "plan or scheme" that Shkreli might hatch in the future. *McComb*, 336 U.S. at 192.

e. As noted above, Shkreli hypothesizes that the injunction's ban on "participating" in the pharmaceutical industry "could be broad enough to prohibit[]" him from being a clinical trial test subject or a Walgreens cashier. Br. 58. There is no Rule 65(d) vagueness problem here: As Shkreli concedes, the

order forbids such conduct when "read literally." *Id.* The argument therefore pertains to breadth, not vagueness. And as discussed at pp. 42-44, the district court acted within its discretion when concluding that an industry-wide bar was justified as a prophylactic measure to prevent circumvention of the law and similar dangerous violations by Shkreli in the future, even if it could apply to "[a]cts entirely proper when viewed alone." *Gypsum*, 340 U.S. at 89.

f. Finally, Shkreli complains that the order is vague because its access-to-information requirement directs Shkreli to make himself available for interviews and provide access to records "that relate to compliance with this Order." SPA-169 (¶ V). Shkreli argues that the order places no limits "as to duration, frequency, or topics to be covered." Br. 60. But it is for the district court to determine based on the specific circumstances whether the FTC's information demands reasonably relate to compliance with the order. If Shkreli believes that a specific request exceeds that standard, he may ask the district court for relief.

CONCLUSION

The judgment of the district court should be affirmed.

Respectfully submitted,

JOEL MARCUS
Deputy General Counsel

March 23, 2023

/s/ Bradley Grossman
BRADLEY DAX GROSSMAN
Attorney

FEDERAL TRADE COMMISSION
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580
bgrossman@ftc.gov
202-326-2994

Of Counsel:
MARKUS H. MEIER
BRADLEY S. ALBERT
MAREN HANEBERG
NEAL J. PERLMAN
DANIEL W. BUTRYMOWICZ

FEDERAL TRADE COMMISSION
Washington, D.C. 20580

CERTIFICATE OF COMPLIANCE

I certify that the foregoing brief complies with the volume limitations of Local Rule 32.1(a)(4)(A) because it contains 13,976 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f), and that it 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 was prepared using Microsoft Word in 14-point Times New Roman type.

March 23, 2023

/s/ Bradley Grossman
Bradley Dax Grossman
Attorney
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

CERTIFICATE OF SERVICE

I certify that on March 23, 2023, I served the foregoing on counsel of record using the Court's electronic case filing system. All counsel of record are registered ECF filers.

March 23, 2023

/s/ Bradley Grossman
Bradley Dax Grossman
Attorney
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580