# APPENDIX

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*Appendix A*

**UNITED STATES COURT OF APPEALS**
**FOR THE SECOND CIRCUIT**

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No. 22-728

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FEDERAL TRADE COMMISSION, et al.,

*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*,

VYERA PHARMACEUTICALS, LLC, et al.,

*Defendants*.

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Decided: Jan. 23, 2024

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Present: BARRINGTON D. PARKER, MYRNA PÉREZ,
SARAH A.L. MERRIAM, *Circuit Judges*.

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SUMMARY ORDER

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Appeal from a judgment of the United States District Court for the Southern District of New York (Cote, *J.*).

**UPON DUE CONSIDERATION, IT IS HEREBY ORDERED, ADJUDGED, AND DECREED** that the February 4, 2022, judgment of the district court is **AFFIRMED**.

Plaintiffs-Appellees Federal Trade Commission ("FTC"); the commonwealths of Pennsylvania and Virginia; and the states of California, Illinois, New York, North Carolina, and Ohio filed suit against Defendant-Appellant Martin Shkreli and others in the United States District Court for the Southern District of New York. Plaintiffs-Appellees alleged violations of federal and state antitrust laws for conduct involving the distribution of Daraprim, a brand-name drug used to treat a parasitic infection called toxoplasmosis. Shkreli's co-defendants settled before trial.

Following a seven-day bench trial, the district court found that Plaintiffs-Appellees carried their burden of establishing that Shkreli committed antitrust violations. The district court issued a final judgment that, among other things: (1) ordered disgorgement against Shkreli jointly and severally with defendant Vyera; and (2) entered a permanent injunction imposing a lifetime ban on Shkreli from the pharmaceutical industry. This appeal followed.

For the reasons set forth below, we affirm. We assume the parties' familiarity with the underlying facts, the procedural history of the case, and the issues on appeal, which we reference only as necessary to explain our decision.

## I. Disgorgement

Shkreli argues for the first time on appeal that the district court erred by relying on federal law remedies in imposing joint and several disgorgement on him under New York law. Though Shkreli does not dispute that New York law allows for disgorgement relief, he contends that New York law precludes disgorgement on a joint and several basis. Shkreli never made this argument to the district court, and he proffers no reason now for his failure to raise the arguments there. Additionally, in the district court, Shkreli himself relied exclusively on federal equity jurisprudence in contending that he should not be ordered to disgorge profits. *See* Dist. Ct. ECF No. 462 at 4-6; *see also* Dist. Ct. ECF No. 860 at 1234-35 (Shkreli's trial counsel arguing "in terms of equitable monetary relief, your Honor, the *Liu* [*v. SEC*, 140 S. Ct. 1936, 207 L. Ed. 2d 401 (2020),] case from the Supreme Court says that disgorgement should not be a joint and several remedy"). Therefore, the circumstances here do not persuade us that we should exercise our discretion to address this new argument on appeal. *See Greene v. United States*, 13 F.3d 577, 586 (2d Cir. 1994) ("Entertaining issues raised for the first time on appeal is discretionary with the panel hearing the appeal."); *see also Doe v. Trump Corp.*, 6 F.4th 400, 410 (2d Cir. 2021). Given his strategic decision in the district court, there

is no injustice to Shkreli by us declining to address his new argument.[1]

## II. Permanent Injunction

Next, Shkreli provides three unpersuasive reasons to disturb the district court's entry of the permanent injunction in this case.

First, Shkreli contends that the district court abused its discretion by entering an overbroad injunction against him that imposes a lifetime ban from the pharmaceutical industry. Second, Shkreli argues that the injunction unconstitutionally limits his public speech. Third, Shkreli asserts that the injunction is not specific enough and that it thus violates Federal Rule of Civil Procedure 65(d). We address each argument in turn below.

First, we note that Section 13(b) of the Federal Trade Commission Act authorizes the FTC to bring actions seeking injunctive relief for violations of the Act. *See* 15 U.S.C. § 53(b). Section 13(b) imposes prospective, not retrospective, relief. *See AMG Cap. Mgmt, LLC v. FTC*, 141 S. Ct. 1341, 1347-48, 209 L. Ed. 2d 361

[1] Even if this argument were not waived, it would still fail. We do not read Shkreli's principal case, *J.P. Morgan Sec. Inc. v. Vigilant Ins. Co.*, 37 N.Y.3d 552, 162 N.Y.S.3d 851, 183 N.E.3d 443 (N.Y. 2021), to hold that joint and several disgorgement relief is unavailable against codefendants engaged in concerted wrongdoing to wrongfully obtain profits under New York equity jurisprudence.

(2021). Upon a proper showing, a district court may issue a permanent injunction. *See id.*[2]

In general, a district court has broad discretion in framing an injunction in terms it deems reasonable to prevent wrongful conduct. *See Seibert v. Sperry Rand Corp.*, 586 F.2d 949, 951 (2d Cir. 1978). Appellate review of the terms of the injunction is limited to whether there has been an abuse of that discretion. *See SEC v. Posner*, 16 F.3d 520, 521-22 (2d Cir. 1994). A district court has abused its discretion if it: (1) based its ruling on an erroneous view of the law, (2) made a "clearly erroneous factual finding," or (3) rendered a decision that "cannot be located within the range of permissible decisions." *SEC v. Dorozhko*, 574 F.3d 42, 45 (2d Cir. 2009) (internal citations and quotation marks omitted).

We conclude that the district court did not abuse its discretion by imposing a lifetime ban from the pharmaceutical industry on Shkreli because an injunction of that scope was within the range of permissible decisions. The district court found, and Shkreli does not dispute, that Shkreli's illegal scheme was "egregious, deliberate, repetitive, long-running, and ultimately dangerous." Special App'x at 140. The district court found that Shkreli's comprehensive and effective scheme led to the price increase of a life-saving drug, Daraprim, from $17.50 to $750 per tablet and

[2] The Donnelly Act was modeled on the federal Sherman Act of 1890, and thus should generally be construed considering federal precedent. *See People v. Rattenni*, 81 N.Y.2d 166, 171, 613 N.E.2d 155, 597 N.Y.S.2d 280 (1993).

successfully blocked the entry of generic drug competition to maintain Daraprim's inflated price. The district court further found that Shkreli's scheme was far-reaching and was implemented using many means. It pointed to the record demonstrating that Shkreli facilitated extensive research; established at least two companies; recruited and worked through others even while in prison; and took advantage of regulatory requirements designed to safeguard the pharmaceutical industry to carry out his illegal scheme.

The district court's injunction was a reasonable measure to protect the public from the risk of recurring anticompetitive conduct in the pharmaceutical industry by Shkreli. In his direct written testimony, Shkreli indicated that after release from prison, "[i]f I do pursue employment within the pharmaceutical industry . . .I hope to continue playing a role in the discovery of cures and treatments for rare and life-threatening diseases . . . and focus on experimental and research-based opportunities related to discovery of new medicines and new uses for existing medicines." App'x at 801. Given Shkreli's pattern of past misconduct, the obvious likelihood of its recurrence, and the life-threatening nature of its results, we are persuaded that the district court's determination as to the proper scope of the injunction was well within its discretion.

Shkreli fares no better in his challenge to Paragraph II(D) of the permanent injunction. Shkreli argued in the district court that imposing Paragraph II(D) without limits would infringe his free speech rights by prohibiting him entirely from, among other

things, using social media to discuss the pharmaceutical industry. In response to Shkreli's concerns, the record reflects that the district court added the following text to Paragraph II(D):

> Shkreli's public statements about a Pharmaceutical Company will be deemed an action taken to influence or control the management or business of any Pharmaceutical Company if Shkreli intended the statement to have that effect or if a reasonable person would conclude that the statement has that effect.

Special App'x at 166.

The district court added this language to set limitations in light of Shkreli's concerns, while also enjoining possible future antitrust violations. In light of that addition, we are persuaded that Paragraph II(D)'s public statement ban is in the range of permissible decisions, preventing possible future antitrust violations without treading on Shkreli's free-speech rights. *See Nat'l Soc'y. of Pro. Eng'rs v. United States*, 435 U.S. 679, 697-98, 98 S. Ct. 1355, 55 L. Ed. 2d 637 (1978) ("In fashioning a remedy, the District Court may, of course, consider the fact that its injunction may impinge upon rights that would otherwise be constitutionally protected, but those protections do not prevent it from remedying the antitrust violations."); *see also Jews for Jesus, Inc. v. Jewish Cmty Rels. Council of N.Y., Inc.*, 968 F.2d 286, 296 (2d Cir. 1992) ("[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.").

Lastly, we conclude that the terms of the district court's injunction are sufficiently clear, specific in terms, and described in reasonable detail to satisfy Federal Rule Civil Procedure 65(d). We review de novo whether the injunction complies with Rule 65(d). *See City of New York v. Mickalis Pawn Shop, LLC*, 645 F.3d 114, 143 (2d Cir. 2011). "To comply with the specificity and clarity requirements" of Rule 65(d), "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) (quotation marks omitted); *see also* Fed. R. Civ. P. 65(d)(1). Shkreli contends that the injunction is vague because it lacks definitions for two of its key terms: "participating" in the pharmaceutical industry and "pharmaceutical industry." But the district court was not required to define unambiguous terms. Terms of an injunction are construed "according to the general interpretive principles of contract law." *Mastrovincenzo v. City of New York*, 435 F.3d 78, 103 (2d Cir. 2006). Therefore, undefined terms should be given their plain meaning and construed in light of normal usage. *See id.*

To be sure, "participating" is "taking part" in an undertaking.[3] In this case, the undertaking is the pharmaceutical industry. And the district court's

[3] Merriam-Webster Online Dictionary, https://perma.cc/W6FM-G5PC (last visited January 5, 2024).

injunction, read in context, is sufficiently clear to put Shkreli on notice as to what the "pharmaceutical industry" consists of. The injunction even defines Pharmaceutical Company, and Pharmaceutical Companies undoubtedly make up the pharmaceutical industry. Therefore, the plain language is hardly vague. It squarely forbids Shkreli from directly or indirectly *taking part* in any manner in the pharmaceutical industry, including taking any action to directly or indirectly influence or control the management or business of any Pharmaceutical Company.[4]

The language of the permanent injunction requires Shkreli to notify the Plaintiffs-Appellees if he wishes to accept "Qualified Employment" in order to provide an opportunity to object. *See* Special App'x at 166-67. As the district court made clear, if Shkreli feels that the Plaintiffs-Appellees have unreasonably objected to appropriate employment, he may apply for relief. *See Pasadena City Bd. of Educ. v. Spangler*, 427 U.S. 424, 437, 96 S. Ct. 2697, 49 L. Ed. 2d 599 (1976) ("[S]ound judicial discretion may call for the modification of the terms of an injunctive decree if the circumstances, whether of law or fact, obtaining at the time of

[4] The injunction contains a few exceptions: "Shkreli may retain an Ownership Interest in securities that are under the control of the receiver appointed in *Koestler v. Shkreli*, 1:16cv7175;" and may accept "Qualified Employment" "with a Pharmaceutical Company that is not *primarily* involved in the research, Development, manufacture, commercialization, or marketing of Drug Products or [active pharmaceutical ingredients] and" derives less than 10% of its gross revenues from such activity. Special App'x at 165-66 (emphasis added).

its issuance have changed, or new ones have since arisen.") (quoting *Sys. Fed'n No. 91, Ry. Emps.' Dep't v. Wright*, 364 U.S. 642, 647 (1961)).

* * *

We have carefully considered Shkreli's remaining arguments and find them to be without merit. For the foregoing reasons, we **AFFIRM** the judgment of the district court.

FOR THE COURT:

/s/ Catherine O'Hagan Wolfe
Catherine O'Hagan Wolfe, Clerk of Court

*Appendix B*

**UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF NEW YORK**

No. 20-cv-706

FEDERAL TRADE COMMISSION, et al.,
*Plaintiffs,*
v.
VYERA PHARMACEUTICALS, LLC, et al.,
*Defendants*.

Filed: Feb. 4, 2022

ORDER FOR PERMANENT INJUNCTION
AND EQUITABLE MONETARY RELIEF

Plaintiffs, the Federal Trade Commission ("FTC" or "Commission"), by its designated attorneys, and the states or commonwealths of New York, California, Illinois, North Carolina, Ohio, Pennsylvania, and Virginia (collectively "Plaintiff States"), by and through their Attorneys General, pursuant to Section 13(b) of the Federal Trade Commission Act, 15 U.S.C. § 53(b), Section 16 of the Clayton Act, 15 U.S.C § 26, Section 342 of the New York General Business Law, Section 63(12)

of the New York Executive Law, Sections 16700 *et seq*. and 17200 *et seq*. of the California Business and Professions Code, Section 7 of the Illinois Antitrust Act, 740 ILCS 10/1 *et seq.*, North Carolina Unfair or Deceptive Practices Act, N.C. Gen. Stat. §75-1 *et seq.*, Chapter 1331and Section 109.81 of the Ohio Revised Code, Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P. S. § 201-1 *et seq*. and Common Law Doctrine against Restraints of Trade proceeding under 71 P.S. §732-204 (c) and the Virginia Antitrust Act, Virginia Code § 59.1-9.1 *et seq.*, filed their Amended Complaint for Permanent Injunctive and Other Equitable Relief against Defendants Vyera Pharmaceuticals, LLC ("Vyera"), Phoenixus AG ("Phoenixus"), Martin Shkreli, and Kevin Mulleady to remedy and prevent their anticompetitive conduct and unfair methods of competition in or affecting commerce in violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, Section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a), and state law. This Order is entered against Defendant Martin Shkreli pursuant to the Opinion and Order issued by this Court on January 14, 2022, and today's Order and Opinion.

## I. DEFINITIONS

**IT IS ORDERED** that, as used in this Order, the following definitions shall apply:

A. "Defendant Shkreli" means Defendant Martin Shkreli, an individual defendant. Defendant

Shkreli is the founder of Phoenixus AG and Vyera Pharmaceuticals, LLC.

B. "Commission" means the United States Federal Trade Commission.

C. "Plaintiff States" mean the states or commonwealths of New York, California, Illinois, North Carolina, Ohio, Pennsylvania, and Virginia.

D. "Corporate Defendants" mean Defendants Vyera Pharmaceuticals LLC and Phoenixus AG.

E. "Designated State Representatives" mean the following named individuals or another representative identified by each respective Plaintiff State:

1. Elinor R. Hoffmann, Chief, Antitrust Bureau, Office of the New York State Attorney General, 28 Liberty Street, New York, NY 10005, elinor.hoffmann@ag.ny.gov;

2. Michael D. Battaglia, Deputy Attorney General, California Department of Justice, 455 Golden Gate Avenue, Suite 11000, San Francisco, CA 94102, michael.battaglia@doj.ca.gov;

3. Richard S. Schultz, Assistant Attorney General, Antitrust Bureau, Office of the Illinois Attorney General, 100 West Randolph Street, Chicago, IL 60601, richard.schultz@ilag.gov;

4. Jessica V. Sutton, Special Deputy Attorney General, Consumer Protection Division, North Carolina Department of Justice, 114 West Edenton Street, Raleigh, NC 27603, jsutton2@ncdoj.gov;

5. Beth A. Finnerty, Assistant Chief, Antitrust Section, Office of the Ohio Attorney General, 30 East Broad Street, 26th Floor, Columbus, OH 43215, Beth.Finnerty@ohioAGO.gov;

6. Joseph S. Betsko, Senior Deputy Attorney General, Pennsylvania Office of Attorney General, Strawberry Square, Harrisburg, PA 17120, jbetsko@attorneygeneral.gov; and

7. Tyler T. Henry, Assistant Attorney General, Office of the Attorney General of Virginia, 202 North Ninth Street, Richmond, VA 23219, thenry@oag.state.va.us.

F. "API" means any active pharmaceutical ingredient that is used in the manufacture of a Drug Product.

G. "Development" means all preclinical and clinical research and development activities related to a Drug Product, including discovery or identification of a new chemical entity, test method development, all studies for the safety and efficacy of a Drug Product, toxicology studies, bioequivalence and bioavailability studies, pharmaceutical formulation, process development, manufacturing scale-up, development-stage manufacturing, quality assurance/quality control development, stability testing, statistical analysis and report writing, for the purpose of obtaining any and all FDA Authorizations, licenses, approvals, or registrations necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, and sale of a Drug Product, and regulatory affairs related to the foregoing.

H. "Drug Product" means any product that is subject to an FDA Authorization, or any product that is regulated through an over-the-counter drug monograph.

I. "Entity" means any partnership, joint venture, firm, corporation, association, trust, unincorporated organization, or other business or government entity, and any subsidiaries, divisions, groups, or affiliates thereof.

J. "FDA" means the United States Food and Drug Administration.

K. "FDA Authorization" means any of the following applications:

1. An application filed or to be filed with the FDA pursuant to 21 C.F.R. Part 314 et seq., including "New Drug Application" ("NDA"), "Abbreviated New Drug Application" ("ANDA"), or "Supplemental New Drug Application" ("SNDA"), and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto;

2. An "Investigational New Drug Application" ("IND") filed or to be filed with the FDA pursuant to 21 C.F.R. Part 312, and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto; or

3. A Biologic License Application ("BLA") filed or to be filed with the FDA pursuant to 21 C.F.R. 601.2, et seq., and Section 351 of the Public Health Service Act, and any NDA deemed to be a BLA by the FDA, and all supplements, amendments, revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto.

L. "Ownership Interest" means any voting or non-voting stock, share capital, or equity in an Entity. Ownership Interest shall not include any unexercised options or other unexercised instruments that are convertible into any voting or non-voting stock.

M. "Pharmaceutical Company" means any Entity engaged in the research, Development, manufacture, commercialization, or marketing of any Drug Product or API.

N. "Qualified Employment" means an employment or a consulting engagement that:

1. is with a Pharmaceutical Company that is not primarily involved in the research, Development, manufacture, commercialization, or marketing of Drug Products or APIs and whose gross revenues from this activity accounts for less than 10% of the total gross revenues of the Pharmaceutical Company, and

2. does not violate Paragraph II.A of this Order.

## II. PERMANENT INJUNCTION

**IT IS FURTHER ORDERED** that Defendant Shkreli is hereby banned and enjoined for life from directly or indirectly participating in any manner in the pharmaceutical industry, including by:

A. Participating in or directing the research, Development, manufacture, commercialization, distribution, marketing, importation, or sale of a Drug Product or API, whether through compensated or uncompensated employment, consulting, advising, board membership, or otherwise;

B. Participating in the formulation, determination, or direction of any business decisions of any Pharmaceutical Company;

C. Acquiring or holding an Ownership Interest in a Pharmaceutical Company (other than indirectly through a mutual fund, exchange-traded fund, or other diversified, investment vehicle that is not specifically focused on Pharmaceutical Companies),

*Provided, however*, Defendant Shkreli may retain an Ownership Interest in securities that are under the control of the receiver appointed in *Koestler v. Shkreli*, 1:16cv7175 (S.D.N.Y.) until the earlier of (a) the sale of the securities by the receiver or (b) 180 days after the receiver returns the securities to Defendant Shkreli so long as Defendant Shkreli does not exercise any rights as owner of the securities, including voting rights, while the securities are under the control of the receiver or under the control of Defendant Shkreli;

D. Taking any action to directly or indirectly influence or control the management or business of any Pharmaceutical Company; Shkreli's public statements about a Pharmaceutical Company will be deemed an action taken to influence or control the management or business of any Pharmaceutical Company if Shkreli intended the statement to have that effect or if a reasonable person would conclude that the statement has that effect;

E. Serving on, nominating, or otherwise seeking or obtaining representation on the board of directors of a Pharmaceutical Company; or

F. Obtaining, holding, or exercising any voting or other shareholder rights in a Pharmaceutical Company, including rights assigned to Defendant Shkreli by an Entity or individual, including rights assigned in connection with Shkreli's transfer of Ownership Interest in a Pharmaceutical Company to the Entity or individual.

G. Defendant Shkreli may submit a notice of his intent to accept Qualified Employment ("Notice") to the Commission and each of the Designated State Representatives by submitting the Notice electronically to the Secretary of the Commission at ElectronicFilings@ftc.gov, the Compliance Division of the Commission at bccompliance@ftc.gov, and the Designated State Representatives at the email addresses provided in Paragraph I.E of the Order. The Notice must include a written offer of Qualified Employment, and a verified statement describing the scope and nature of the Qualified Employment and the date on which Defendant Shkreli seeks to accept such Qualified

Employment. Any Plaintiff that receives a Notice complying with the requirements of this Paragraph II.G and does not, within 20 working days after receiving the Notice, inform Defendant Shkreli in writing that it objects to Defendant Shkreli accepting the Qualified Employment because such Qualified Employment involves participation in the pharmaceutical industry, is barred from filing an action for contempt against Defendant Shkreli on the basis that the Qualified Employment violates Paragraph II.B or Paragraph II.D of this Order.

## III. MONETARY JUDGMENT

**IT IS FURTHER ORDERED** that:

A. Judgment in the amount of $64.6 million is entered in favor of Plaintiff States against Defendant Shkreli, provided that up to $40 million of the judgment is subject to a setoff equal to the equitable monetary relief paid by the Corporate Defendants to the Plaintiff States on or before December 6, 2031 pursuant to the Stipulated Order for Permanent Injunction and Equitable Monetary Relief entered in this matter on December 7, 2021.

B. Defendant Shkreli is ordered to pay to the Plaintiff States $64.6 million within 30 days of entry of this Order by electronic fund transfer in accordance with the instructions provided by the Plaintiff States, provided that this payment shall be reduced by an amount equal to the equitable monetary relief already paid by Corporate Defendants to the Plaintiff States.

C. Except as required by Paragraph III.D below, Plaintiff States shall deposit the monetary judgment paid by Defendant Shkreli into a fund administered by Plaintiff New York or its designee ("Equitable Relief Fund"). The Equitable Relief Fund shall be used for equitable relief, including consumer redress and other equitable relief Plaintiff States determine to be reasonably related to Defendant Shkreli's violative practices and injury, any attendant expenses for the administration and distribution of such funds by the Plaintiff States, and repayment of out-of-pocket expenses incurred by the Plaintiff States in this litigation. Any money remaining in the Equitable Relief Fund after such distributions shall be deposited by the Plaintiff States as disgorgement to be used consistently with their respective state laws, including the funding of future antitrust enforcement. Any interest earned on amounts deposited into the Equitable Relief Fund will remain in, and become a part of, that fund.

D. All payments received from Defendant Shkreli that exceed $24.6 million shall be held in a separate escrow account administered by Plaintiff New York. Plaintiff New York shall refund to Defendant Shkreli monies from the escrow account sufficient to offset the amount of equitable monetary relief paid by the Corporate Defendants in this matter. On December 6, 2022 and annually thereafter until December 5, 2031, Plaintiff New York shall refund to Defendant Shkreli monies from the escrow account equal to the amount of equitable monetary relief paid by the Corporate Defendants to the Plaintiff States during the preceding year, less any attendant expenses for the administration and

distribution of such funds and repayment of out-of-pocket expenses. All monies remaining in the escrow account on December 7, 2031 shall be deposited into the Equitable Relief Fund.

E. Defendant Shkreli relinquishes dominion and all legal and equitable right, title, and interest in all assets transferred pursuant to this Order and may not seek the return of any assets except as explicitly permitted in Paragraph III.D of this Order. For avoidance of doubt, nothing in this Order shall interfere with any right to appeal from or to move to stay the Court's Order that may otherwise exist.

F. Defendant Shkreli has no right to challenge any actions that Plaintiff States, or their representatives, may take pursuant to this Equitable Monetary Relief Section of the Order.

## IV. COMPLIANCE REPORTING REQUIREMENTS

**IT IS FURTHER ORDERED** that:

A. Defendant Shkreli shall submit to the Commission and to each of the Designated State Representatives verified written reports ("Compliance Reports") setting forth in detail the manner and form in which he intends to comply, has complied, and is complying with this Order, in accordance with the following:

1. Within 60 days of the entry of this Order;

2. One year after the entry of this Order, and annually thereafter until the later of 10 years or payment of the monetary judgment ordered herein; and

3. At such other times as the Commission or a Plaintiff State may require.

B. Each Compliance Report shall contain:

1. A verified statement by Defendant Shkreli that he is not directly or indirectly participating in any manner in the pharmaceutical industry, except as permitted by Paragraph II.G of this Order;

2. Each Qualified Employment engagement that Defendant Shkreli has accepted and the following information about the Qualified Employment:

a) the Entity or individual for whom Defendant Shkreli performed or is performing the Qualified Employment and the name, position, phone number and email address for Defendant Shkreli's primary contact with the Entity or individual,

b) the starting and ending date of the Qualified Employment,

c) a description of the Qualified Employment, and

d) a verified statement that Defendant Shkreli is not and has not violated Paragraphs II.A and II.C in performing the Qualified Employment; and

3. If Defendant Shkreli has not fully satisfied the monetary judgment ordered by this Court, a copy of Defendant Shkreli's most recent tax return, a full and complete accounting of all Defendant Shkreli's assets, and a full and

complete accounting of all assets that Shkreli has transferred, sold or otherwise disposed of during the 12 month period preceding the submission of the Compliance Report.

C. Defendant Shkreli shall submit each Compliance Report to the Commission and each of the Designated State Representatives by submitting the report electronically to the Secretary of the Commission at ElectronicFilings@ftc.gov, the Compliance Division of the Commission at bccompliance@ftc.gov, and the Designated State Representatives at the email addresses provided in Paragraph I.E of the Order.

## V. ACCESS TO INFORMATION

**IT IS FURTHER ORDERED** that, for purposes of determining or securing compliance with this Order, including payment of the monetary judgment, upon 5 days' notice, Defendant Shkreli shall:

A. Make himself available for interview, in the presence of counsel, by a duly authorized representative of the Commission or a Designated State Representative; and

B. Provide to any duly authorized representative of the Commission or a Designated State Representative, during business hours and in the presence of counsel, access to inspect and copy all books, ledgers, accounts, correspondence, memoranda, tax returns, financial statements and all other records and documents in Defendant Shkreli's possession or control that relate to compliance with this Order.

## VI. ATTORNEYS' FEES AND COSTS

**IT IS FURTHER ORDERED** that Plaintiff States may seek attorneys' fees, costs, and related nontaxable expenses in this matter. Any application for attorneys' fees, costs, and related nontaxable expenses must be filed by motion within 30 days of the entry of this Order.

## VII. RETENTION OF JURISDICTION

**IT IS FURTHER ORDERED** that this Court shall retain jurisdiction of this matter for the purposes of construction, modification, and enforcement of this Order.

SO ORDERED THIS 4th day of February, 2022.

/s/ Denise Cote
The Honorable Denise Cote

*Appendix C*

**UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF NEW YORK**

No. 20-cv-706

FEDERAL TRADE COMMISSION, et al.,

*Plaintiffs,*

v.

MARTIN SHKRELI,

*Defendant*.

Filed: Jan. 14, 2022

OPINION AND ORDER

[TABLES INTENTIONALLY OMITTED]

DENISE COTE, *District Judge*:

In 2015, Martin Shkreli raised the price of the life-saving pharmaceutical Daraprim by 4,000% and initiated a scheme to block the entry of generic drug competition so that he could reap the profits from Daraprim sales for as long as possible. Through his tight control of the distribution of Daraprim, Shkreli prevented generic drug companies from getting access to the quantity of Daraprim they needed to conduct

testing demanded by the Food and Drug Administration ("FDA"). Through exclusive supply agreements, Shkreli also blocked off access to the two most important manufacturers of the active pharmaceutical ingredient ("API") for Daraprim. Through these strategies, Shkreli delayed the entry of generic competition for at least eighteen months. Shkreli and his companies profited over $64 million from this scheme.

The Federal Trade Commission ("FTC") and seven States[1] (the "States"; collectively, "Plaintiffs") filed this action in 2020. At a bench trial held over seven days between December 14 and 22, 2021, the Plaintiffs carried their burden to establish that Shkreli violated federal and state laws that ban anticompetitive conduct. Based on the trial evidence, Shkreli will be barred for life from participating in the pharmaceutical industry and is ordered to disgorge $64.6 million in net profits from his wrongdoing. This Opinion contains the Findings of Fact and Conclusions of Law from the trial.

## Procedural History

The Plaintiffs filed this action on January 27, 2020 and brought claims for violations of §§ 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1-2, § 5(a) of the FTC Act, 15 U.S.C. § 45(a), and various state statutes.[2] They

[1] The seven state plaintiffs are the States of New York, California, Ohio, Illinois, and North Carolina, and the Commonwealths of Pennsylvania and Virginia.

[2] The States pursuing statutory claims sue under the Sherman Act and under the California Cartwright Act, Cal. Bus. & Prof. Code § 16700, and California Unfair Competition Law, Cal.

brought these claims against Shkreli, Vyera Pharmaceuticals, LLC and its parent company Phoenixus AG ("Phoenixus"; together, "Vyera"), and Kevin Mulleady ("Mulleady"), former Vyera CEO and member of the Phoenixus Board of Directors (collectively, "Defendants"). The Defendants' motion to dismiss was largely denied through an Opinion of August 18, 2020.[3] *See Fed. Trade Comm'n v. Vyera Pharms., LLC*, 479 F. Supp. 3d 31 (S.D.N.Y. 2020).

Two decisions in 2021 addressed the Plaintiffs' requests for equitable monetary relief.[4] A June 2, 2021 Order granted the FTC's motion for leave to withdraw its prayer for equitable monetary relief pursuant to the Supreme Court's decision in *AMG Cap. Mgmt., LLC v. Fed. Trade Comm'n*, 141 S. Ct. 1341, 1352, 209 L. Ed. 2d 361 (2021). An Opinion of September 24 denied the Defendants' motion for partial summary judgment on the nationwide scope of the States' prayer for equitable monetary relief, and granted the Plaintiffs' cross-motion for summary judgment on the same issue.

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Bus. & Prof. Code § 17200; Illinois Antitrust Act, Ill. Comp. Stat. 10/3(3); the New York Donnelly Act, N.Y. Gen. Bus. Law § 340 *et seq.*, and New York Executive Law, N.Y. Exec. Law § 63(12); North Carolina Unfair or Deceptive Practices Act, N.C. Gen. Stat. § 75-1 *et seq.*; Ohio Valentine Act, Ohio Rev. Code Ann. § 1331; and Virginia Antitrust Act, Va. Code Ann. § 59.1 *et seq.* Pennsylvania sues under the Sherman Act and its common law doctrine against restraint of trade.

[3] Pennsylvania's statutory claim under the Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P.S. §§201-1 *et seq.*, was dismissed.

[4] On March 30, 2021, the Plaintiffs waived their right to money damages and therefore their right to a jury trial.

*See Fed. Trade Comm'n v. Vyera Pharms., LLC*, No. 20CV00706 (DLC), 2021 U.S. Dist. LEXIS 183303, 2021 WL 4392481, at *5 (S.D.N.Y. Sept. 24, 2021).

Only Shkreli proceeded to trial; on the eve of trial Vyera and Mulleady settled with both the FTC and the States. Before those settlements were reached, the parties' submitted their Joint Pretrial Order, proposed findings of fact and conclusions of law, motions *in limine*, and pretrial memoranda on October 20. Following rulings on redactions, these submissions were filed on November 29.

As is customary for this Court's non-jury proceedings, and with consent of the parties, the direct testimony of those witnesses under a party's control were submitted with the Joint Pretrial Order.[5] The parties also served copies of all exhibits and deposition testimony that they intended to offer as evidence in chief at trial.[6]

Prior to trial, the motions *in limine* were decided. On November 5, Shkreli's motion *in limine* to preclude

[5] These affidavits were ordered to be filed on the day on which the witness testified or was deemed to have testified at trial.

[6] The Court's procedures for non-jury trials were discussed in detail at a conference of December 10, 2021. As the parties were informed, the Court prepared a draft opinion in advance of the bench trial based on the witness affidavits and other documents submitted with the Pretrial Order and the arguments of counsel in their trial memoranda. At trial, the affiants swore to the truth of the contents of their affidavits and were tendered for cross and redirect examination, and the other trial evidence was formally received.

evidence relating to Retrophin, Inc. ("Retrophin"), a pharmaceutical company that Shkreli and Mulleady founded in 2011, was denied. *Id.*, 2021 U.S. Dist. LEXIS 214751, 2021 WL 5154119 (S.D.N.Y. Nov. 5, 2021). On November 10, motions by Shkreli and Mulleady to exclude the testimony of current and former employees of Vyera were addressed in an Opinion that set forth the standards that would govern the admissibility of such testimony. *Id.*, 2021 U.S. Dist. LEXIS 218530, 2021 WL 5236333 (S.D.N.Y. Nov. 10, 2021). An Opinion of November 12 denied the Defendants' motion to exclude certain testimony of Plaintiffs' expert Professor C. Scott Hemphill ("Hemphill"), an economist and Professor of Law at New York University, and granted the Plaintiffs' motion to exclude certain opinions offered by Dr. Anupam B. Jena ("Dr. Jena"), a physician, economist, Professor of Health Care Policy and Medicine at Harvard Medical School, and Internal Medicine Specialist in the Department of Medicine at Massachusetts General Hospital. *Id.*, 2021 U.S. Dist. LEXIS 219493, 2021 WL 5279465 (S.D.N.Y. Nov. 12, 2021). Opinions of November 15 granted the Plaintiffs' motion to exclude designated deposition testimony of Rule 30(b)(6), Fed. R. Civ. P., deponents that were not based on personal knowledge, *id.*, 2021 U.S. Dist. LEXIS 219964, 2021 WL 5300019 (S.D.N.Y. Nov. 15, 2021), and excluded testimony from Defendants' expert Justin McLean, *id.*, 2021 U.S. Dist. LEXIS 221384, 2021 WL 5300031 (S.D.N.Y. Nov. 15, 2021). An Opinion of November 16 struck most of the testimony offered by Defendants' expert Sheldon Bradshaw. *Id.*, 2021 U.S. Dist. LEXIS 222166, 2021 WL 5336949 (S.D.N.Y. Nov. 16,

2021).[7] On November 18, the Plaintiffs' motion to exclude portions of testimony by Defendants' expert John S. Russell ("Russell"), Managing Partner for ASDO Consulting Group, a pharmaceutical consulting company, was largely granted. *Id.*, 2021 U.S. Dist. LEXIS 224146, 2021 WL 5403749 (S.D.N.Y. Nov. 18, 2021).

At trial, eleven fact witnesses and four expert witnesses called by the Plaintiffs testified. The Plaintiffs' fact witnesses included one current Vyera executive—Nicholas Pelliccione ("Pelliccione"), Vyera's Senior Vice President of Research and Development ("R&D")—and four former executives and employees: Howard Dorfman, Vyera's General Counsel between December 2014 and August 2015; Christina Ghorban, Vyera's Head of Marketing and Business Analytics between April 2015 and October 2016; Dr. Eliseo Salinas ("Dr. Salinas"), Vyera's President of R&D between June 2015 and April 2017 and interim CEO between April and July 2017; and Mulleady, who worked at Vyera from October 2014 to June 2016, was appointed to Vyera's Board in June 2017, served as Executive Director and then CEO between October 2017 and February 2019, and was chairman of the Phoenixus Board of Directors until December 2020. The Plaintiffs called six additional fact witnesses: Frank DellaFera ("DellaFera"), CEO and founder of Fera Pharmaceuticals, Inc. ("Fera"); Susan McDougal ("McDougal"), Fera's Vice President; Abhishek

[7] Thereafter, Shkreli withdrew the testimony of Bradshaw and the Plaintiffs withdrew the testimony of their rebuttal expert, Mansoor A. Khan.

Mukhopadhyay ("Mukhopadhyay"), Head of Business Development at Dr. Reddy's Laboratories, Inc. ("Dr. Reddy's"); Nilesh Patel ("Patel"), co-founder and Compliance and Regulatory Officer of InvaTech Pharmaceuticals LLC ("InvaTech"); Manish Shah ("Shah"), co-founder and President of Cerovene Health, Inc. ("Cerovene"); and Satya Valiveti ("Valiveti"), co-founder and co-owner of Reliant Specialty LLC ("Reliant").

The Plaintiffs' expert witnesses were James R. Bruno, managing director of Chemical and Pharmaceuticals Solutions, Inc., a pharmaceutical consulting company; Edward V. Conroy, President and Chief Operating Officer of Ed Conroy & Associates, a pharmaceutical consulting firm; Dr. W. David Hardy, a physician and Adjunct Clinical Professor of Medicine in the Division of Infectious Diseases at the Keck School of Medicine at the University of Southern California and former Chair of the Board of Directors of the HIV Medicine Association ("HIVMA") of the Infectious Diseases Society of America ("IDSA"); and Hemphill.[8]

The Plaintiffs also intended to call at trial three additional fact witnesses to testify: Shkreli; Eve Costopoulos ("Costopoulos"), Vyera's former General Counsel from November 2015 to July 2017; and Anne Kirby ("Kirby"), a member of Vyera's sales team from June 2015 to late 2018, CEO from late 2018 to early 2019, and current Executive Vice President of

[8] The Plaintiffs filed affidavits constituting the direct testimony of five of their fact witnesses and all of their experts. The five fact witnesses were DellaFera, McDougal, Mukhopadhyay, Patel, and Shah.

Commercial and Operations. Shkreli is incarcerated in federal prison, serving a sentence on an unrelated federal conviction.[9] He opted not to attend the trial. The parties agreed that the affidavit that he had prepared to present as his direct testimony would be received at the trial and that his cross-examination and redirect examination would be conducted through the designation of his pretrial deposition testimony.

Neither Kirby nor Costopoulos appeared at trial. The parties agreed that Kirby's affidavit would be received as her direct testimony and that cross-examination and redirect would be conducted by deposition designation. The parties also agreed to designate portions of Costopoulos' deposition to serve as her trial testimony.

At the time the Pretrial Order was submitted, Shkreli intended to call eleven of the Plaintiffs' witnesses in his own case in addition to testifying on his own behalf: Mulleady, Pelliccione, Kirby, Costopoulos, Dr. Salinas, DellaFera, McDougal, Mukhopadhyay, Patel, Shah, and Valiveti.[10] Affidavits constituting the

[9] Shkreli was arrested in December 17, 2015 on federal criminal charges. A jury convicted him on August 4, 2017. He was sentenced on March 8, 2018, principally to a term of imprisonment of eighty-four months (seven years). Shkreli was remanded to federal custody on September 13, 2017. He is currently scheduled to be released on October 11, 2023, or one year earlier pending successful completion of an early release program.

[10] The parties had agreed that each witness would take the stand a single time at trial. To the extent Shkreli had also intended to call the witness on his own case, his "cross-examination" of the witness was not restricted by the scope of the direct testimony.

direct testimony of defense witnesses Shkreli, Mulleady, Pelliccione, and Kirby were received into evidence. Shkreli also called two expert witnesses: Russell and Dr. Jena.

The parties offered excerpts from the depositions of the following additional witnesses associated with Vyera: Jonathan Haas, Vyera's Former Director of Patient Access; Christopher Lau ("Lau"), Vyera's Director of Analytics and Business Intelligence; Akeel Mithani ("Mithani"), Senior Vice President of Business Development of Vyera and former member of the Phoenixus Board of Directors; Averill Powers, CEO and former Chairman of the Phoenixus Board, and Vyera's General Counsel; Marco Polizzi, CEO of Vyera subsidiary Oakrum Pharma, LLC; Nancy Retzlaff ("Retzlaff"), Vyera's former Chief Commercial Officer; Michael Smith ("Smith"), co-founder of Vyera and former member of the Business Development team; and Ron Tilles ("Tilles"), Vyera's former CEO and Chairman of the Phoenixus Board. They also offered excerpts from the depositions of seventeen additional fact witnesses: Nilaben Desai, former manager at ASD Healthcare ("ASD"); Michael Hatch, Head of Global Project Management for R&D for Mylan N.V. ("Mylan") affiliate Viatris Inc.; Courtney Johnson, former Director of Global Sourcing & Business Development for Cardinal Specialty ("Cardinal"); Hamilton Lenox, Senior Vice President of Business Development at LGM Pharma; Amanda Lopez, Clinical Trial Supervisor for Durbin USA; Jacob Mathew, Chairman of RL Fine Chem. Pvt. Ltd. ("RL Fine"); Ravi Patel, part-owner of Espee

Biopharma & Fine Chem; Donovan Quill, founder and CEO of Optime Care, Inc. ("Optime"); Paula Raese, Senior Director of API Sourcing for Mylan; A.R. Ramachandra, General Manager of Marketing and Sales at RL Fine; Dennis Saadeh, Chief of Formulation Strategy for Harrow Health, parent company of Imprimis; Dr. Lucas Schulz, Clinical Coordinator for Infectious Diseases in the Department of Pharmacy at the University of Wisconsin Health; Devang Shah, Director of Aadivignesh Chem.; Dr. Eric Sredzinski, formerly the head of clinical affairs and quality assurance for Avella; Dr. John Vande Waa, Division Director of the Division of Infectious Diseases for the University of South Alabama Health; and Kevin Wessels, Senior Director of Trade Relations at Zinc Health Services, a subsidiary of CVS Health ("CVS").[11]

As noted, the bench trial was held from December 14 to December 22, 2021, and this Opinion presents the Court's findings of fact and conclusions of law. The findings of fact appear principally in the Background section, but also appear in the remaining sections of the Opinion.

[11] Excerpts of the deposition of a witness from an API manufacturer, the name of which has been sealed, were also received into evidence.

## Background

### I. FDA Drug Approval Process for Generic Drugs

Shkreli's scheme unfolded against the backdrop of the U.S. regulatory process for the approval and sale of pharmaceutical drugs. The FDA is the federal agency that approves the sale of branded and generic drugs in the United States. The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, commonly known as the Hatch-Waxman Act, allows a generic manufacturer of an already approved brand-name drug to obtain expedited approval from the FDA to market the generic equivalent by filing an Abbreviated New Drug Application, or ANDA. *See FTC v. Actavis, Inc.*, 570 U.S. 136, 142, 133 S. Ct. 2223, 186 L. Ed. 2d 343 (2013) ("*Actavis*"). The ANDA process is designed to help expedite market introduction of low-cost generic drugs in order to further competition. *Id.*

Any pharmaceutical company applying for FDA approval of a generic competitor to a branded drug must obtain the API used in the branded drug—that is, the drug's critical ingredient that provides its therapeutic effect—from an approved supplier. The API to be used in the generic drug is evaluated for impurities and stability. 21 C.F.R. §§ 211.165, 211.170.

An API supplier's manufacturing process must also comply with FDA standards known as current Good Manufacturing Practices ("cGMPs"). FDA regulations set minimum standards for the methods,

facilities, controls, and documentation for manufacturing, processing, and packing of the pharmaceutical, including its API.

A pharmaceutical company may demonstrate that the manufacturing process of the API used in its drug product complies with cGMPs either by supplying that information to the FDA in the ANDA itself or, more commonly, by referencing information filed by an API supplier with the FDA in a standalone drug master file ("DMF"). The FDA categorizes DMFs for APIs as Type II DMFs. To file a Type II DMF, an API supplier must pay a fee and submit enough materials, including confidential documents about the manufacturer's facilities, processing, packaging, and storing of human drug products, to permit the FDA to conduct a full scientific review for any ANDAs that reference the DMF. The FDA conducts a completeness assessment of an API supplier's newly-filed DMF at the time it is submitted, but does not fully review a DMF's documented manufacturing process for cGMPs compliance until the DMF is referenced in a new drug application ("NDA") or ANDA. 21 CFR § 314.420(a).

In order to obtain the API for a particular drug product a pharmaceutical company may invest in developing an API supplier's manufacturing processes, or it may shorten the process significantly by partnering with an API supplier that has already filed a DMF for the API. Because developing and documenting a cGMPs-compliant API manufacturing process from scratch is time-consuming and expensive—it can take twelve to eighteen months or more and may cost over

$1 million—generic pharmaceutical companies prefer to use a supplier that already has an FDA-approved DMF for the API.

Therefore, any generic company that seeks to launch a product as fast as possible generally attempts to partner with a DMF-holding supplier whose API is already in use in another FDA-approved product. A less desirable option is partnering with an API manufacturer that currently produces the API but does not have a DMF filed in the U.S. The least attractive option is to develop a cGMPs-compliant manufacturing process from scratch, which is costly and can take years.

Proof of therapeutic equivalency is also central to the ANDA process. A generic manufacturer applying for approval of its drug must demonstrate that the generic drug "has the same active ingredients as, and is biologically equivalent to, the already-approved brand-name drug." *Actavis*, 570 U.S. at 142 (citation omitted); see also 21 C.F.R. §§ 314.92(a)(1), 314.3(b).

Bioequivalence ("BE") testing compares the generic product to samples of the branded drug, commonly referred to as the reference listed drug ("RLD"). BE studies are used to evaluate whether there is any significant difference in the rate and extent to which the product's active ingredient becomes available in the body.[12] 21 C.F.R. § 320.33. BE testing demonstrates

[12] FDA regulations define bioequivalence as "the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug

to the FDA that the proposed generic drug product is safe, effective, and comparable to the RLD.

In a BE study, human subjects are given dosages of the generic drug and the RLD. These studies, which take two to six weeks to complete, are typically run by a third-party clinical organization concurrently with the FDA-required shelf stability testing for the first batch of the finished generic product. The stability testing can take three to six months.

In order to conduct BE testing, a generic drug applicant must procure sufficient quantities of the brand-name drug or RLD and retain those quantities before and after approval of an ANDA. FDA regulations require applicants to retain at least five times the amount of the RLD needed to perform BE testing. 21 C.F.R. § 320.38(c).

The RLD used in the testing must come from the same manufacturing lot and be unexpired. Obtaining sufficient quantities of RLD usually takes only a few days or, at most, a month.

Consistent with its policy of encouraging price competition for prescription pharmaceuticals, the FDA expresses the view that "a path to securing samples of brand drugs for the purpose of generic drug development should always be available."[13] By utilizing an

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action when administered at the same molar dose under similar conditions in an appropriately designed study." 21 CFR §§320.1, 314.3(b).

[13] Statement from FDA Commissioner Scott Gottlieb, M.D., on New Agency Efforts to Shine Light on Situations Where Drug

RLD license permitting them to buy prescription drugs without a prescription, pharmaceutical companies often procure the RLD samples needed to develop generic drug products through drug wholesalers or specialty pharmacies.

If the FDA determines that a proposed generic drug is therapeutically equivalent to the brand-name drug listed in the FDA's "Orange Book,"[14] the agency assigns an "AB" rating to that drug. But if the FDA finds major deficiencies in an ANDA and the applicant does not address its inquiries during the review period, the FDA sends the applicant a complete response letter detailing the identified deficiencies.

To foster price competition among pharmaceuticals, the law provides various incentives to pharmaceutical companies. *See* Generic Drug User Fee Act, 21 U.S.C. § 356h. These include the FDA's prioritization of its review of the first generic entrant to file an ANDA. The first generic drug product to enter a market in competition against the brand name drug is

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Makers May Be Pursuing Gaming Tactics to Delay Generic Competition, FDA (May 17, 2018), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-agencyefforts-shine-light-situations-where-drug.

[14] The FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the Orange Book, "identifies drug products approved on the basis of safety and effectiveness by the [FDA] under the Federal Food, Drug, and Cosmetic Act." Orange Book Preface, FDA (January 21, 2021), https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface.

known in the pharmaceutical industry as the "first-to-market" generic.

As generic drugs typically enter a market at a discount, the entry of the first generic competitor generally results in price erosion of approximately 30% to 40% from the prevailing price of the brand-name drug. The brand name drug's sales volume also experiences a significant decline of approximately 60% to 70% when the first generic enters the market. Six months after generic entry, the brand name drug's sales will typically have fallen by 80%. The branded drug's sales volume and price usually continue to decline as additional generic products enter the market. The full decline in the price of the drug usually occurs after three or four generic drugs have entered the market.

## II. Distribution of Prescription Drugs in the U.S.

When introducing a branded drug or its generic equivalent into the U.S. market, the manufacturer can choose to distribute it with fewer or more restrictions. The poles of this spectrum are referred to in the pharmaceutical industry as open distribution, representing the least restrictive means, and specialty distribution, which can range from minor limitations to severe restrictions on how freely a drug is sold. Restrictions are set by the manufacturer in agreements with its distribution partners.

Seventy percent of prescription drugs sold in the U.S. is in open distribution. In an open system, the

manufacturer typically partners with a major distributor to deliver the product to licensed dispensaries such as retail pharmacies, hospitals, clinics, and nursing homes. Open distribution maximizes patient access to a given drug and is generally appropriate for pharmaceutical products that do not require special handling, do not present safety concerns, and are self-administered by the patient or are clinically simple to administer.

By contrast, approximately 30% of the volume of U.S. prescription drugs is sold through some degree of specialty distribution. Also known as closed distribution, a drug that is circulated in a specialty distribution system is referred to in the pharmaceutical industry as being "in specialty" or as having a "class of trade" restriction. Drugs in specialty distribution tend to be novel drugs, have special shipping, handling, and storage requirements (such as cold-chain storage), or require ongoing clinical monitoring or skilled patient administration (such as injections). Highly closed distribution systems usually lower patient access and reduce sales.

Safety concerns may also mark a particular drug as a prime candidate for specialty distribution. Specialty distribution is more frequent, for instance, when the FDA requires a "black box" warning on the label of drugs that present safety risks or when it has put the drug in a Risk Evaluation and Mitigation Strategies ("REMS") program. REMS is a drug safety program that the FDA may require for certain medications that present serious safety risks.

The percentage of prescription drugs on the U.S. market that are sold in specialty distribution has risen in recent years. This trend, however, is largely driven by the advent of new, complex therapies for illnesses such as cystic fibrosis and cancer. Drug manufacturers do not commonly put oral tablets that do not require complex patient administration in specialty distribution, as closed distribution reduces sales.

## II. Retrophin

Shkreli road-tested the scheme at issue here at another company that he founded, Retrophin. Shkreli is thirty-eight years old. He graduated from Baruch College in 2004 with a degree in Business Administration. After graduation, he worked as a healthcare and technology analyst for a hedge fund until he left in 2006 to found his own investment firm. In 2009, Shkreli founded the hedge fund MSMB Capital Management ("MSMB").

While still working at MSMB, in 2011 Shkreli cofounded Retrophin, a publicly-traded biopharmaceutical company, with Mulleady. Mulleady is now thirty-nine years old. He graduated from Rutgers University in 2005, having majored in mechanical and aerospace engineering. He worked in real estate and finance following graduation. While working at Morgan Stanley Smith Barney (now Morgan Stanley Wealth), he met Shkreli in 2011.

Shkreli hired Mulleady as Chief Operating Officer at MSMB, where Mulleady worked from 2011 to 2013.

Shkreli served as Retrophin's CEO from December 2012 to September 2014, and designed its business model. Retrophin acquired brand-name drugs approved to treat so-called orphan diseases[15] that were the sole source in the U.S. for that treatment, closed the drugs' distribution to prevent generic drug manufacturers from acquiring the RLD, and substantially increased the drugs' prices. This was a pattern that Shkreli would repeat at Vyera.

At Retrophin, Shkreli closed the distribution systems of two branded drugs, Chenodal and Thiola, to cut off access to the RLD needed for BE testing and impede generic drug competition. Shkreli described his strategy and its purpose frankly in calls with Retrophin investors. On one such call, he explained that "we do not sell Retrophin products to generic companies" and "[t]he whole model that generics rely upon is turned upside down with specialty pharmacy distribution." He explained in another call that a closed distribution system did not allow generic drug companies to access the branded product "to conduct bioequivalence studies." Shkreli boasted in an email to a potential investor that the specialty distribution method Retrophin had adopted "reliably eliminated" generic competition "by refusing to supply the product to generic companies for [BE] studies required for ANDAs."

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[15] An orphan disease is a rare condition (defined in the United States as affecting fewer than 200,000 people) or a common condition in undeveloped countries that is rare in developed countries.

As noted, Shkreli put his strategy into practice with two drugs. Retrophin acquired Chenodal, a drug approved for the treatment of cerebrotendinous xanthomatosis ("CTX"), and restricted distribution through distributor agreements.[16] Retrophin then raised Chenodal's price from $100,000 to $515,000 per patient per year. Retrophin also licensed Thiola, a drug approved for the prevention of cystine stone formation in patients with cystinuria,[17] restricted its distribution, and raised its price from $4,000 to $80,000 per patient per year.

**III. Vyera is Founded.**

Only one month after departing Retrophin, in October 2014 Shkreli founded Turing Pharmaceuticals LLC ("Turing"), a privately-held pharmaceutical company with its principal place of business in New York. Shkreli also founded Turing Pharmaceuticals AG ("Turing AG"), Turing's parent company, based in Switzerland. Turing's name was later changed to Vyera, and Turing AG became Phoenixus.

From day one, Shkreli focused his new venture on acquiring sole-source drugs that were the gold standard treatment option for life-threatening diseases with a small patient population and inferior alternative

[16] CTX is a life-threatening cholate excretion disorder. The patient population for CTX is very small, with roughly 2,000 patients in the United States.

[17] Cystinuria is a rare kidney stone disorder, also with a very small patient population.

treatments, with the intent to raise their prices, block generic competition, and reap extraordinary profits. Shkreli highlighted to early Turing investors his "track record of successful transactions" at Retrophin and explained that "[e]xclusivity (closed distribution) creates a barrier and pricing power."

Shkreli remained CEO of Turing until his arrest on December 18, 2015 for securities fraud related to his prior business ventures, including at Retrophin. He served as chairman of the Board of Turing AG until January 20, 2016, resigning from the Board entirely on February 10, 2016. After Shkreli departed, Turing was renamed Vyera and Turing AG was renamed Phoenixus in order to distance the companies from Shkreli in the public mind. Shkreli remained the largest shareholder, however, and continued to control them and direct their strategy. At no time after Shkreli left the Board did Vyera deviate from the strategy Shkreli had designed and initiated.

Shkreli brought with him to Vyera several Retrophin executives, including Mulleady, Tilles, Smith, Lau, Edwin Urrutia (a Vyera co-founder and Chief Financial Officer between October 2014 and June 2016), and Patrick Crutcher (a Vyera co-founder and Senior Vice President and Head of Business Development between October 2014 and May 2017). Mulleady in particular was one of Shkreli's closest allies at Vyera before earning Shkreli's ire in 2020. Mulleady held the title of Phoenixus' Managing Director from October 27, 2014 until Vyera terminated his employment on June 3, 2016. Mulleady returned to Vyera a year later when,

on June 21, 2017, he was elected to Phoenixus' Board of Directors in a Shkreli power play.

### A. Vyera Acquires Daraprim.

At Shkreli's direction, Vyera's sales and business development teams evaluated market opportunities for Vyera to acquire sole-source drugs. By the Spring of 2015, Vyera focused on Daraprim as a prime candidate. Smith, Vyera's Senior Director of Business Development, instructed the sales team in April 2015 to investigate acquiring both Daraprim and another sole-source drug, sulfadiazine (often used in combination with Daraprim), because it would be "the classic closed distribution play." Smith testified that Daraprim provided an opportunity to build a foothold "where no one is paying attention to it." Daraprim was first approved by the FDA in 1953, and approved by the FDA in 1958 for the treatment of toxoplasmosis specifically.

Toxoplasmosis is a parasitic infection that can cause severe disease and death. The parasite is present in approximately 10% of the population, but is usually dormant. An opportunistic infection, toxoplasmosis principally impacts immunosuppressed and immunocompromised individuals such as patients who are HIV positive or recipients of organ transplants. Toxoplasmosis can cause disease in many parts of the body, but the most common manifestations are infections of the brain (toxoplasma encephalitis), eye (ocular toxoplasmosis), and in utero.

Toxoplasma encephalitis is the most common and acute presentation of the disease among immunosuppressed patients. Toxoplasmosis fatalities have dropped significantly since the launch of antiretroviral therapies in 1996, which significantly limited opportunities for a toxoplasmosis infection to become acute in HIV-positive patients. If an infection becomes active and advanced, a patient presenting with toxoplasma encephalitis could die within twelve to twenty-four hours unless treated. There is also a risk of severe brain damage in those who survive. As a result, physicians must have an effective treatment on hand to halt the progress of an active infection as quickly as possible.

The Opportunistic Infections Guidelines (the "Guidelines"), an authoritative publication on which physicians depend,[18] gives its highest recommendation to a pyrimethamine-based regimen for the treatment of acute toxoplasmosis. Pyrimethamine is the API of Daraprim.

The Guidelines rank recommended treatment options for certain diseases with a letter and a numeral. The letter grade signifies the strength of the recommendation and the Roman numerals indicate the

[18] The Guidelines are published by the Centers for Disease Control and Prevention, the National Institutes of Health, and HIVMA. The Guidelines reflect the medical consensus for the benefit of "clinicians, health care providers, patients with HIV, and policymakers in the United States." They are updated and reviewed regularly. The section addressed to the treatment of toxoplasmosis was last updated on July 25, 2017, and last reviewed on June 26, 2019.

quality of the evidence supporting the recommendation. Accordingly, an A-I grade is a recommendation based on the strongest, highest-quality evidence derived from randomized control clinical trials, or, if randomized control trials have not been conducted, methodologically sound cohort studies or meta-analyses. Lower grades are given to treatment options that have been shown to be effective but are not preferred, or are based on less methodologically reliable studies.

Under the Guidelines, pyrimethamine plus sulfadiazine and leucovorin[19] is given the strongest possible recommendation for treating active toxoplasma encephalitis: A-I. The recommended dosage of Daraprim, available only as a 25 milligram tablet, is an initial dose of 200 milligrams (eight pills) followed by 50 to 75 milligrams (two to three pills) daily for at least six weeks. For patients who cannot tolerate a sulfa drug, the recommended treatment is pyrimethamine plus clindamycin.

The pyrimethamine-based regimen is preferred to alternative treatments because of its efficacy and safety, long history of successful clinical use, superior potency in comparison to other treatments, and diagnostic utility when a biopsy is not feasible. A significant decrease in the size, inflation, or number of lesions in the brain following a week or more of treatment confirms the diagnosis. Because a biopsy of the brain

[19] Leucovorin is administered to mitigate pyrimethamine's suppression of the bone marrow, which would decrease white and red blood cells if left untreated.

carries extreme risks, pyrimethamine's diagnostic utility is particularly important. Pyrimethamine remains the only drug approved by the FDA for the treatment of toxoplasmosis. And, until the entry of FDA-approved generic pyrimethamine in 2020, Daraprim was the only FDA-approved pyrimethamine product on the market.

Before Vyera acquired Daraprim, it commissioned a physician survey to determine whether doctors "would continue to prescribe Daraprim" following a price hike. In response to the survey, doctors indicated that they considered the drug to be the "backbone of therapy" for toxoplasmosis and were "at a loss to think of an appropriate alternative." Shkreli and others at Vyera recognized Daraprim as "the gold standard" therapy for toxoplasmosis, rendering Daraprim "essentially unsubstitutable."

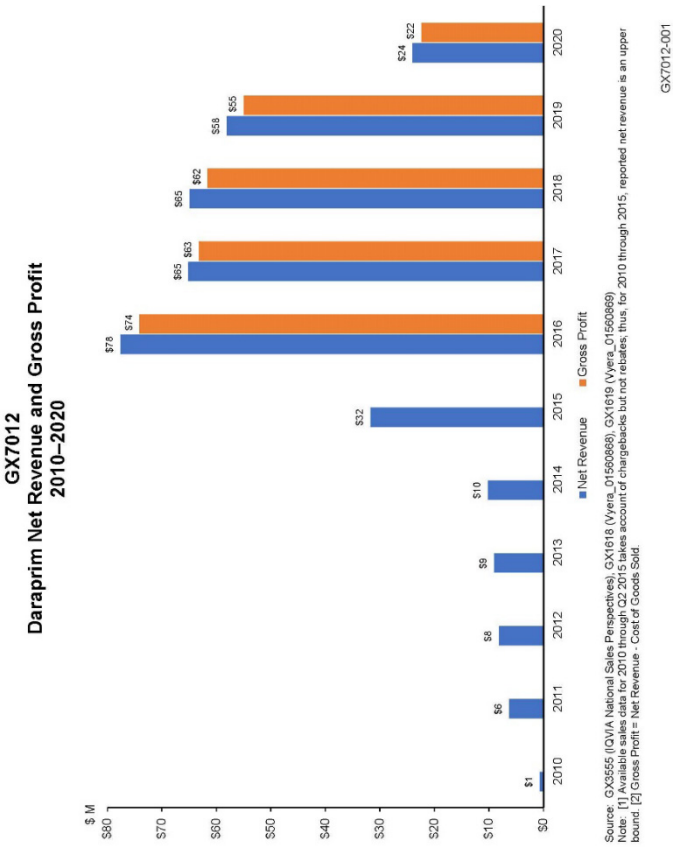
In April 2015, Vyera made Impax Laboratories, Inc. ("Impax"), then the owner of the U.S. licensing rights to Daraprim, an unsolicited offer of $60 million. This offer represented a considerable premium over Daraprim's market value. Annual net sales of Daraprim constituted roughly $4 million at the time, and Impax assessed its net present value as $19 million. In a transaction that closed on August 7, 2015, Vyera paid Impax $55 million, more than eleven times Daraprim's 2014 net revenues.

### B. Daraprim's 2015 Price Hike and Vyera's Revenues

Until 2010, Daraprim had been owned by GlaxoSmithKline ("GSK"), a global pharmaceutical company based in the United Kingdom. Between 2011 and 2015, the new owners of Daraprim had raised the list price—also called the wholesale acquisition cost ("WAC")—of a tablet from $6.74 to $17.60. These price increases ranged from 15% to 30% at a time. Within days of Vyera's purchase of Daraprim and at Shkreli's direction, Vyera raised the WAC from $17.60 to $750 per tablet effective August 11, 2015. From roughly 2016 to 2019, the average net price of Daraprim (the price per tablet after subtracting discounts, chargebacks, and rebates off the WAC) ranged between $228 and $305 per tablet. Dr. Salinas testified that the price hike was the "poster child of everything that is considered wrong about the pharmaceutical industry."

Comparing the nine-month period preceding and following Vyera's price hike, Daraprim's sales volume dropped by 66%. In September 2015, sales data from IQVIA (formerly IMS Health), a commercial data aggregator commonly used for market research in the pharmaceutical industry, indicated that the market size for Daraprim was around one million tablets annually. After that steep decline, the sales volume stabilized at roughly 200,000 to 250,000 tablets per year between 2016 and 2019. These sales remained steady until the first generic pyrimethamine product entered the market in March 2020.

From 2016 through 2019, Vyera made between $55 and $74 million in annual gross profits from its sales of Daraprim. Daraprim revenues in the years between 2010 to 2014 had amounted at most to $10 million a year. Vyera's estimated gross profit margin from Daraprim, calculated by subtracting Vyera's reported production costs, ranged between 89% and 98% in 2016 through 2019. The Figure below illustrates net revenue and gross profit for Daraprim sales between 2010 and 2020.



From August 2015 to the end of 2019, Daraprim sales amounted to over 96% of Vyera's total revenues.[20]

## IV. Vyera's Implementation of a Closed Distribution System for Daraprim

Even before finalizing its acquisition of the rights to the drug, Shkreli made it a priority to close the Daraprim distribution channels. In June 2015, Shkreli directed Retzlaff, who ran Vyera's sales team, to move Daraprim from retail distribution into a closed distribution system "as swiftly as possible." As the interim project manager in charge of the initiative, Mulleady ensured that Shkreli's wishes for Daraprim's closed distribution system were implemented.

Shkreli recognized that generic entry into the pyrimethamine market was inevitable, but Shkreli hoped to delay that entry for at least three years. In July 2015, Shkreli remarked to an investor that he felt "very good that there are no incoming generics and now that it is closed distribution there will not be any going forward . . . even if we get 3 years, it is a great payout."

Daraprim had been in open distribution from its introduction into the market in the 1950s until 2015. After he had initiated his own plans to move Daraprim into specialty distribution, Shkreli learned that a prior owner of Daraprim had already begun to do so. By the

[20] In that period, Vyera earned revenue only from sales of one other drug, Vecamyl.

time Vyera acquired Daraprim, Daraprim was distributed through two wholesale distributors and specialty pharmacies, AmerisourceBergen Corporation ("ABC") and Walgreens Specialty Pharmacy ("Walgreens").[21] Vyera continued the terms of the assigned contract with Walgreens and slowly expanded the number of distribution partners for Daraprim to five distributors and specialty pharmacies. They were ASD (a subsidiary of ABC), BioRidge Pharma LLC ("BioRidge"), Cardinal, Optime, and Walgreens (together, the "Distributors"). Despite expanding the number of distribution partners, however, Vyera imposed class of trade restrictions in its distribution contracts, limiting the types of customers who could buy Daraprim. The end result was that no Distributor could sell Daraprim to a retail pharmacy or a generic drug company without Vyera's approval.

Vyera's distribution restrictions on Daraprim were not justified by a need to protect either patient health or Vyera from lawsuits asserting that a patient had experienced an adverse drug reaction. As noted above, Daraprim had been sold through open distribution for decades. It was considered a safe drug; the FDA never put Daraprim in a REMS program or required a black box warning on the label. Daraprim is an oral tablet that does not require special shipping, handling,

[21] Impax had just transitioned Daraprim from retail distribution to Walgreens specialty distribution. Orders to Walgreens were to be fulfilled by another distribution partner that Vyera inherited when it acquired Daraprim, ICS, an affiliate of ABC and ASD.

storage, or administration. When the first generic pyrimethamine product was launched in March 2020, it was sold through an open distribution system.

### A. Class of Trade Restrictions

Between 2015 and 2020, Vyera's Distributors were restricted to selling only to authorized customers that included government customers, hospitals, specialty pharmacies, and other specialized entities. The authorized customers or types of customers approved to buy Daraprim did not include generic drug companies or their agents. No Distributor was permitted to sell Daraprim to a generic drug manufacturer or their agent without Vyera's express approval. There is no evidence that Vyera ever gave such approval.

Vyera's contract with ASD, executed on September 2015, provides an example of the class of trade restrictions. It simply stated that the "Distributor may only sell Daraprim to Government Customers and hospitals."[22] In 2016, Vyera expanded ASD's authorized customer list to include "certain state AIDS Drug Assistance Programs (ADAPs), subject to the Company's prior written approval." An amendment in 2018 revised the authorized customer clause as follows:

> Distributor may only sell Daraprim to licensed wholesalers and specialty pharmacies that support certain state [ADAPs], subject to the Company's prior written approval,

[22] Government Customers were defined in the contract as the Department of Veterans Affairs or Department of Defense sites.

> Government Customers, hospitals, and 'covered entities', as defined by Section 340B of the Public Health Services Act ("340B Customers"). [Vyera] will approve any new authorized customers via email and will maintain and update a monthly authorized customer file.[23]

Effective February 25, 2020—just as the first generic competitor to Daraprim was about to receive FDA approval—the authorized customer list was expanded to permit sales to "340B contract pharmacies, any customers on the approval list provided by Company, and any new customers approved by Company in writing (with email being sufficient)."

Equivalent restrictions were in place for each Vyera Distributor. For example, as of December 2015, BioRidge was only authorized to distribute Daraprim to Walgreens Specialty Pharmacies. In 2017, Vyera entered a contract with Cardinal that limited distribution to hospitals, ADAPs, and § 340B entities. A 2018 contract with Optime permitted distribution to hospitals, ADAPs, government customers, health departments ("with a valid 340b ID"), hospital distributors ("defined as a distributor that supplies a single hospital system"), and correctional facilities.

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[23] Entities covered by § 340B of the Public Health Services Act, a federal discount pricing program for entities that serve indigent populations, may purchase prescription drugs at steep discounts. 42 U.S.C. § 256b. A § 340B entity was permitted to buy Daraprim for $1 per 100-pill bottle.

Vyera also had contracts with roughly a hundred hospitals to supply them with Daraprim directly at a discounted price so long as they agreed to limit their use of it to their "own use" and not to resell Daraprim. For example, Vyera's agreement with one distinguished medical system provided that "[p]rices available under this Term Sheet shall only apply with respect to product purchased by Hospital for its 'own use' as that term is described in *Abbott Laboratories Inc. v. Portland Retail Druggists*, 425 U.S. 1, 96 S. Ct. 1305, 47 L. Ed. 2d 537 (1976), [without regard to whether Company is a non-profit entity described in section 501 of the Internal Revenue Code]."

### B. Bottle Limits

Vyera also controlled the distribution of Daraprim by imposing limits on the number of Daraprim bottles that a single customer could purchase at a time. For example, in December 2015, ASD agreed to cap orders from § 340B program participants to five bottles "per week per order," with any exceptions for larger orders requiring approval from Vyera. Vyera's Director of Patient Access openly admitted that the quantity limits imposed in 2015 were introduced to make it harder for generic drug companies to acquire "large quantities" of Daraprim "in order to copy the drug and compete with it." He was quoted in a news article published on October 5, 2015, stating that if a generic drug maker tried to order Daraprim,

> Most likely I would block that purchase. . . . We spent a lot of money for this drug. We would like to do our best to avoid generic competition. It's inevitable. They seem to figure out a way [to make generics], no matter what. But I'm certainly not going to make it easier for them.

Vyera added similar restrictions to its contracts with other Distributors. For example, under its 2018 contract with Optime, "[a]ll orders greater than 3 bottles require[d] Vyera approval."

As the entry of generic competition became more imminent, Shkreli urged that the limits on the sale of Daraprim bottles be further tightened. On August 8, 2019, while incarcerated following his conviction for securities fraud, Shkreli was recorded asking Mithani about the likelihood that a doctor could order more than one bottle of Daraprim at a time. When Mithani responded that it is "very likely", Shkreli responded that "that's what I've been stressing to you guys for the last three years, to look at that very carefully, you know, meet those doctors." Shkreli went on to say "there has to be some way to tighten the supply chain a bit . . . I just want to make sure you guys are doing everything you can." When Mithani told Shkreli that Vyera "can't say no" to hospitals, Shkreli responded, "Okay. Well, that's a shame."

Just days before, upon learning of the efforts made by the generic pharmaceutical company Fera to purchase Daraprim RLD, Shkreli had urged Vyera to limit

all sales of Daraprim to one bottle at a time. Shkreli told Mulleady that

> the company should, you know, just make sure it really doesn't sell more than one bottle at a time, you know. That would be—the number one thing I would do and just really screen every doctor that, you know—even if it drops sales a little bit, it's a good—you know, really make sure he's [referring to Fera's owner] not getting his hands on anything.

### C. Surveillance

Vyera monitored its Distributors' daily and weekly sales reports to prevent the diversion of Daraprim to generic drug companies for BE testing. It promptly followed up on any sales it considered unusual to stop any leakage.

The monitoring began as soon as Vyera acquired Daraprim. For example, on August 13, 2015—just two days after the Daraprim price hike—Vyera saw a sales report from ICS reflecting a sale of 40 bottles to a customer. Vyera asked ICS to cap the maximum number of bottles sold to any one customer, explaining Vyera's

> concern that a generic company could access multiple bottles of our product, perhaps attained through a hospital reselling it or distributing product to surrounding retail pharmacies, and use it to create a generic version.

In response, ICS agreed to limit sales to five bottles at a time. Shkreli was informed of the "[n]eed to investigate the 40 unit buy."

Vyera repeatedly instructed its Distributors to refrain from selling Daraprim to potential competitors for clinical trials. For example, in February 2017, a company that obtains RLD for generic pharmaceutical companies ordered a 30-count bottle of Daraprim from ASD. ASD advised Vyera that it had denied the request due to "the conversation around generics." Later in 2017, Vyera directed ASD to rebuff another company that reached out to ASD to buy Daraprim for use in a clinical trial.

The speed and effectiveness of Vyera's surveillance system is dramatically illustrated by its interception of five bottles of Daraprim intended for a generic drug distributor—Dr. Reddy's—in April 2018. On April 5, ASD delivered the five bottles to a pharmacy pursuant to an order placed on April 4. Vyera's surveillance system flagged the purchase on April 5, investigated the purchaser, learned the bottles were destined for a company that supplies RLD for bioequivalence and clinical trials, and by April 6, Mulleady met with the company's owner in a parking lot to repurchase the bottles for $750,000. This was twice the price the pharmacy had paid for the bottles.

Vyera's frantic interception of this purchase prompted it to lock down Daraprim distribution even more strictly. Vyera instructed ASD to block that pharmacy's access to any Daraprim. It then dramatically

shrank the number of customers to which ASD and Cardinal were permitted to sell Daraprim without specific prior authorization from Vyera. For ASD, this resulted in a reduction of approved customers from approximately 13,000 to roughly 555. Vyera similarly cut Cardinal's list of approved accounts from about 14,700 to fewer than 1,500. Vyera also reduced the number of bottles that ASD could sell to any one of the pre-approved customers, reducing the number to four bottles unless the customer was a § 340B customer.

### D. Benefits to Distributors

The Distributors benefitted financially from their contracts with Vyera despite the restrictions on their sales of Daraprim. This was true for as long as Daraprim was sold at a high price. Vyera compensated the Distributors with either a fixed fee (Optime) or a percentage of WAC based on volume sold (ASD, Cardinal, BioRidge, and Walgreens). ASD, for example, received $2,062.50 for each 100-count bottle of Daraprim it sold. By contrast, when Dr. Reddy's launched its generic pyrimethamine product in March 2020, it offered ASD's parent company a price of only $877.50 per bottle.

## V. Vyera's Restriction of Access to the API Pyrimethamine

Besides blocking access to the Daraprim that generic drug manufacturers needed to conduct BE testing, Shkreli also worked to block their access to pyrimethamine, the API in Daraprim. He was well

aware that the sooner a generic company could find an established API manufacturer the sooner it could launch a generic version of Daraprim. Vyera locked up the supply of pyrimethamine to U.S.-based generic drug companies through exclusive supply agreements with the two most attractive pyrimethamine suppliers: Japan's Fukuzyu Pharmaceutical Company ("Fukuzyu") and India's RL Fine.

### A. Fukuzyu

Fukuzyu, an established and prominent Japanese chemical manufacturer, was the long-term supplier of pyrimethamine for Daraprim. Fukuzyu had been producing pyrimethamine since 1966, had held a DMF for pyrimethamine since 1992, and is the manufacturer referenced in Daraprim's NDA. The only other manufacturer to have filed a pyrimethamine DMF, Ipca, had lost its right to sell pyrimethamine in the United States in 2015.[24]

Fukuzyu typically requires a customer to provide an estimate of how much API it will require for a given period. Such clauses mitigate a purchaser's supply risk and help Fukuzyu manage its production schedule.

Fukuzyu's contract with GSK, for example, requires GSK to produce forecasts of how much API it will need for a defined period and requires Fukuzyu to deliver that amount. GSK holds the worldwide rights to Daraprim outside of North America. The contract

[24] The FDA imposed an import ban on Ipca in 2015.

states that GSK "[s]hall provide [Fukuzyu's] Agent with a rolling forecast schedule of demand showing their estimated requirements for PYRIMETHAMINE for the following twelve (12) months ('Forecast Schedule')," and "[t]he Product detailed in the first 3 months ('Firm Order Period') of each Forecast Schedule will represent firm orders for PYRIMETHAMINE" to which Fukuzyu must respond within five days. "[E]ach Firm Order will be regarded by the Parties as a binding irrevocable commitment" to purchase pyrimethamine from Fukuzyu, which in turn obligates Fukuzyu to manufacture enough API to meet the order. The GSK contract also requires Fukuzyu to ensure that it has "at all times sufficient manufacturing capacity to meet [GSK]'s . . . requirements for PYRIMETHAMINE as shown in the Forecast Schedule." GSK's contract with Fukuzyu does not include an exclusivity clause.

Impax, the company from which Vyera purchased Daraprim, had purchased pyrimethamine from Fukuzyu through a broker without even entering into a supply contract. Shkreli was immediately interested in reversing that practice. He wanted an exclusive supply agreement with Fukuzyu. With the help of a consultant, Vyera eventually succeeded by representing that it had several ambitious projects and hoped to use Fukuzyu as a long-term API supplier for each of those projects. In October 2016, three Vyera executives traveled to Japan to visit Fukuzyu. They were Pelliccione, then Vyera's Senior Vice President for Regulatory Affairs, Dr. Salinas, and Vyera's Head of Chemistry, Manufacturing, and Controls.

Vyera bluntly explained to Fukuzyu that it needed an exclusive supply contract to prevent generic Daraprim from entering the United States market. In November 2016, Dr. Salinas directed Vyera's consultant to inform Fukuzyu that "[i]f generic products are put on the U.S. market" Vyera will face a "serious problem, and may eventually terminate the marketing of Daraprim as well as the R&D in toxoplasmosis"; that generic pyrimethamine "will hamper" Vyera's plans to develop new pharmaceutical products and "may leave toxoplasmosis as a forgotten disease with insufficient therapeutic effects"; and that Vyera's plans are "ONLY POSSIBLE" if Vyera has exclusive access to Fukuzyu's API. The consultant was also to stress that Fukuzyu would "not benefit" if generic companies sold pyrimethamine in the U.S. market since generic companies would sell pyrimethamine at a "significantly lower" price.

By November 22, 2016, Fukuzyu had agreed not to sell pyrimethamine "to generic companies." According to Vyera's consultant, Fukuzyu's CEO was particularly pleased that Vyera planned to "develop four more new compounds and would like [Fukuzyu] to work together" with it on those compounds.[25]

On January 25, 2017, Phoenixus entered into a three-year exclusive supply agreement with Fukuzyu. The exclusivity term states that

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[25] As of 2021, Vyera has filed investigative new drug applications ("INDs") for new potential drugs but has not launched any new product.

> [Fukuzyu] shall provide the API Bulk Drug Substance, pyrimethamine exclusively to [Phoenixus] for the use, sale, and/or distribution in the Territory. To be clear, the use, sale, and/or distribution of pyrimethamine described in this section refers to the use, sale, and/or distribution of the API Bulk Drug Substance for humans only.[26]

The Territory was defined as the United States.

The Fukuzyu contract also provided that the minimum purchase quantity of pyrimethamine was 50 kilograms. Vyera, which contracts for the manufacture of pyrimethamine, needs 35 kilograms for a batch of Daraprim to be manufactured. Since executing the exclusive supply agreement, Vyera has twice purchased pyrimethamine from Fukuzyu.

The agreement with Fukuzyu does not ensure that Vyera will have a supply of pyrimethamine or require Fukuzyu to prioritize Vyera's orders over those from its other customers. It does not, for instance, require Vyera to forecast its API requirements or obligate Fukuzyu to reserve any quantity of pyrimethamine or manufacturing capacity to produce pyrimethamine. It does not even require Fukuzyu to fill a Vyera order.

Under the agreement, Vyera must submit a purchase order to Fukuzyu. If Fukuzyu does not

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[26] Since Fukuzyu sells pyrimethamine to a veterinary drug company that uses it to produce drugs for horses in the United States, there was a carveout permitting Fukuzyu to continue selling the API to other U.S. drug companies for use in animals.

acknowledge the order in writing within ten days, it has no obligation to fill the order. The agreement states that:

> [Daraprim] is historically a low volume product for [Vyera]. Due to the infrequent need to manufacture [Daraprim], [Vyera] will provide [Fukuzyu] a Firm Order for API, in the form of a Purchase Order. Receipt of the Purchase Order denotes [Vyera]'s binding request to purchase API within 180 days of date of Purchase Order. [Fukuzyu] will accept Firm Orders by sending an acknowledgement to [Vyera] within 10 business days of its receipt of the Firm Order.

What Vyera obtained through its agreement with Fukuzyu was the right to bar other buyers, and Vyera strictly enforced that right. For example, in November 2017, Fukuzyu inquired whether it could sell pyrimethamine to a company that intended to resell it to a U.S.-based pharmaceutical company for a drug to be sold in South America. Vyera asked Fukuzyu to include in the sales agreement that the API sold to the US company "will not be used to make pyrimethamine drug product, for human use, that will find its way back to the US for commercial purposes," and "that the API will ONLY be used for drug products sold and used in South America." Fukuzyu agreed.

### B. RL Fine

As of 2015, most generic drug companies would have sought to purchase pyrimethamine from

Fukuzyu. Vyera closed off that avenue of supply with its exclusive supply agreement with Fukuzyu. After Fukuzyu, RL Fine was the second most attractive source of supply. In 2017, after Shkreli learned that generic companies were going to obtain pyrimethamine from RL Fine, he moved quickly to cut off that source of supply as well.

RL Fine is based in Bangalore, India and had been manufacturing pyrimethamine since at least 2004. RL Fine sells pyrimethamine directly to customers; it does not use distributors. As of 2016, RL Fine had a European pyrimethamine DMF but had not filed a U.S. DMF.

In 2017, in defending against an investigation that preceded the filing of this lawsuit, Vyera emphasized the importance of RL Fine to generic drug manufacturers. It downplayed the significance of its exclusive supply agreement with Fukuzyu in a letter to the Office of the New York Attorney General dated May 5, 2017, by asserting that "generics manufacturers can obtain pyrimethamine API from a variety of sources, even without the option to purchase it from Fukuzyu". It cited RL Fine as one of those alternatives. Vyera explained that

> the cost for a potential competitor to qualify API from the European DMF holder RL Fine Chemicals would be less than $100,000, as the company has already validated its production process and has a DMF ready to file in the United States. Such a cost can hardly be deemed a barrier to entry, especially when

> viewed as part of the overall process of drug development.

Yet when Vyera learned from its consultant on August 7, 2017, that two generic drug companies, Mylan and Sandoz, were planning to buy pyrimethamine from RL Fine, Shkreli acted quickly to block their access. On August 24, Shkreli drafted an email from prison for Mithani to send to RL Fine. The email represented that Vyera was "looking to purchase 10-20kg/annually of pyrimethamine API with a US DMF" for a "combination product with leucovorin." Mithani sent Shkreli's drafted email to RL Fine verbatim. RL Fine replied that it was "already working on pyrimethamine and would not be able to offer [it] to you." Vyera was undeterred and continued to negotiate with RL Fine.

In October 2017, Vyera received independent confirmation from executives attending a trade conference in Frankfurt that RL Fine was supporting generic drug companies that would soon file ANDAs. On October 25, Shkreli texted Mulleady from prison using a contraband phone:[27] "its shkreli—trying to get in touch with you urgently—hearing pyri ANDA approval in december 2017."

Within eight days of that email, on November 2 Mulleady offered RL Fine $1,250,000 per year and

[27] For a period of time, Shkreli had a contraband phone in prison that he used to communicate with, among others, Mulleady and Mithani. *Fed. Trade Comm'n v. Vyera Pharms., LLC*, No. 20CV00706 (DLC), 2021 U.S. Dist. LEXIS 102757, 2021 WL 2201382 (S.D.N.Y. June 1, 2021).

other financial enticements "to formalize our exclusive agreement" for pyrimethamine API. In late November, Mulleady and Mithani flew to India to meet with RL Fine. By November 25, Vyera and RL Fine had agreed on the terms of an exclusive supply agreement.

Vyera made no bones about its motive for entering this exclusive supply agreement. It needed to block the access of generic manufacturers to RL Fine pyrimethamine. The minutes of the December 15, 2017 Phoenixus board meeting present the rationale for Vyera's costly agreement with RL Fine as "the potential market entry by generics manufacturers and distributors." According to the minutes, "one or two potential competitors are currently in the process of preparing their market entry." The minutes report that Mulleady and Mithani, by then Board members of Phoenixus and in control of the company's management functions, believed "addressing potential generic competitors are in the Vyera Group's interest" and justified the extraordinary price Vyera agreed to pay RL Fine.

On December 17, Vyera executed two contracts with RL Fine: A Distribution and Supply Agreement ("Supply Agreement") and a Product Collaboration Agreement ("Collaboration Agreement"). The twenty-five-page Supply Agreement gave Vyera "the exclusive right to sell, distribute, and market" RL Fine's pyrimethamine for five years and limited RL Fine to selling pyrimethamine for use outside India only "with the consent" of Vyera.

In return, Vyera paid RL Fine $1 million "towards expenses for filing the US" DMF for pyrimethamine. Vyera also agreed to pay RL Fine royalty payments in the amount of 7.5% of net revenues on its sales of Daraprim, with a guaranteed minimum payment of $3 million. Under the Supply Agreement, Vyera's obligation to make royalty payments other than the guaranteed amount of $3 million would terminate if and when a generic pyrimethamine product entered the U.S. market.

Under the Collaboration Agreement, which had a one-year term, Vyera paid a non-refundable $1 million towards R&D expenses and preparation of a DMF. The Collaboration Agreement acknowledged the parties' Supply Agreement.

Having signed the Supply Agreement, RL Fine stopped supplying pyrimethamine to the generic drug manufacturers Cerovene and InvaTech. Vyera has paid RL Fine approximately $300,000 to $450,000 a month in royalty payments. By October 2019, Vyera had paid RL Fine almost $7 million in monthly royalty payments alone, and almost $9.5 million in total. Vyera's payments to Fukuzyu pale in comparison. Over this time period, Vyera has paid Fukuzyu approximately $500,000.

Neither the Supply Agreement nor the Collaboration Agreement required RL Fine to file a DMF with the FDA or conditioned any payment on RL Fine completing any of the steps necessary to file a U.S. DMF. RL Fine never paid even the $57,795 DMF filing fee to

the FDA, despite receiving $1 million from Vyera to do so, or took any other steps toward filing a DMF for pyrimethamine. Similarly, Vyera never sought FDA approval to use RL Fine's API in Daraprim, or took any other steps to be able to use RL Fine as a backup supplier of pyrimethamine. Pelliccione, Vyera's executive in charge of regulatory matters, didn't even know of the RL Fine contract until he was preparing for this trial. It had never even crossed his mind that Vyera needed a second source for pyrimethamine. In sum, Vyera received nothing in return for the millions of dollars it paid to RL Fine except the foreclosure of generic competitors' access to RL Fine's pyrimethamine.

Facing regulatory pressure, on October 20, 2019, Vyera paid RL Fine $750,000 to terminate the Supply Agreement. RL Fine threatened to speak to the FTC if it did not get a termination fee.

## VI. Delay of Generic Entry

Shkreli's efforts to delay the entry of generic competition to Daraprim succeeded. The following chart sets out the dates on which the four generic manufacturers filed their ANDAs, and the dates on which three of those ANDAs were approved.

| Generic | ANDA Filed | Approved | Time to Approval |
|---|---|---|---|
| Cerovene / Dr. Reddy's | 5/8/2014 | 2/28/2020 | 70 months |
| InvaTech | 7/28/2017 | Pending as of January 2022 | 53+ months |
| Fera | 12/19/2019 | 7/27/2021 | 31 months |
| Teva Pharmaceuticals | 1/27/2021 | 8/13/2021 | 7 months |

Vyera's multifaceted campaign to delay the entry of generic pyrimethamine succeeded in substantially delaying the entry of at least Cerovene and Fera. Vyera made it exceedingly difficult for each of them to obtain the pyrimethamine API and a sufficient quantity of Daraprim RLD for BE testing.

### A. Barriers to Entry

As of 2015 only two API suppliers held a pyrimethamine DMF in the United States: Fukuzyu and Ipca. Fukuzyu was the long-term supplier of the API for Daraprim. Because Ipca's supply of pyrimethamine became subject to an FDA-imposed import ban, Fukuzyu was the only option for any pharmaceutical company in the United States seeking a pyrimethamine API supplier that held an active DMF.

RL Fine was the next-best option for a supply of pyrimethamine for generic drug companies seeking to

compete with Daraprim because it was familiar with the FDA's requirements; it had DMFs on file with the FDA for other APIs. In addition, it marketed its drug products globally, already manufactured significant quantities of pyrimethamine, and held a European pyrimethamine DMF. Possession of a European DMF typically indicates that one can also meet U.S. DMF standards.

With its exclusive supply agreements, Vyera blocked access to these two sources of API. Shkreli began efforts to obtain an exclusive supply agreement with Fukuzyu in 2015. Vyera and Fukuzyu came to terms in November of 2016 and executed their contract in January of 2017. In 2017, at Shkreli's urging, Vyera also entered into an exclusive supply agreement with RL Fine. It paid RL Fine millions of dollars to do so.

Shkreli also cut off access to the RLD that generic drug companies needed to do the BE testing required for FDA approval of an ANDA. Understanding the importance of access to the RLD, Shkreli adopted a closed distribution system for the sale of Daraprim. This was the model he had adopted at Retrophin to block generic competition to Retrophin's pharmaceuticals.

Against this backdrop, several generic drug companies worked for years to obtain an API supplier and quantities of the RLD, a process that in the ordinary course should have taken weeks. Cerovene was the first to get its ANDA approved and its efforts to obtain an API supplier and the requisite RLD will be described first. Fera's path to entering the market will be

described next. Finally, there will be brief descriptions of the experiences of InvaTech and Mylan.

### B. Cerovene and Dr. Reddy's Laboratories

Cerovene, a pharmaceutical research and development firm founded in 2006, is focused on the development of generic drugs. Cerovene does not manufacture API, but manufactures the finished drug product, creates the documents necessary to submit the ANDA to the FDA, works with the FDA to gain approval, and produces a finished product for distribution after approval.

Dr. Reddy's is Cerovene's generic pyrimethamine marketing partner. Dr. Reddy's is a large multinational pharmaceutical company that sells about 150 drug products, primarily generic versions of innovator drugs (that is, the first FDA-approved drug created containing a specific API). As it did with Cerovene, Dr. Reddy's often licenses a third party's developed drug or partners with a third party to develop a drug for Dr. Reddy's to bring to market. After a seven-year effort, Cerovene received FDA approval of its ANDA for generic pyrimethamine on February 28, 2020, and Dr. Reddy's launched the generic product on March 20, 2020.

Cerovene began developing generic Daraprim in 2013 and submitted its ANDA to the FDA on May 8, 2014. It expected that a generic version of Daraprim would be profitable based on the price of Daraprim at the time, which was approximately $12 per tablet. In

late 2015, Dr. Reddy's explored developing a generic version after Vyera dramatically hiked up Daraprim's price. It learned in March 2016 that Cerovene had already filed an ANDA, and on January 3, 2017, Dr. Reddy's and Cerovene entered into a licensing agreement.

In evaluating the market opportunity of generic Daraprim, Dr. Reddy's conservatively expected that Cerovene's ANDA would be approved by August 2017, with the product launch occurring by early 2018. Dr. Reddy's also projected that Cerovene's generic would launch at a 55-70% discount off Daraprim's list price (depending on how many other generic competitors entered the market) and expected to take a significant fraction of the branded drug's sales.

Cerovene's experience in acquiring RLD to support its 2014 ANDA was typical of the process generic drug companies generally encounter. Cerovene had done the BE testing that it included in its May 2014 ANDA with nine 100-tablet bottles of Daraprim that it had purchased in 2013 from an independent pharmacy for a total price of just over $10,000. Shah, Cerovene's co-founder and President, recalled that it had taken approximately one day for the pharmacy to acquire the nine Daraprim bottles on Cerovene's behalf.

Cerovene then encountered a setback. It had planned to obtain pyrimethamine from Ipca and had referenced Ipca's DMF in its ANDA, but the 2015 FDA import ban on Ipca's products required it to find a new supplier. In October 2015 and March 2016, Cerovene

and Ipca wrote letters to the FDA seeking an exemption to the import ban for Ipca-manufactured pyrimethamine. The FDA denied the requests on April 15, 2016.

Meanwhile, Cerovene attempted to purchase 50 kilograms of pyrimethamine from Fukuzyu. Cerovene first contacted Fukuzyu in 2015, and Fukuzyu supplied a sample of pyrimethamine for Cerovene to assess for suitability. By September 2016, Shah believed that Fukuzyu had agreed to supply Cerovene with pyrimethamine to develop its generic product. But in October—the same month that Vyera executives visited Japan—Fukuzyu refused to supply the API. In a letter to Cerovene dated October 4, 2016, Fukuzyu explained that it would not supply pyrimethamine "to anyone because of low business potential and high risk associated with the business." Yet, as described above, Fukuzyu executed an exclusive supply agreement with Vyera in January 2017.

Cerovene promptly turned its sights on RL Fine as the next-best option. Although RL Fine did not have an FDA-approved DMF for pyrimethamine, Cerovene considered it a promising alternative supplier due to its experience manufacturing pyrimethamine for use outside the U.S. and because it held DMFs for other products.

On November 16, 2016, Cerovene and RL Fine executed a five-year supply agreement. The agreement obligated RL Fine to provide a pyrimethamine DMF that would be referenced in an amendment to

Cerovene's ANDA. In return, Cerovene paid RL Fine $100,000, with another $100,000 due upon approval of its ANDA.

Cerovene's agreement with RL Fine had an exclusivity provision. That provision was intended to protect Cerovene's investment in getting RL Fine qualified as an API supplier in the United States and forestall free riding by other generic drug companies on Cerovene's investment. RL Fine confirmed that it would support Cerovene's pyrimethamine ANDA in early 2017 and supplied 33.5 kilograms of API, which was enough for Cerovene to test and launch its product.

On April 2, 2017, Cerovene submitted a major amendment to its ANDA changing its API supplier from Ipca to RL Fine. In the amendment, Cerovene informed the FDA that RL Fine had been manufacturing pyrimethamine on a commercial basis in European and Asian markets and noted that the FDA had inspected RL Fine as recently as June 2015. Cerovene included RL Fine's manufacturing information as an amendment to its ANDA instead of relying on RL Fine to handle the DMF process separately. This appeared to Cerovene to be the fastest way to get FDA approval.

Because of the switch in supplier from Ipca to RL Fine, the FDA issued a complete response letter to Cerovene's amended ANDA dated December 26, 2017, requiring Cerovene to conduct new BE testing using RL Fine's API and an unexpired lot of RLD. New BE testing was the only substantial correction required by the FDA, but the Daraprim that Cerovene had purchased

in 2013 had expired, so Cerovene immediately tried to buy five more bottles.

Cerovene made an extensive search for the RLD that proved futile. It tried and failed to acquire RLD from five different suppliers, on occasion making simultaneous prepayments. It made multiple applications to the FDA requesting partial waivers of the BE retesting requirement. After roughly twelve months of effort, Cerovene had purchased only three bottles of Daraprim. It did so in November 2018 at a total cost of $375,000.

Cerovene first sought RLD on December 29, 2017, from the pharmacy that had supplied it with Daraprim bottles in 2013, but the pharmacy was no longer able to supply it with Daraprim. The next day, Cerovene ordered five bottles at a cost of $112,000 each from another pharmacy but cancelled the order in February 2018 when the pharmacy proved unable to fill the order.

On January 22, 2018, Cerovene asked the FDA to reconsider its new BE testing requirement due to its difficulty acquiring Daraprim RLD. Cerovene explained that "the RLD is inaccessible and unavailable in the US for BE or other testing because it is the subject of a restricted distribution program." On June 29, 2018, the FDA denied Cerovene's requests to conduct new BE testing by using its expired lots of Daraprim or to conduct alternative studies. The FDA noted that it "did not have additional recommendations that can address the issue of RLD inaccessibility" and that

"Daraprim is not subject to a REMS, and the restrictions on supply of Daraprim described in your letter are not required by the [FDA]." The agency added,

> If you have been unable to obtain supplies of the drug from the manufacturer or other distributers, and you believe this refusal constitutes anticompetitive behavior, we encourage you to raise the matter with the Federal Trade Commission, which is responsible for addressing anticompetitive practices.

Throughout 2018, Cerovene struggled to find a distributor that could deliver sufficient RLD. Dr. Reddy's did not typically help its partners procure RLD but by the end of January, it had stepped in to aid Cerovene. As a far larger company, Dr. Reddy's believed that its connections might work.

Dr. Reddy's efforts included prepaying $550,000 in March 2018 to Reliant for five bottles of Daraprim. Reliant is a New Jersey-based pharmaceutical wholesale company that "procure[s] branded Innovator Samples/Reference Listed Drugs for bioequivalence and clinical trials." Reliant, however, was unable to purchase any Daraprim from its normal sources.

When Reliant tried to buy Daraprim bottles from ASD, ASD directed Reliant to place its order directly with Vyera. Vyera never responded to Reliant's request for five bottles.

Relying on a family connection, Reliant turned to a small New Jersey pharmacy and arranged for the pharmacy to order five bottles of Daraprim from ASD.

As described above, Vyera immediately flagged that transaction and hurried to repurchase the five bottles for twice their purchase price during a meeting in a Starbucks parking lot in New Jersey.

The pharmacy had placed its order with ASD on April 4, 2018 for five bottles, which were delivered the next day. Vyera's Kirby emailed ASD on April 5 to verify that the pharmacy was an "approved account type[]" and requested that ASD put a hold on the pharmacy's account for "placing further orders until we can determine if there is alignment with our distribution model." ASD answered that it had approved the sale in error and confirmed that the purchase could not be stopped as the bottles had already shipped. A Vyera employee then called the pharmacy and spoke to the owner.

Vyera repurchased the five bottles for $750,000 on April 6, 2018. Vyera's CEO Mulleady drove to Parsippany, New Jersey to meet Reliant's owner in a Starbucks parking lot and repurchased the bottles. Mulleady also handed the owner of Reliant a draft contract titled "Product Purchase and Collaboration Agreement." The document proposed that Reliant and its affiliates "agree not to purchase, directly or indirectly, or their own account or on account of others, or to cause or direct any third party to purchase, directly or indirectly, any Daraprim, except directly through normal commercial channels." Reliant never signed the document. Despite its continuing efforts, Reliant only delivered one bottle of Daraprim in June of 2018.

Cerovene and Dr. Reddy's also used a Swiss distributor, ProSupplier GmbH ("ProSupplier"), which also required an advance payment to begin locating Daraprim RLD. Cerovene and Dr. Reddy's initially resisted prepaying both Reliant and ProSupplier for RLD that may never materialize; they had also heard that ProSupplier was in fact attempting to obtain Daraprim through Reliant. As more time passed, however, Dr. Reddy's and Cerovene decided to accept the risk of holding open two orders at the same time and prepaid $375,000 to ProSupplier in September for three bottles of Daraprim, with another $375,000 to be paid after delivery.

ProSupplier delivered three bottles of Daraprim in November 2018, but as they came from a different manufacturing lot than the one bottle obtained by Reliant, the four bottles could not be combined to meet the FDA's BE testing and the RLD retention requirements. With the three bottles in hand, Dr. Reddy's cancelled its outstanding order with Reliant.

Cerovene had written the FDA again in July 2018 to stress that Daraprim appeared to be subject to a restricted distribution program and was inaccessible in the United States. It requested a reduction in the amount of RLD needed for BE testing and retention. In April 2019, the FDA permitted Cerovene to conduct BE testing with just the three bottles of Daraprim that it had been able to acquire from ProSupplier.

Meanwhile, due to Vyera's interference, Cerovene was forced to search for yet another API supplier.

During a November 30, 2017 meeting in India, RL Fine informed Cerovene's Shah that, notwithstanding their five-year contract, it would no longer supply Cerovene with any more pyrimethamine.

Cerovene returned to Ipca, which had acquired another company with manufacturing facilities. Cerovene executed a supply agreement on February 19, 2019, that was conditioned on FDA approval of Ipca's affiliate as Cerovene's API supplier. Cerovene invested in developing the company's pyrimethamine manufacturing capacity from scratch, but even with Ipca transferring its manufacturing process, it took until late 2019 for the company to provide Cerovene with the materials necessary to supplement its ANDA.

From May to June 2019, Cerovene proceeded to conduct BE testing using the RL Fine API that it had received in 2017 and the three bottles of Daraprim obtained from ProSupplier in November 2018. It submitted its results to the FDA in September 2019. Then, on February 25, 2020—after Vyera terminated its exclusive agreement with RL Fine in October 2019—RL Fine agreed once more to supply Cerovene with pyrimethamine pursuant to their 2016 agreement. Three days later, Cerovene's generic pyrimethamine product received FDA approval and an AB rating to Daraprim. Dr. Reddy's launched the generic on March 20, 2020. Cerovene began manufacturing commercial batches of generic pyrimethamine using RL Fine's API in 2021.

Vyera delayed Cerovene's entry into the market by roughly thirty months, that is, from September 2017

to its actual entry date of March 2020. This timeline is premised on Cerovene having been able to obtain API from Fukuzyu in October 2016 and being able to obtain Daraprim without any delay. Cerovene, as explained at trial by its principal, would have needed approximately eleven months to obtain approval for an amended ANDA in these circumstances.[28] Shah testified that it would have taken one month to manufacture a registration batch of the generic drug product. He would have redone the BE testing during the three-month period needed for stability testing. He predicted that he would have filed an amended ANDA changing Cerovene's API supplier to Fukuzyu in or around February 2017. Assuming that the FDA would have taken six months to review of Cerovene's amendment, it would have approved Cerovene's ANDA by August 2017. Dr. Reddy's would have launched Cerovene's FDA-approved generic pyrimethamine one month later, by September 2017.

As was true when Dr. Reddy's actually launched Cerovene's generic competitor to Daraprim in 2020, the effect of the entry of FDA-approved generic pyrimethamine on the price of Daraprim would have been immediate. Upon the entry of the Dr. Reddy's generic product, Vyera began to compete on price by offering steep rebates and brand-for-generic deals to various pharmacies and pharmaceutical benefit managers.[29]

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[28] Shkreli did not challenge this testimony at trial.

[29] A brand-for-generic rebate is a rebate offered on the price of a brand name drug by a pharmaceutical company in exchange

### C. Fera

The second pharmaceutical company to bring FDA-approved generic pyrimethamine to the market is Fera. Fera is based in Locust Valley, New York, and develops generic and branded drugs. DellaFera founded Fera in 2009 to develop niche products that face barriers to entry and are often overlooked by the pharmaceutical industry.

Fera is a virtual drug company, which means that it does not have its own manufacturing capacity; it contracts with other manufacturers to produce its products. When developing a new drug, Fera usually partners with reputable API suppliers that have experience complying with the FDA's cGMPs regulations.

In September 2015, Fera decided to develop generic pyrimethamine after learning about Vyera's Daraprim price hike in the media. After confirming that about one million tablets of Daraprim were being sold per year at the time, Fera began to search for API suppliers holding a U.S. DMF for pyrimethamine.

In February 2016, Fera inquired of Fukuzyu about purchasing pyrimethamine. Fukuzyu did not respond.

On June 13, 2016, Fera entered into an agreement with another manufacturer to develop a pyrimethamine API manufacturing process exclusively for Fera's

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for a pharmacy agreeing to dispense the brand name drug in lieu of the generic version when filling prescriptions. The end payer pays the generic cost of the copay despite receiving the brand name drug.

use. That manufacturer had never made pyrimethamine. Fera invested about $2 million for the development of a pyrimethamine manufacturing process. The company completed its work in October 2017.[30]

Meanwhile, Fera continued its efforts to acquire the API from an already established source. Despite its investment in an API development process, Fera understood that its ANDA would be approved more quickly if it relied on a supplier that already had an FDA-approved pyrimethamine DMF.

In September 2017, Fera reached out to Fukuzyu a second time. Fera sought a sample of pyrimethamine API to test against the API being produced by its manufacturing partner, and also hoped that Fukuzyu would agree to become its pyrimethamine supplier for generic Daraprim. That proved to be impossible. At Vyera's direction, Fukuzyu's agent told Fera that it had to guarantee that Fukuzyu's pyrimethamine would not be used in a drug for human use in the United States "either via normal prescription drug distribution" or via compounding.[31]

In the Fall of 2016, Fera also sought to purchase Daraprim RLD for BE testing and to use as a

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[30] Due to the difficulty obtaining RLD, Fera did not begin working on a DMF until late 2018. It filed the DMF on May 28, 2019.

[31] Drug compounding is a practice whereby a pharmacist combines, mixes, or alters pharmaceutical ingredients to create a medication in a non-FDA-approved facility. Compounded drugs are not reviewed by the FDA for safety or efficacy.

comparator with the product being produced by its manufacturing partner. Its efforts were largely fruitless.

On November 7, 2016, Fera's McDougal reached out to Pharmaceutical Buyers, Inc. ("PBI"), a distributor, to acquire samples of Daraprim. PBI responded that Daraprim was "only available to hospitals and government facilities at this time." McDougal next inquired of a hospital pharmacist at a major university, who responded that "according to our hospital policy and distributor contract, I can only procure from what is defined as own use for hospital business." Fera was finally able to acquire small amounts of Daraprim by using a physician's prescription at a pharmacy. That Daraprim would not meet FDA requirements for BE testing, however, because the sample contained too few tablets, was provided in an unsealed vial, and had no manufacturing lot number.

Fera also attempted to procure Daraprim through its contract research organization ("CRO"), Xcelience. Fera had entered into an agreement with Xcelience on December 22, 2016, to develop a generic prototype and manufacture the end product. Xcelience quickly ran into the same roadblocks Fera had met in its own efforts to acquire RLD. On January 4, 2017, Xcelience relayed to Fera that "the manufacturer is now limiting distribution of Daraprim only to hospitals and government agencies directly." When Xcelience reached out to Vyera, Vyera explained that Fera would have to enter into an agreement accepting full liability from any use of Daraprim. This is the first time a purchase of RLD

had been conditioned on Fera executing an indemnification clause. Fera replied by striking the proposed indemnity clause, which ended negotiations.

McDougal continued to inquire of PBI in February and again in May of 2017, to no avail. In July 2017, Fera ended its relationship with Xcelience at least in part because it had failed to procure the RLD.

Fera signed a development contract with another CRO in November 2017. Fera also negotiated a partnership with a contract manufacturing organization ("CMO"). That CMO completed its first manufacture of Fera's generic pyrimethamine product in March 2019.

Meanwhile, in January 2018, Fera succeeded in purchasing two 100-count bottles of Daraprim from Reliant at a cost of $115,000 per bottle. Fera declined to purchase more bottles at that time, partly because the bottles came from a manufacturing lot that expired in Summer 2019, that is, before Fera was sure that it could conduct BE testing. Fera intended to purchase additional bottles from Reliant as its development timeline became clearer. In April 2018, Reliant informed Fera that Vyera's Mulleady had repurchased its inventory of Daraprim and that it could not acquire more.

Using an industry broker, Vyera's Mulleady asked to meet with Fera in April of 2018. DellaFera met with Mulleady in April and May of 2018. Following instructions from Shkreli, Mulleady quizzed DellaFera about his plans, dangling the possibility of a joint venture as he did. Mulleady told DellaFera that he had

repurchased Reliant's entire stock of Daraprim. He also related that he had flown to India to lock RL Fine into an exclusive contract in order to prevent it from supplying two major pharmaceutical companies, Mylan and Sandoz, with pyrimethamine. He explained that Vyera was paying RL Fine a royalty on Daraprim sales. When Mulleady added that he knew the identity of Fera's API supplier, DellaFera understood this as a threat that Vyera was willing to interfere with Fera's source of API as well. At this point, DellaFera became concerned that Fera might never get pyrimethamine into the market. DellaFera had no interest in a joint venture with Vyera and the discussions came to a close.

Like Cerovene, Fera had already asked the FDA for a waiver of its BE testing requirements due to difficulty acquiring RLD. In October 2017, Fera proposed performing a pharmacokinetic study, which would not require Daraprim RLD, in lieu of BE testing. Fera explained that

> the unavailability due to the restricted access program created by the RLD has made the development of a generic version of the product largely impossible. Additionally, the cost of the RLD is exorbitant, forcing even patients to forego this medically necessary treatment.

The FDA denied Fera's request.

On June 1, 2018, Fera requested a competitive generic therapy designation from the FDA that would allow for expedited review of Fera's application. It also

asked for a meeting with the relevant FDA officials to ensure that its ANDA was on track. In August 2018, Fera sought a waiver "for the minimum number of RLD samples required to be retained from the conduct of the Fed and Fasting BE studies." Fera pointed out that

> [t]he RLD sponsor for this drug product, Vyera, utilizes a closed pharmacy distribution model. This has resulted in extreme difficulty in obtaining sufficient samples of drug product normally needed to meet all ANDA test analysis and BE study requirements.

In January 2019, the FDA again denied Fera's request.

On March 4, 2019, Fera's team participated in a call with the FDA's Office of Generic Drugs. DellaFera stressed how difficult it was to locate RLD and that it had taken over a year to buy just two bottles. He described his conversations with Mulleady, including Mulleady's admission that Vyera had entered an exclusive API supply agreement with RL Fine to eliminate competition from Mylan and Sandoz. In April, Fera formally requested another waiver to conduct BE testing with only two bottles of Daraprim, which the FDA granted in June.

Fera immediately conducted BE testing of its generic pyrimethamine product, undertook six months of stability testing, and filed its ANDA in December 2019. The FDA responded by requiring Fera to conduct additional tests on its API, and in August 2020, the FDA sent Fera a complete response letter citing deficiencies

in the impurity profile of Fera's API. Due to the COVID-19 pandemic, it took Fera until December 2020 to complete the resubmission. On July 27, 2021, the FDA approved Fera's generic pyrimethamine ANDA.

Vyera delayed Fera's entry into the generic pyrimethamine market by roughly twenty-four months. This timeline assumes that Fukuzyu would have agreed to supply Fera with pyrimethamine after Fera reached out to it for a second time in September 201 and that Fera had unimpeded access to Daraprim RLD. DellaFera estimates that, operating on those assumptions, Fera's generic Daraprim would have entered the market twenty-three months later, or in August 2019 instead of shortly after Fera's ANDA was approved in July of 2021.

As DellaFera explained at trial, Fera would have acted promptly to finalize an agreement with a CMO partner to manufacture the drug. The CMO would have taken between three o four months—or up to April 2018 at the latest—to manufacture the necessary batches of generic pyrimethamine for six months of stability testing, bringing the timeline to October 2018. During this six-month period, Fera would have conducted BE testing, assembled its ANDA, and been prepared to file its ANDA by November 2018. Presuming eight months for review, the FDA would have approved Fera's ANDA in July 2019, avoiding any delays caused by the COVID-19 pandemic. As Fera's CMO would have been producing batches of generic pyrimethamine for commercial sales while awaiting FDA approval,

Fera would have been ready to launch its product within a month, or by August 2019.[32]

### D. InvaTech

InvaTech has also filed an ANDA for generic pyrimethamine. Identifying RL Fine as its supplier of API, InvaTech filed an ANDA on July 28, 2017. Due to its exclusive supply agreement with Vyera, however, RL Fine stopped cooperating with InvaTech and InvaTech was forced to find a new supplier of API. Although Vyera's actions have delayed InvaTech's entry into the market, there are too many unknowns to attribute any particular period of delay to Vyera. InvaTech has still not received FDA approval for its ANDA.

InvaTech, founded in 2009, is a New Jersey pharmaceutical company that develops and markets around twenty products. In 2014, it began its effort to develop generic pyrimethamine. In October of 2014, InvaTech bought six 100-tablet bottles of Daraprim for a total of just over $8,000.

Like Cerovene, InvaTech initially chose Ipca as its API supplier, but was forced to look elsewhere following the FDA's 2015 Ipca import ban. In the summer of 2015, RL Fine agreed to supply pyrimethamine to InvaTech. In February 2017, InvaTech and RL Fine executed a Preliminary Collaboration Agreement covering pyrimethamine and two other products for which

[32] At trial, Shkreli did not take issue with this timeline.

RL Fine would supply the API. RL Fine agreed to file a DMF for pyrimethamine. While the Agreement left RL Fine free to supply pyrimethamine to other companies, InvaTech was given preferential pricing. The Agreement specified that InvaTech would file its pyrimethamine ANDA in either 2017 or 2018.

InvaTech used RL Fine's API to conduct BE testing. Because RL Fine had not yet filed a DMF, InvaTech requested in June 2017 that RL Fine provide it with the documentation regarding its pyrimethamine manufacturing process for InvaTech to include in its ANDA. With that information, on July 28, 2017, InvaTech filed its pyrimethamine ANDA.

On September 11, 2017, the FDA sent a response that included questions about RL Fine's API, setting an answer deadline of September 18. InvaTech sought assistance from RL Fine, but RL Fine ignored each of its requests. By that time, Vyera and RL Fine were in the midst of negotiating their exclusive supply agreement.

Given the urgency of the situation, Patel flew to India in September for a two-hour meeting with RL Fine. In that meeting and through other communications, Patel learned that RL Fine would no longer support InvaTech's pyrimethamine ANDA even though it continued to support InvaTech's work on the other two products.

On May 22, 2018, the FDA issued a complete response letter to InvaTech's ANDA. The FDA cited major deficiencies, including deficiencies with the API

information. RL Fine again ignored InvaTech's requests for help.

Having lost first Ipca and then RL Fine as its API supplier, InvaTech turned to a third company. On July 31, 2019, InvaTech amended its ANDA to reflect the transfer of its API source to that third company. To this day, InvaTech continues to work toward approval of a generic Daraprim product.

### E. Mylan

Vyera was successful in preventing one of the largest manufacturers of generic drugs in the United States from entering the market. Prompted by the dramatic increase in Daraprim's price, Mylan explored developing generic pyrimethamine. In February 2016, Mylan began to search for potential pyrimethamine API suppliers. By December 2016 Mylan concluded that RL Fine was the only supplier that could provide pyrimethamine "off the shelf and not require a development agreement." By that time, however, RL Fine had entered the exclusive supply agreement with Cerovene.

Like Cerovene and Fera, Mylan was also unable to acquire Daraprim RLD through its regular distributors and approved vendors. It could not get "even a single bottle." Mylan's Head of Global Project Management can only recall two or three other times out of hundreds of projects in which Mylan had such trouble. In those instances, the difficulties were easily explained by the fact that the RLD was part of a REMS

program. Unable to find a source of the API or to obtain Daraprim, Mylan abandoned its nascent plans to develop generic pyrimethamine.

## VII. Impact of Competition on Prices of Daraprim

In early 2020, Vyera braced for the imminent approval of Cerovene's ANDA and subsequent launch of Dr. Reddy's FDA-approved generic pyrimethamine product. In an internal forecast prepared in March 2020, Vyera projected that the net price for a Daraprim tablet would immediately drop from $278 to $126 after generic entry, based on the assumption that Dr. Reddy's generic would launch at a 61% discount on April 1, 2020. Assuming that another generic competitor would enter the market on September 1, Vyera projected that the business lost by the end of the year due to generic competition would increase to $2.1 million per month and amount to close to $13 million for the year 2020.

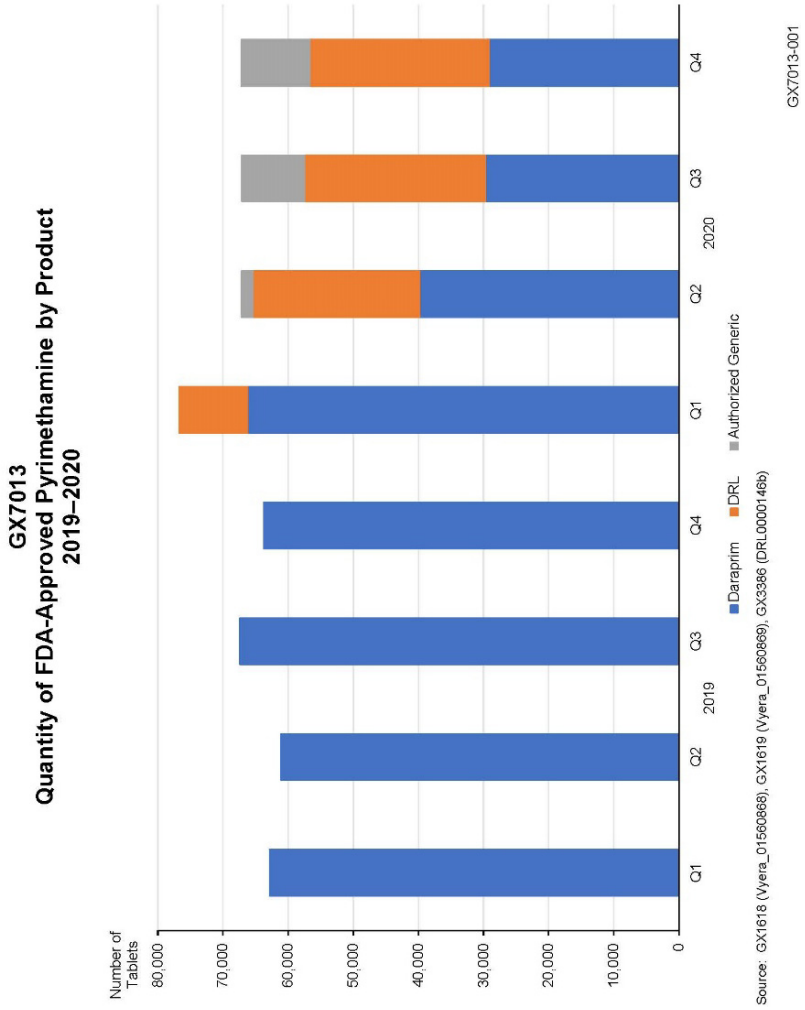
Dr. Reddy's FDA-approved generic pyrimethamine launched with a WAC of $292.50. Daraprim immediately faced stiff price competition, and the net price of FDA-approved pyrimethamine products dropped substantially. During its first nine months on the market, the average net price of Dr. Reddy's generic pyrimethamine was $197 per tablet, a significant discount from $228, which was the average net price of Daraprim in the prior year. By the end of 2020, Dr. Reddy's generic pyrimethamine had

captured 41% of the sales volume for all FDA-approved pyrimethamine. At the same time as the price of FDA-approved pyrimethamine dropped, the total volume of FDA-approved pyrimethamine sales increased. The sales volume expanded by 9% when 2020 sales are compared to 2019 sales. This expansion recovered some of the sales lost when Vyera hiked Daraprim's price by 4,000% in 2015.

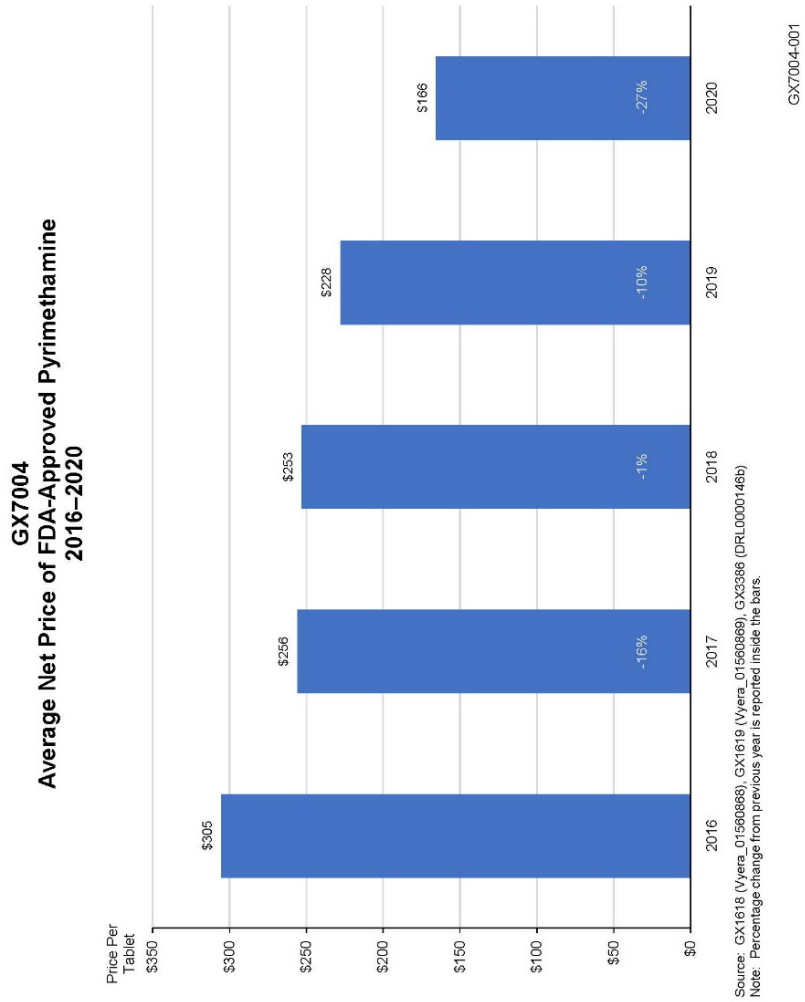
In March 2020, Vyera launched its own generic pyrimethamine tablet (the "Vyera AG").[33] The Vyera AG had captured only 16% of the FDA-approved pyrimethamine market by the end of 2020.

The chart below illustrates the relative market share of Daraprim, the Vyera AG (identified as "Authorized Generic"), and Dr. Reddy's generic pyrimethamine (identified as "DRL") between the first quarter of 2019 and the last quarter of 2020.

[33] A generic of a brand name drug may be launched under the brand's preexisting FDA approval. It is known as an authorized generic.




The next chart illustrates the change in the average net price of all FDA-approved pyrimethamine, which dropped from $228 in 2019 to $166 in 2020—a decrease of 27%. This rate of decrease exceeded any year-over-year net price drop that had occurred since 2016.




In response to the entry of Dr. Reddy's generic pyrimethamine, Vyera cut the net price of Daraprim through steep rebates and brand-for-generic offers to pharmacies and pharmacy benefit managers. Despite these offers from Vyera, the availability of generic alternatives to Daraprim allowed pharmacy benefit managers to cover the cheaper generic competitors at

the lowest tiers of their formularies and to exclude Daraprim from their formularies. For example, in January 2021 CVS Caremark moved Daraprim to "excluded status" on its standard control formulary. It explained its decision as follows: CVS Caremark, like most payors, promotes a "generic-first strategy." Where the branded drug is expensive and two generics became available, it is "a very cost-effective strategy" to exclude the brand from the formulary. With the entry of more generic competitors in the FDA-approved pyrimethamine market, the price of FDA-approved pyrimethamine can be expected to fall further.

## VIII. The Role of Martin Shkreli at Vyera

Shkreli founded Vyera. He did so with the intention to use Vyera to acquire a pharmaceutical that was the sole source of treatment for a life-threatening ailment, raise the drug's price sky-high, and keep it sky-high for as long as possible by blocking generic competition.

Shkreli was Vyera's first CEO, a position he held from October 10, 2014 to December 18, 2015. It was Shkreli who made the decision to acquire Daraprim and to implement his scheme with Daraprim. He directed his team to identify a small, essential drug out of patent protection and without generic competition that could be priced exorbitantly. That drug was Daraprim. Shkreli signed off on Vyera's unsolicited bid to acquire it at a price far above its present value.

Shkreli raised the price of Daraprim to $750 per tablet. When Vyera's General Counsel objected to the price hike, Shkreli fired him.

To block generic competition, Shkreli devised a highly restrictive, closed distribution system for Daraprim and told Vyera that it was a top priority to put it in place by the time of the price hike. Shkreli also instructed his staff to buy back Daraprim inventory from wholesalers and distributors.

Having checked the FDA's pyrimethamine DMF list, Shkreli decided to pursue an exclusive supply contract with Fukuzyu. As Tilles, Shkreli's immediate successor as CEO, explained, the 2017 Fukuzyu contract was "something [Shkreli] wanted and it happened." As the arrival of a generic competitor grew more likely, in 2017 Shkreli decided to pursue an exclusive supply contract with pyrimethamine manufacturer RL Fine as well.

Shkreli remained in functional control of Vyera's management and its business strategy even after his arrest in December 2015 and in spite of management's occasional resistance. He was Vyera's largest shareholder and at any one time controlled between 43.07% and 49.44% of its voting shares. Even during his incarceration, Shkreli worked to ensure that his grand strategy not only remained in place but actually worked. Critically, none of the resistance put up by Shkreli's successors included unwinding Vyera's anticompetitive strategy. To the contrary, all of Vyera's CEOs pursued Shkreli's original vision.

Shkreli recruited employees and agents to carry out his vision at Vyera and picked the men who ran Vyera after he stepped down as its CEO. That those agents' names appear on documents executed after Shkreli's formal departure in lieu of his own does not shield him as the scheme's prime mover from individual liability. Shkreli initiated every anticompetitive decision that Vyera pursued to its conclusion. He maintained "shadow control" of the company, staying in close contact with Vyera's directors and officers, providing guidance on how to maintain control of the market, and threatening to use his authority as the largest shareholder to call an extraordinary general meeting ("EGM") that would install more pliant officers and directors. He did exactly that in 2017 and again in 2020, each time installing loyalists.

As Tilles has testified, he couldn't do anything "major" as CEO of Vyera without Shkreli's approval. When Shkreli became frustrated with Tilles, he replaced him with Dr. Salinas. Shkreli quickly became dissatisfied with Dr. Salinas too, proclaiming in one email that Dr. Salinas was a "cockroach that needed to be stomped or crushed."

Utilizing his controlling voting shares, Shkreli replaced Dr. Salinas with Mulleady. In June of 2017, Shkreli called an EGM of the shareholders to vote on a new slate of Directors. The Phoenixus Board and Shkreli put up competing slates.

In its Invitation to shareholders, the Board strongly opposed Shkreli's slate as unqualified and conflicted. The Board advised that

> many third parties—including regulatory authorities—will likely deem the newly elected Board members to be serving merely as straw men acting on Mr. Shkreli's behalf, and could further deem Mr. Shkreli to be in a position to influence, direct or control the Board and thus, the Company as well.

At the EGM held on June 21, 2017, Shkreli's slate was elected.

The new Board members notably lacked experience in the pharmaceutical industry. Those new members included Mulleady and Mithani. Tilles had fired Mulleady after Shkreli's arrest because Mulleady lacked "any skills" to offer the company. Mithani had graduated from college just three years earlier. His only prior employment was at a distressed debt brokerage firm, which he had quit to manage his own investment portfolio. Mithani has admitted that he was not qualified to join the board of a pharmaceutical company and that he was placed on the Board because Shkreli wanted "people he can trust."

The next day, the Board placed Dr. Salinas, then interim CEO, on leave and established an Executive Committee to "perform executive functions and take over the task of the Senior Management (CEO, CFO, CCO and CLO)." The Executive Committee had only two members: Mulleady and Mithani.

Mulleady promptly sent a reassuring email to Vyera's sales force, which was confronting an FDA announcement that it would expedite review of pyrimethamine ANDAs. He explained,

> In my opinion, this not an immediate concern. Getting to the point of filing an ANDA is a cumbersome process. Personally, I can tell you the FDA approval is generally not the main barrier to entry for generics in our class. Amongst other necessities, a company would have to successfully create the active ingredient on scale using a well-controlled process and then formulate. Next they would have to obtain RLD (registered listed drug), 10 labelled and unexpired bottles (informed estimation), of Daraprim to complete a study in healthy volunteers to demonstrate bioequivalence.
>
> Getting to the front of the line is helpful, but getting to the line is not an easy task. I can't imagine ANDA submission preparation taking less than 18 months (extremely conservative). Since [Vyera] actively collects competitive intelligence concerning other potential developers, we would most likely be aware of this process going on and have plenty of time to prepare.

Mulleady also ordered a "full out audit" of Daraprim to know where "every bottle" of Daraprim went. He made sure that Shkreli got the audit results.

If anything, Shkreli tightened his control over Vyera as his criminal problems progressed. Concern

was expressed at an August 30, 2017 Board meeting that the company was buying back shares at a price below par value "to increase Martin Shkreli's holding in the Company and to facilitate his control over it." At Mulleady and Mithani's urging, the Board nonetheless approved the buyback. The Board then appointed Mulleady CEO in October 2017.[34]

Shkreli kept in regular contact with both Mulleady and Mithani to discuss when a generic Daraprim drug might enter the market and what should be done to slow that entry. As shown in an Excel spreadsheet maintained by Mulleady, between December 26, 2019 and July 14, 2020 alone, at a time when Shkreli was in prison, Mulleady and Shkreli communicated over 1,500 times.

In the few recordings of Shkreli's conversations from prison with Vyera management that are part of the trial record, Shkreli openly discussed his control over Vyera. He observed that he had "EGM power." Shkreli said "I have no problem firing everybody to be frank, if you guys can't figure it out." In September 2020, Shkreli told Mulleady that any dissenters amongst the Directors needed to understand that "being on the board of Phoenixus means, you know, you're on the Martin and Kevin board." Shkreli compared

[34] Mulleady served as the interim Executive Director of Vyera and Phoenixus from October to December 2017, then became Vyera's CEO from January 1, 2018 until February 19, 2019. Mulleady was removed as the Chairman of the Board of Phoenixus on November 17, 2020 and removed from the Board on December 11 at another EGM called by Shkreli.

himself to Mark Zuckerberg and Vyera to Facebook, noting that Zuckerberg "just happens to own the thing and that's the way it is," and "[y]ou can't go in there and tell Zuckerberg what to do."

In February 2020, Shkreli used his EGM power to change Vyera's management team once again. This time, he removed Mulleady. Mulleady had added a "confidential" item to the agenda of an upcoming Board meeting. It was intended to address Shkreli's meddlesome involvement with Vyera. But before it could be discussed, Shkreli called for an EGM, Mulleady was removed from the Board, and Shkreli's new directors were installed.

**Discussion**

The FTC has brought claims against Shkreli for violations of §§ 1 and 2 of the Sherman Act. The States have brought claims against Shkreli based on violations of various state statutes and Pennsylvania common law, all of which follow federal precedent. After finding that the Plaintiffs have carried their burden of proving by a preponderance of the evidence that Shkreli violated §§ 1 and 2 of the Sherman Act and the state laws at issue here, the Plaintiffs' requests for relief will be addressed.

## I. Legal Standard

### A. Section 5 of the FTC Act

The FTC brings this action pursuant to authority given to it in the FTC Act. The FTC Act declares "[u]nfair methods of competition" to be unlawful, 15 U.S.C. § 45, and directs the FTC to prevent violations of the FTC Act. "Unfair methods of competition" under the FTC Act encompass violations of the Sherman Act. *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 454-55, 465-66, 106 S. Ct. 2009, 90 L. Ed. 2d 445 (1986).

### B. Section 1 of the Sherman Act

Section 1 of the Sherman Act outlaws "[e]very contract, combination . . . , or conspiracy, in restraint of trade or commerce among the several States." 15 U.S.C. § 1. The "primary purpose of the antitrust laws is to protect interbrand competition. Low prices . . . benefit consumers." *State Oil Co. v. Khan*, 522 U.S. 3, 15, 118 S. Ct. 275, 139 L. Ed. 2d 199 (1997).

To prove a § 1 violation, a plaintiff must show that there was "a combination or some form of concerted action between at least two legally distinct economic entities that constituted an unreasonable restraint of trade." *United States v. Apple, Inc.*, 791 F.3d 290, 313 (2d Cir. 2015) (citation omitted). "[O]fficers or employees of the same firm do not provide the plurality of actors imperative for a § 1 conspiracy" because "an internal agreement to implement a single, unitary firm's policies does not raise the antitrust dangers that § 1 was designed to police." *Copperweld Corp. v. Indep.*

*Tube Corp.*, 467 U.S. 752, 769, 104 S. Ct. 2731, 81 L. Ed. 2d 628 (1984).

"The first crucial question in a Section 1 case is . . . whether the challenged conduct stems from independent decision or from an agreement, tacit or express." Apple, 791 F.3d at 314-15 (citation omitted). Courts presumptively apply a rule of reason analysis to challenged agreements to determine whether they restrain trade. *1-800 Contacts, Inc. v. Fed. Trade Comm'n*, 1 F.4th 102, 114 (2d Cir. 2021) (citing *Texaco Inc. v. Dagher*, 547 U.S. 1, 5, 126 S. Ct. 1276, 164 L. Ed. 2d 1 (2006)). Therefore, "antitrust plaintiffs must demonstrate that a particular contract or combination is in fact unreasonable and anticompetitive before it will be found unlawful." *Texaco*, 547 U.S. at 5. Anticompetitive effects may be shown through direct evidence of increased prices in the relevant market. *1-800 Contacts*, 1 F.4th at 118.

Under the rule of reason,

> [a] plaintiff bears the initial burden of showing that the challenged action has had an actual adverse effect on competition as a whole in the relevant market. After a prima facie case of anticompetitive conduct has been established, the burden shifts to the defendant to proffer procompetitive justifications for the agreement. Assuming defendants can provide such proof, the burden shifts back to the plaintiffs to prove that any legitimate competitive benefits offered by defendants

> could have been achieved through less restrictive means.

*Id.* at 114 (citation omitted).

The rule of reason analysis requires a court to weigh "the relevant circumstances of a case to decide whether a restrictive practice constitutes an unreasonable restraint on competition." *Anderson News, L.L.C. v. Am, Media, Inc.*, 680 F.3d 162, 183 (2d Cir. 2012) (quoting *Monsanto Co. v. Spray—Rite Service Corp.*, 465 U.S. 752, 761, 104 S. Ct. 1464, 79 L. Ed. 2d 775 (1984)). Such factors may include "specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect." *State Oil Co.*, 522 U.S. at 10.

Exclusive dealing arrangements "implicate § 1 because they have the potential unreasonably to exclude competitors or new entrants from a needed supply, or to allow one supplier to deprive other suppliers of a market for their goods." *Geneva Pharms. Tech. Corp. v. Barr Lab'ys Inc.*, 386 F.3d 485, 508 (2d Cir. 2004). Exclusive dealing is a § 1 violation "only when the agreement freezes out a significant fraction of buyers or sellers from the market." *Id.*

Exclusive dealing agreements may "have pro-competitive purposes and effects, such as assuring steady supply, affording protection against price fluctuations, reducing selling expenses, and promoting stable, long-term business relationships." *Id.* In analyzing the pro-competitive effects of these agreements, "courts must

take care to consider the competitive characteristics of the relevant market." *Id.*

### C. Section 2 of the Sherman Act

Under § 2 of the Sherman Act, it is unlawful to "monopolize, or attempt to monopolize . . . any part of the trade or commerce among the several States." 15 U.S.C. § 2. A claim brought under § 2 of the Sherman Act has two elements: "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Takeda Pharm. Co. Ltd.*, 11 F.4th 118, 137 (2d Cir. 2021) (quoting *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71, 86 S. Ct. 1698, 16 L. Ed. 2d 778 (1966)). "To safeguard the incentive to innovate, the possession of monopoly power will not be found unlawful unless it is accompanied by an element of anticompetitive *conduct." In re Adderall XR Antitrust Litig.*, 754 F.3d 128, 133 (2d Cir. 2014) (quoting *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407, 124 S. Ct. 872, 157 L. Ed. 2d 823 (2004)).

#### a. Monopoly Power

Monopoly power is "the power to control prices or exclude competition." *Geneva Pharms.*, 386 F.3d at 500 (quoting *United States v. E. I. du Pont de Nemours &*

*Co.*, 366 U.S. 316, 334, 81 S. Ct. 1243, 6 L. Ed. 2d 318 (1961)). Defendants with monopoly power have "the ability (1) to price substantially above the competitive level and (2) to persist in doing so for a significant period without erosion by new entry or expansion." *AD/SAT, Div. of Skylight, Inc. v. Associated Press*, 181 F.3d 216, 227 (2d Cir. 1999). A plaintiff can establish a defendant's monopoly power either "directly through evidence of control over prices or the exclusion of competition, or it may be inferred from a firm's large percentage share of the relevant market." *Geneva Pharms.*, 386 F.3d at 500.

"While market share is not the functional equivalent of monopoly power, it nevertheless is highly relevant to the determination of monopoly power." *Tops Markets, Inc. v. Quality Markets, Inc.*, 142 F.3d 90, 98 (2d Cir. 1998). As such, "defining a relevant market is generally a necessary component of analyzing a monopolization claim." *PepsiCo, Inc. v. Coca-Cola Co.*, 315 F.3d 101, 108 (2d Cir. 2002). "Once a relevant market is determined, the defendant's share in that market can be used as a proxy for market power." *Id.*

"The relevant market must be a market for particular products or services, the outer boundaries of which are determined by the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it." *US Airways, Inc. v. Sabre Holdings Corp.*, 938 F.3d 43, 64 (2d Cir. 2019) (quoting *Brown Shoe Co. v. United States*, 370 U.S. 294, 325, 82 S. Ct. 1502, 8 L. Ed. 2d 510 (1962)). "[A] single brand of a product or service may be a

relevant market under the Sherman Act if no substitute exists for that brand's products or services." *US Airways*, 938 F.3d at 66 (citation omitted). On the other hand, products "need not be identical" to exist in the same market. *AD/SAT*, 181 F.3d at 227. Pharmaceutical drugs that are "therapeutically equivalent" can nevertheless exist in separate markets. *Geneva Pharms*., 386 F.3d at 496. To define the boundaries of the relevant market, courts can look toward

> such practical indicia as industry or public recognition of the submarket as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors.

*US Airways*, 938 F.3d at 64 (quoting *Brown Shoe*, 370 U.S. at 325).

Courts will find sufficient cross-elasticity of demand if "consumers would respond to a slight increase in the price of one product by switching to another product." *Geneva Pharms*., 386 F.3d at 496. One of the tests that courts employ to discern the relevant market is the hypothetical monopolist test ("HMT"). Under that test, courts ask "[w]hether a hypothetical monopolist acting within the proposed market would be substantially constrained from increasing prices by the ability of customers to switch to other products." *United States v. Am. Express Co.*, 838 F.3d 179, 198-199 (2d Cir. 2016) (citation omitted).

> The Court implements the HMT by imagining that a hypothetical monopolist has imposed a small but significant non-transitory increase in price ("SSNIP") within the proposed market. If the hypothetical monopolist can impose this SSNIP without losing so many sales to other products as to render the SSNIP unprofitable, then the proposed market is the relevant market. By contrast, if consumers are able and inclined to switch away from the products in the proposed market in sufficiently high numbers to render the SSNIP unprofitable, then the proposed market definition is likely too narrow and should be expanded.

*Id.* at 199.

The Department of Justice and the FTC most often use a SSNIP of five percent. U.S. Dep't of Justice & Fed. Trade Comm'n, *Horizontal Merger Guidelines* § 4.1.2 (2010). Once the relevant market is established, courts have found that "a market share of over 70 percent is usually strong evidence of monopoly power." *Tops Markets*, 142 F.3d at 99.

### b. Anticompetitive Conduct

The second element of the monopolization claim "requires a plaintiff to establish that the defendant has engaged in improper conduct that has or is likely to have the effect of controlling prices or excluding competition." *Takeda*, 11 F.4th at 137 (citation omitted). "For there to be an antitrust violation, generics need

not be barred from all means of distribution if they are barred from the cost-efficient ones." *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 656 (2d Cir. 2015) ("*Actavis PLC*") (citation omitted).

"[O]nce a plaintiff establishes that a monopolist's conduct is anticompetitive or exclusionary, the monopolist may proffer nonpretextual procompetitive justifications for its conduct. The plaintiff may then either rebut those justifications or demonstrate that the anticompetitive harm outweighs the procompetitive benefit." *Actavis PLC*, 787 F.3d at 652 (citation omitted).

## II. Plaintiff States' Laws

Seven States have joined in this action. They are the States of New York, California, Ohio, Illinois, and North Carolina, and the Commonwealths of Pennsylvania and Virginia.

### A. New York

The New York Donnelly Act, New York's antitrust statute, declares illegal

> Every contract, agreement, arrangement or combination whereby . . . [c]ompetition or the free exercise of any activity in the conduct of any business, trade or commerce or in the furnishing of any service in this state is or may be restrained or whereby . . . for the purpose of establishing or maintaining any such monopoly or unlawfully interfering with the free exercise of any activity in the conduct of any

> business, trade or commerce or in the furnishing of any service in this state any business, trade or commerce or the furnishing of any service is or may be restrained.

N.Y. Gen. Bus. Law § 340(1). The New York Donnelly Act is "modeled after the Sherman Act and should generally be construed in light of Federal precedent." *Biocad JSC v. F. Hoffmann-La Roche*, 942 F.3d 88, 101 (2d Cir. 2019) (citation omitted).

Section 63(12) of the New York Executive Law authorizes the New York Attorney General to seek equitable relief. In relevant part, § 63 provides:

> Whenever any person shall engage in repeated fraudulent or illegal acts or otherwise demonstrate persistent fraud or illegality in the carrying on, conducting or transaction of business, the attorney general may apply . . . for an order enjoining the continuance of such business activity or of any fraudulent or illegal acts, [and] directing restitution and damages. . . . The term "persistent fraud" or "illegality" as used herein shall include continuance or carrying on of any fraudulent or illegal act or conduct. The term "repeated" as used herein shall include repetition of any separate and distinct fraudulent or illegal act, or conduct which affects more than one person.

N.Y. Exec. Law § 63(12).

"Any conduct which violates state or federal law or regulation is actionable" under Executive Law

§ 63(12). *People ex rel. Vacco v. World Interactive Gaming Corp.*, 185 Misc. 2d 852, 714 N.Y.S.2d 844, 848 (N.Y. Sup. Ct. 1999). When a defendant engages in conduct within New York prohibited by Executive Law § 63(12), the Attorney General is authorized to seek relief on behalf of out-of-state residents injured by the wrongdoing. *People ex rel. Cuomo v. H & R Block, Inc.*, 58 A.D.3d 415, 870 N.Y.S.2d 315, 316 (1st Dep't 2009); *see also Vyera*, 2021 U.S. Dist. LEXIS 183303, 2021 WL 4392481, at *4.

### B. California

The California Cartwright Act, Cal. Bus. & Prof. Code § 16700 et seq., prohibits "conspiracies or agreements in restraint or monopolization of trade." *Exxon Corp. v. Superior Ct.*, 51 Cal. App. 4th 1672, 60 Cal. Rptr. 2d 195, 200 (1997), *as modified on denial of reh'g* (Feb. 13, 1997). The analysis of claims brought under California's Cartwright Act "mirrors the analysis under federal law because the Cartwright Act . . . was modeled after the Sherman Act." *Cnty. of Tuolumne v. Sonora Cmty. Hosp.*, 236 F.3d 1148, 1160 (9th Cir. 2001) (citation omitted).

The California Unfair Competition Law prohibits "any unlawful, unfair or fraudulent business act or practice." Cal. Bus. & Prof. Code § 17200. In actions brought by the Attorney General, courts may "grant such mandatory injunctions as may be reasonably necessary to restore and preserve fair competition in the

trade or commerce affected by the violation." Cal. Bus. & Prof. Code § 16754.5.

### C. Illinois

The Illinois Antitrust Act ("IAA") instructs that "[w]hen the wording of this Act is identical or similar to that of a federal antitrust law, the courts of this State shall use the construction of the federal law by the federal courts as a guide in construing this Act." 740 Ill. Comp. Stat. 10/11. "Illinois courts interpret the state antitrust law in harmony with federal case law construing analogous provisions of federal legislation." *McGarry & McGarry, LLC v. Bankr. Mgmt. Sols., Inc.*, 937 F.3d 1056, 1062 (7th Cir. 2019) (citation omitted). Section 10/7(1) of the IAA authorizes the Illinois Attorney General to bring actions to prevent and restrain violations of § 3 of the IAA, and courts are directed to enter such judgment as they consider necessary to remove the effects of any such violations. 740 Ill. Comp. Stat. 10/7(1).

### D. North Carolina

Under the North Carolina Unfair or Deceptive Practices Act, N.C. Gen. Stat. § 75-1, "[e]very contract, combination in the form of trust or otherwise, or conspiracy in restraint of trade or commerce in the State of North Carolina is hereby declared to be illegal." N.C. Gen. Stat. § 75-1. The Attorney General is authorized to investigate "all corporations or persons doing business in this State . . . with the purpose of acquiring

such information as may be necessary to enable him to prosecute any such corporation, its agents, officers and employees for crime, or prosecute civil actions against them if he discovers they are liable and should be prosecuted." N.C. Gen. Stat. § 75-9.

### E. Ohio

The Ohio Valentine Act, Ohio Rev. Code Ann. § 133, is "patterned after the Sherman Antitrust Act, and as a consequence [Ohio's highest] court has interpreted the statutory language in light of federal judicial construction of the Sherman Act." *C. K. & J. K, Inc. v. Fairview Shopping Ctr. Corp.*, 63 Ohio St. 2d 201, 407 N.E.2d 507, 509 (Ohio 1980). "Ohio has long followed federal law in interpreting the Valentine Act." *Johnson v. Microsoft Corp.*, 106 Ohio St. 3d 278, 2005- Ohio 4985, 834 N.E.2d 791, 794-95 (Ohio 2005). The Ohio Attorney General has a duty to "do all things necessary" to enforce the antitrust laws, by bringing suits for "equitable relief." O.R.C. § 109.81.

### F. Pennsylvania

To establish a claim under Pennsylvania's common law doctrine against unreasonable restraint of trade, the plaintiff may show that "the illegal bargain tends to create or has for its purpose to create a monopoly in prices or products," or that "competition has in fact been restricted by the monopolistic agreement." *Collins v. Main Line Board of Realtors*, 452 Pa. 342, 304 A.2d 493, 496-97 (Pa. 1973). The Pennsylvania

Supreme Court has applied federal courts' interpretation of the Sherman Act to state common law antitrust claims. *See id.*

### G. Virginia

Virginia Code § 59.1-9.5 parallels § 1 of the Sherman Act and provides that "[e]very contract, combination or conspiracy in restraint of trade or commerce of this Commonwealth is unlawful." Section § 59.1-9.6 parallels § 2 of the Sherman Act and provides that "[e]very conspiracy, combination, or attempt to monopolize, or monopolization of, trade or commerce of this Commonwealth is unlawful." The Virginia Antitrust Act, Va. Code Ann. § 59.1 *et seq*, requires that the statute "shall be applied and construed to effectuate its general purposes in harmony with judicial interpretation of comparable federal statutory provisions." Va. Code Ann. § 59.1-9.17. The Virginia Attorney General may seek "injunctive relief" for violations of the Act. Virginia Code § 59.1-9.15(a).

## III. Liability

The Plaintiffs have shown that Shkreli is liable for Vyera's unreasonable restraint of trade and monopolization of the FDA-approved pyrimethamine market in violation of §§ 1 and 2 of the Sherman Act. His conduct also violated the competition laws of each of the Plaintiff States.

Shkreli's anticompetitive scheme was made up of two simple but effective sets of vertical restraints.[35] Shkreli does not dispute that it was his intention to impede generic pharmaceutical companies from launching competitive products that would threaten the price of Daraprim. The Plaintiffs have shown that the restraints Vyera implemented succeeded in doing just that.

The two restraints—restrictive distribution contracts for Daraprim and exclusive supply agreements for pyrimethamine—exploited features of the FDA approval process for generic drug products by unreasonably and unlawfully restricting the markets for RLD and API. These agreements violated § 1 of the Sherman Act. Through these agreements, Shkreli and Vyera unlawfully and willfully maintained a monopoly in FDA-approved pyrimethamine, which is the relevant market in which Shkreli and Vyera operated their anticompetitive scheme. Vyera maintained that monopoly through anticompetitive conduct and not "from growth or development as a consequence of a superior

[35] The Plaintiffs proved at trial that separate provisions in Vyera's contracts with Distributors were intended to impede the entry of generic drug companies into the FDA-approved pyrimethamine market by depriving those companies of accurate information about Daraprim sales. Through these data-blocking provisions, Distributors agreed not to provide Daraprim sales data to data aggregators such as IQVIA, Symphony Health, and Wolters Kluwer. Because the absence of this normally available market data did not impede the entry of either Cerovene or Fera, the data-blocking scheme need not be further described. The Cerovene and Fera experiences are central to the calculation of the disgorgement the State Plaintiffs seek.

product, business acumen, or historic accident." *Takeda*, 11 F.4th at 137 (citation omitted).

### B. The Relevant Market

The analysis under §§ 1 and 2 of the Sherman Act relies, as a threshold matter, on the definition of the relevant market. The Plaintiffs have proven that, by any established method, FDA-approved pyrimethamine is the relevant product market and the United States is the relevant geographic market. Shkreli does not dispute that the United States is the relevant geographic market.

Apart from a generic equivalent to Daraprim that receives FDA approval, no reasonably interchangeable substitute for Daraprim exists for the treatment of toxoplasmosis. This is true in terms of both the use of Daraprim to treat toxoplasmosis, particularly active toxoplasma encephalitis, as well as the cross-elasticity of demand for FDA-approved pyrimethamine for treatment of that disease.

In terms of its use, Daraprim is the only pharmaceutical to receive an A-I rating in the Guidelines for the treatment of active toxoplasma encephalitis. It has many unique features. Among other qualities, FDA-approved pyrimethamine targets toxoplasmosis specifically, has been successfully used in its treatment for decades, and permits a diagnosis of toxoplasma encephalitis without resort to a biopsy of the brain, which would present significant risks to patients if performed. Because death and/or significant brain

damage can occur within hours, its endorsement in the Guidelines assists physicians throughout the United States to treat a highly dangerous infection with confidence, quickly, and successfully.

An analysis of the cross-elasticity of demand for FDA-approved pyrimethamine confirms this definition of the relevant market. Even in response to Vyera's drastic price hike in August 2015, appreciable numbers of physicians and their patients continued to use Daraprim. Vyera was profitably able to keep Daraprim's list price at $750 per tablet and maintain a high average net price for the drug for the four years and seven months that it marketed Daraprim without generic competition. The average net price was very substantially above the competitive price level, whether that level is measured by Daraprim's price in the years before Vyera acquired it, or in the period after its first generic competitor entered the market. As more generic competitors enter the market, of course, the average net price will fall even further.

The high degree of cross-elasticity in demand between Daraprim and FDA-approved generic pyrimethamine is demonstrated as well by the market reaction to Dr. Reddy's March 2020 launch of its first-to-market generic. In the period following that launch, both the price and sales of Daraprim (as well as Vyera's revenue and profits) promptly declined as Dr. Reddy's generic tablet was substituted for Daraprim. Daraprim sales dropped 49% in the nine-month period after March 2020 compared to the same period prior to

entry, and Vyera's revenue and gross profits from Daraprim sales declined 59% between 2019 and 2020.

Finally, practical indicia of the relevant market support a finding that it is FDA-approved pyrimethamine. Shkreli and Vyera considered that to be the relevant market, as did Vyera's consultants and those the consultants interviewed. Generic drug companies also assessed the relevant market to be FDA-approved pyrimethamine. There is no evidence that the price hike for Daraprim affected the prices of any other pharmaceutical. Lastly, FDA-approved pyrimethamine is the only FDA-approved drug that specifically targets toxoplasmosis.

In response to this cascade of evidence that FDA-approved pyrimethamine is the relevant product market, Shkreli argues that drug therapies trimethoprim-sulfamethoxazole ("TMP-SMX") and compounded pyrimethamine are sufficient economic and medical substitutes for Daraprim and that they must be included in the relevant antitrust market. These therapies are not part of the relevant market.

TMP-SMX is a broad-spectrum antibiotic medication approved by the FDA in 1973 and sold under the brand names Bactrim and Septra. TMP-SMX is FDA-approved to treat certain infections, including pneumocystis jirovecii pneumonia ("PCP"). It is also available as a generic. Although TMP-SMX is not FDA-approved to treat toxoplasmosis, a fact that Vyera itself emphasized to the market, it is prescribed in certain circumstances.

TMP-SMX is an effective prophylactic treatment because it has been effective at preventing multiple opportunistic infections that tend to occur together. For example, TMP-SMX is the recommended medication as primary prophylaxis for PCP, and patients at risk for toxoplasma encephalitis but who are not suffering from an acute infection of the brain are also at risk for PCP. These patients are often prescribed TMP-SMX medications to prevent both infections and reduce the "pill burden" for patients. For this reason, TMP-SMX is also effective at the secondary prophylaxis stage, in which the goal is to prevent a relapse in a patient that has recovered from an active infection. TMP-SMX, which may be administered intravenously, is a recommended alternative treatment when a patient is incapable of swallowing pills; pyrimethamine may only be taken orally.

The most difficult stage in treating toxoplasmosis, however, is an active infection. At that point the treatment goal is to medicate the patient within hours of presenting symptoms. A pyrimethamine treatment regimen is the gold standard treatment in the case of an acute infection of toxoplasmosis. Even Vyera's Dr. Salinas viewed TMP-SMX as "medically inferior" because not enough of the drug reaches the brain or the retina (in the case of ocular toxoplasmosis) to treat an infection properly. Studies have shown that TMP-SMX is 25-to 50-times less potent than pyrimethamine. In the Guidelines, TMP-SMX is graded B-I for the treatment of toxoplasma encephalitis and recommended only "if pyrimethamine is unavailable or there is a

delay in obtaining it." As a broad-spectrum antibiotic, TMP-SMX also cannot be reliably used to confirm the diagnoses of toxoplasma encephalitis, while pyrimethamine aids in diagnosis because it is targeted to treat toxoplasmosis. Finally, TMP-SMX cannot be taken by patients with a sulfa hypersensitivity or allergy, which constitutes roughly 30-35% of all HIV-positive patients.[36]

The other therapy suggested by Shkreli as a potential substitute for Daraprim is compounded pyrimethamine, which two specialty pharmacies began selling in 2015. Compounding contains no assurance that the end product will deliver the correct amount of the API, and compounded products are not FDA-approved.

Vyera itself objected to the mass production of compounded drugs as dangerous. On November 30, 2015, Vyera warned the FDA that Imprimis, a compounding pharmacy, intended to mass produce compounded pyrimethamine. Vyera objected that

[36] Although Shkreli made no developed argument regarding this third alternative treatment, Shkreli suggests that atovaquone was another therapeutic alternative to Daraprim for the treatment of toxoplasmosis. Atovaquone is an FDA-approved antimicrobial drug for treatment of PCP and is prescribed for patients who cannot tolerate TMP-SMX. The Guidelines give atovaquone a C-III grade for primary prophylaxis of toxoplasmosis and a B-II grade as an alternative treatment for active toxoplasma encephalitis. Shkreli has not shown that atovaquone was either therapeutically or economically substitutable with Daraprim.

> [c]ompounded drugs can pose serious health risks to patients. Compounded drugs are not FDA-approved. There is no FDA premarket review. No data and information are required to demonstrate a compounded drug is safe and effective for its intended purposes. . . . Compounding large volumes of drugs without obtaining FDA approval, which Imprimis apparently intends to do, circumvents important public health requirements. As a result, it is not appropriate to use a compounded product in lieu of an FDA approved, commercially available product unless the compounded drug provides a medically necessary and unavailable drug for a specific patient.

Vyera's alarm that compounded pyrimethamine sales might eat into Daraprim sales was unfounded. Despite compounded pyrimethamine capsules being priced at $1 to $5, there were never significant sales of the compounded drug produced by Imprimis. The only way a patient could get Imprimis' compounded pyrimethamine product was with a specific prescription for that product, which did not permit *en masse* market substitution. Imprimis sold fewer than 22,000 compounded pyrimethamine capsules in 2016, and its sales declined thereafter. Avella, another compounding pharmacy, sold a total of 1,280 compounded pyrimethamine capsules, with no sales after 2018 due to a lack of customers.

Shkreli has pointed out that demand for Daraprim, represented by sales volume, dropped precipitously immediately after the 2015 price hike. The

defendant suggests that consumers must have substituted alternative therapies for Daraprim. None of the parties have offered comparative data regarding TMP-SMX to support or contradict that hypothesis. It would be difficult to draw any conclusions from TMP-SMX data in any event because it is a broad-spectrum antibiotic prescribed for multiple infectious diseases. Sales of mass-production compounded pyrimethamine during the period of Vyera's sale of Daraprim were minimal at best. What can be said with certainty is that the market for FDA-approved pyrimethamine was sufficiently bound that Vyera was able to raise Daraprim's price to never before seen heights and earn record revenues and profits after doing so.

The practical indicia enumerated in *Brown Shoe* and the other evidence described above strongly support the conclusion that doctors and pharmaceutical buyers did not react to the astronomical rise in Daraprim's price by freely switching to other, cheaper drugs to treat toxoplasmosis. The demand for FDA-approved pyrimethamine remained relatively stable at approximately 250,000 tablets per year between 2016 and 2019 after the initial drop in sales in 2015. If there had been any material cross-price elasticity between Daraprim and other products at the time of the 4,000% price hike in 2015, purchasers would have abandoned Daraprim in favor of cheaper products on the market. And if alternative toxoplasmosis treatments had been constraining the price of Daraprim before March 2020, generic entry would not have resulted in the significant

drop in the price for FDA-approved pyrimethamine that occurred.

In sum, as a result of its distinctive attributes, FDA-approved pyrimethamine constitutes the relevant market. It treats a distinct patient population; in economic terms, it has a distinct kind of customer.

### C. Monopoly Power

Having defined the relevant market, the conclusion that Vyera had a monopoly in that market follows easily. Vyera controlled 100% of the market for FDA-approved pyrimethamine market between August 2015 and March 2020. Shkreli controlled the price of Daraprim, which he acquired precisely because it was a sole-source drug in a market of its own. Vyera profitably charged a per-tablet average net price for Daraprim ranging between $228 and $305 during the full years of 2016, 2017, 2018, and 2019. These prices were also substantially above any competitive price level, which was at most $160.[37]

[37] To arrive at a figure of $160, the Plaintiffs' economic expert Hemphill observed the average net price of Daraprim, Dr. Reddy's generic pyrimethamine, and the Vyera AG tablet for a sustained period after Dr. Reddy's generic pyrimethamine entered the market. The real-world evidence of Daraprim's price, volume, and market share after Dr. Reddy's entry in March 2020 starkly demonstrates not only that Vyera had a monopoly over Daraprim, but also that the high price maintained in that monopoly depended entirely on the absence of competition.

### D. Anticompetitive Conduct

The Plaintiffs have met their burden under § 1 of the Sherman Act of showing that the contracts at issue here were an unreasonable restraint on trade and had an adverse effect on competition. In response, Shkreli has not shown that the contracts had procompetitive benefits.

Shkreli does not dispute that he intended to block generic competition to Daraprim and strove to do so for as long as possible. Each of the API supply agreements and the restrictive distribution agreements was entered in service of that strategy. Similarly, Vyera's continued monopolistic control of the FDA-approved pyrimethamine market did not occur by accident and self-evidently harmed competition. Shkreli raised the price of Daraprim by 4,000%. Over more than four years, the average net price of a single Daraprim tablet remained hundreds of dollars. Its price did not meaningfully decline until Dr. Reddy's generic pyrimethamine penetrated the market barriers Vyera had erected.

#### a. Distribution Contracts

Vyera's restrictions in its distribution contracts substantially delayed generic pharmaceutical companies from acquiring sufficient RLD to conduct BE testing and receive FDA approval of their ANDAs. Those restrictions included class of trade restrictions and caps on the number of bottles that could be sold to a customer. Vyera drastically reduced the number of customers to which its distributors were authorized to

sell. Vyera monitored distributors' sales closely to ensure there was no leakage. It repurchased inventory and conducted audits to learn where every bottle of Daraprim was heading. Vyera's Mulleady even went to a parking lot in New Jersey to buy back five bottles of Daraprim, paying twice the purchase price, to prevent those bottles from going to a generic pharmaceutical company.

This extraordinarily tight control of the supply of Daraprim had its intended effect. It actually delayed the entry of generic pharmaceutical companies.

Vyera paid a sizeable premium to its downstream partners to keep Daraprim RLD out of the hands of its competitors. Those partners agreed to and enforced the resale restrictions, and in doing so benefitted significantly. They profited handsomely with each sale so long as Daraprim's price remained inflated.

All of Shkreli's purportedly procompetitive justifications for these distribution agreements are pretextual. He has argued that putting Daraprim in specialty distribution benefitted patients by giving them access to services that specialty pharmacies can provide. These purported benefits include advice on defraying the high cost of the drug, assistance in getting insurance coverage, and help reducing and monitoring adverse effects.

Shkreli offered no evidence, however, that patients were assisted in any of these ways. Patients didn't need help figuring out how to pay for Daraprim, of course, until Shkreli raised its price to a scandalous level and

put his anticompetitive scheme in place to protect that price. And there is no evidence that FDA-approved pyrimethamine has any serious side effects, much less side effects that could be or were addressed by any specialty pharmacy. Specialty pharmacies and closed distribution are tailor-made for the administration and monitoring of drugs that have an altogether different profile from that of Daraprim. For decades Daraprim was administered safely and without problems through open distribution, and both Dr. Reddy's and Vyera's own generic entrant, the Vyera AG, returned to the open distribution model. In sum, Shkreli has failed to justify his choice of a closed distribution system. It was designed and used solely to restrict competition.

**b. Exclusive Supply Agreements**

Vyera's agreements with Fukuzyu and RL Fine closed off access to the two most viable suppliers of pyrimethamine for years. Vyera's exclusive supply agreements achieved their intended effect and delayed the entry of generic pyrimethamine into the market.

While the pyrimethamine manufacturing process is relatively simple, it still takes time and money to design the process, set it up, and test it. Shut out of access to Fukuzyu's and then RL Fine's API, Fera, Cerovene, and InvaTech were required to undertake a time-consuming and costly journey to develop alternative API manufacturers. Other than a desire to block

competition, there was no reason to tie either Fukuzyu or RL Fine to exclusive supply agreements.

Fukuzyu had provided pyrimethamine for Daraprim in the United States without any exclusive supply agreement, and at times without any supply agreement at all, to Vyera's predecessors. Shkreli decided to change that. After months of courting, Vyera and Fukuzyu entered into an exclusive supply agreement in January 2017. In October 2016, the same month that Vyera's science executives visited Fukuzyu in Japan, Fukuzyu upset Cerovene's plans and refused to supply it with pyrimethamine. In September of 2017, Fukuzyu refused to supply Fera with pyrimethamine in a message that repeated, word-for-word, the restrictions against human use in the United States that Vyera's Pelliccione relayed to Fukuzyu.

Vyera's agreement with RL Fine had a similarly anticompetitive purpose and effect. Vyera had no need for any agreement at all with RL Fine. Learning that generic competitors were working with RL Fine to obtain pyrimethamine, however, Vyera entered into an exclusive supply agreement with RL Fine on December 17, 2017. Vyera's pursuit of this agreement had the immediate effect of disrupting and delaying Cerovene's and InvaTech's ANDA approval process. Vyera paid millions of dollars to RL Fine for the sole purpose of blocking its rivals from access to RL Fine's pyrimethamine. The Phoenixus Board Minutes of December 2017 justified the expense in these very terms. Witness after witness from Vyera has confirmed as much.

The impact on competitors was immediate. In November 2016, Cerovene had entered a five-year exclusive supply agreement with RL Fine. In the months that followed, Cerovene invested heavily first to support RL Fine filing a DMF and then, switching its plans, to support Cerovene itself incorporating the RL Fine manufacturing information and data within its own ANDA. Cerovene amended its ANDA in April 2017 to list RL Fine as its API supplier. But, on November 30, 2017—five days after Vyera and RL Fine reached an agreement in principle—RL Fine reneged on its contract with Cerovene and refused to supply pyrimethamine or cooperate further on a Cerovene pyrimethamine ANDA. RL Fine stopped cooperating as well with InvaTech in the Fall of 2017, preventing InvaTech from responding to the FDA's questions about RL Fine's API and requiring InvaTech to begin from scratch and develop a new supplier.

Shkreli's attempt to justify the exclusivity provisions in these two agreements fail. He relies on the following procompetitive justifications: that the agreements ensured a steady supply of pyrimethamine and, in the case of Fukuzyu, promoted a long-term business relationship. Shkreli contends that the exclusivity clauses thus mitigated Vyera's supply risk. Neither contract did so.

Shkreli has offered no evidence that any manufacturer of Daraprim had ever been unable to obtain pyrimethamine from Fukuzyu. Moreover, Vyera's contract with Fukuzyu contained no provision that protected it against the risk that Fukuzyu might be

unable to supply Vyera with FDA-approved pyrimethamine. For example, it contained no provision requiring Fukuzyu to maintain cGMPs-compliant facilities, to ensure the purity of its API, or to keep an active DMF. It did not even require Fukuzyu to fill Vyera's orders for pyrimethamine. There is nothing in the agreement that prevented Fukuzyu from selling its entire inventory of pyrimethamine to others for use outside the United States or for the treatment of animals in the United States.

There are standard provisions that protect against the risk of a loss of supply. Those provisions were absent in the Vyera contracts, but tellingly, were present in the GSK contract with Fukuzyu. Those provisions include clauses addressed to the forecasting of requirements, customer priority, reserve capacity, and firm order dates.

Moreover, while it may be common for companies to enter into exclusive supply agreements with API manufacturers when a company has invested time and money with that manufacturer to develop a new API manufacturing process, there was no such justification here. Fukuzyu already had a DMF on file and had been supplying pyrimethamine for Daraprim for decades.

Shkreli suggests that its contract with Fukuzyu was motivated by a desire to build a long-term relationship for future toxoplasmosis products. Dr. Salinas testified that Vyera has even filed INDs for some of these nascent projects. While Vyera may have used its promise of future projects to entice Fukuzyu during

the contract negotiations, Shkreli has failed to explain the relevance of those projects to his desire to include a pyrimethamine exclusivity clause in the contract. The exclusivity clause had only one purpose, to eliminate competition with Daraprim.

Shkreli's justification for the RL Fine contract fails entirely. Shkreli asserts that it is common in the pharmaceutical industry to have a backup supplier. But, Vyera has failed to offer any evidence that either Vyera or any of its predecessors ever needed a backup supplier of pyrimethamine. Vyera didn't even pursue a contract with RL Fine until it learned that RL Fine was going to supply generic drug companies with pyrimethamine.

Moreover, Vyera's contract with RL Fine did not ensure that RL Fine could operate as a backup supplier if Vyera ever needed it to do so. The contract did not require RL Fine to file a DMF and RL Fine never did. Nor did the contract require RL Fine to do anything to support Vyera if Vyera amended Daraprim's NDA to include RL Fine's manufacturing process. Instead, during the life of the contract, Vyera paid RL Fine almost $9.5 million to do nothing except stop cooperating with Vyera's competitors. To put this outlay in perspective, through March 2019, Vyera spent only $500,000 buying pyrimethamine from Fukuzyu.

Finally, Shkreli highlights the fact that the exclusive supply agreements were not executed until a date after each supplier refused to supply each generic company. Sophisticated contracts are not executed on the

same day they are negotiated. The evidence is overwhelming that Fukuzyu and RL Fine stopped cooperating with generic drug companies who wanted to enter the U.S. market because they were negotiating exclusive supply contracts with Vyera that they considered to be more attractive. The incentives that Vyera offered to RL Fine were so enticing that it even stopped performing on its five-year contract with Cerovene.

### c. Degree of Burden on Generic Competitors

Finally, Shkreli argues that the plaintiffs failed to establish that the contracts had a substantial anticompetitive effect in the relevant market. Relying on *Ohio v. American Express Co.*, 138 S. Ct. 2274, 2284, 201 L. Ed. 2d 678 (2018) ("*American Express*"), he emphasizes that it is the Plaintiffs' burden to show a "substantial" anticompetitive effect from his activities and that they have failed to do so. Shkreli contends that, whatever his intent may have been, the generic manufacturers made a series of bad business decisions and were unwilling to spend the money necessary to enter the market faster. Shkreli principally points to occasions on which Fera or Cerovene did not accept an offer by an RLD supplier to find more bottles of Daraprim for them.

Shkreli did not actually prove at trial that RLD suppliers were able to acquire more bottles of Daraprim for generic pharmaceutical companies after

Vyera set up its closed distribution system. To the contrary, RLD suppliers struggled to fill orders for Daraprim. And, when Reliant used its personal connection to a pharmacy to circumvent Vyera's closed distribution system and succeeded in obtaining five bottles of Daraprim, Mulleady rushed to buy those bottles back and paid twice their purchase price to do so.

Shkreli similarly argues that Vyera's competitors foolishly pursued doomed requests to the FDA to modify BE testing requirements, and in doing so lost precious time waiting for waivers that never came. He argues that it was their flawed tactics and not his restrictive agreements that were responsible for the delays that occurred here. He is wrong.

The Plaintiffs proved that Shkreli's actions had a very substantial impact on competition. Under § 1, the Plaintiffs may show the existence of anticompetitive effects from restraints on trade through direct evidence of increased prices in the relevant market, which they have done. *See 1-800 Contacts*, 1 F.4th at 118. Under the rule of reason test, the Plaintiffs have the burden of showing an "actual adverse effect on competition as a whole in the relevant market." *Id.* at 114. Under § 2, the Plaintiffs must show that Shkreli's improper conduct "has or is likely to have the effect of controlling prices or excluding competition." *Takeda*, 11 F.4th at 137 (citation omitted). The Plaintiffs have more than carried each of these burdens.

Shkreli's reliance on *American Express* is misplaced. The holding in that case turned on whether the

plaintiffs' direct evidence of price increases on just one side of the two-sided credit card transaction market demonstrated any anticompetitive effect at all. *American Express*, 138 S. Ct. at 2287.

More importantly, *American Express*' unremarkable statement of the law did not revise the longstanding rule of reason test in antitrust cases. As the Supreme Court has explained, the rule of reason steps

> do not represent a rote checklist, nor may they be employed as an inflexible substitute for careful analysis. . . . [W]hat is required to assess whether a challenged restraint harms competition can vary depending on the circumstances. The whole point of the rule of reason is to furnish an enquiry meet for the case, looking to the circumstances, details, and logic of a restraint to ensure that it unduly harms competition before a court declares it unlawful.

*Nat'l Collegiate Athletic Ass'n v. Alston*, 141 S. Ct. 2141, 2160, 210 L. Ed. 2d 314 (2021) (citation omitted). Even under Shkreli's rigid view of the law, Shkreli's Daraprim scheme substantially impacted competition in the market for FDA-approved pyrimethamine.

Generic drug companies need not undertake herculean efforts to overcome significant anticompetitive barriers specifically erected to prevent their entry into a market. It bears repeating that "generics need not be barred from all means of distribution if they are barred from the cost-efficient ones." *Actavis PLC*, 787 F.3d at 656 (citation omitted). "The test is not total foreclosure,

but rather whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit." *Id.* While exclusive supply and restrictive distribution agreements are not inherently unlawful, here their sole purpose and effect was to foreclose generic pharmaceutical companies from acquiring the API and RLD that would have otherwise been readily available to them in the ordinary course and that were critical to their efforts to compete with Vyera.

### E. Shkreli is Individually Liable

An individual may be held liable under the Sherman Act to the extent that the individual has "participated in violations of" the antitrust laws, such as by "negotiating, voting for[,] or executing agreements which constituted steps in the progress of the conspiracy." *Hartford-Empire Co. v. United States*, 323 U.S. 386, 407, 65 S. Ct. 373, 89 L. Ed. 322, 1945 Dec. Comm'r Pat. 607 (1945); *see also Lorain Journal Co. v. United States*, 342 U.S. 143, 145 n.2, 72 S. Ct. 181, 96 L. Ed. 162 (1951) (officers and directors "participated in the conduct alleged to constitute the attempt to monopolize").

Shkreli is liable for the violations of §§ 1 and 2 of the Sherman Act and the parallel violations of state law. Shkreli conceived of, implemented, maintained, and controlled Vyera's anticompetitive and monopolistic scheme. His control continued after he stepped down as Vyera's CEO and even after he entered federal

prison. As the company's largest shareholder, he freely changed its management and directed its policy.

Shkreli pioneered Vyera's business model at Retrophin and brought many of Retrophin's employees with him to replicate the "classic closed distribution play" at Vyera. Shkreli frankly and repeatedly acknowledged that his goal was to delay entry of a generic competitor with Daraprim for at least three years. He then planned, managed, and controlled the execution of his scheme. He erected and policed barriers around the FDA-approved pyrimethamine market in order to maintain a monopoly price for Daraprim.

Shkreli emphasizes that he did not sign any of the contracts at issue. The absence of his signature from a document does not immunize him from antitrust liability.

Shkreli argues that after December 2015 he was no longer a Vyera executive and that his ability to influence Vyera's operations was severely restricted after he was imprisoned in September 2017. The Plaintiffs have shown that Vyera remained under Shkreli's control throughout the years it maintained its monopoly on FDA-approved Daraprim. Even when incarcerated, Shkreli managed to direct its policies and choose Vyera's executives. Whether he used a smuggled phone or the prison's authorized phones, he stayed in touch with Vyera's management and exercised his power over Vyera as its largest shareholder.

## IV. Remedies

The Plaintiffs seek injunctive relief and the State Plaintiffs seek disgorgement. They have shown that Shkreli should be banned for life from the pharmaceutical industry and required to pay $64.6 million in disgorgement.

### A. Injunctive Relief

Section 13(b) of the FTC Act authorizes the FTC to pursue permanent injunctive relief in federal court only "in proper cases . . . and after proper proof." 15 U.S.C. § 53(b). Plaintiffs must prove an ongoing or likely future violation of the antitrust laws and that injunctive relief will not only remedy that violation but also "be in the interest of the public." *Id.* § 53(b)(1)-(2).

A permanent injunction is appropriate where a plaintiff shows that

> there exists some cognizable danger of recurrent violation, something more than the mere possibility which serves to keep the case alive. . . . To be considered are the bona fides of the expressed intent to comply, the effectiveness of the discontinuance and, in some cases, the character of the past violations.

*United States v. W.T. Grant Co.*, 345 U.S. 629, 633, 73 S. Ct. 894, 97 L. Ed. 1303 (1953) (Clayton Act).

To assess the likelihood of recurrence, courts consider

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

*Sec. & Exch. Comm'n v. Commonwealth Chem. Sec., Inc.*, 574 F.2d 90, 100 (2d Cir. 1978).

In assessing whether to issue injunctive relief, a court balances the equities and considers the public interest. *E.E.O.C. v. KarenKim, Inc.*, 698 F.3d 92, 100 (2d Cir. 2012). "A Government plaintiff, unlike a private plaintiff, must seek to obtain relief necessary to protect the public from *further* anticompetitive conduct and to redress anticompetitive harm." *Apple*, 791 F.3d at 339 (quoting *F. Hoffmann-La Roche Ltd. v. Empagran S.A.*, 542 U.S. 155, 170, 124 S. Ct. 2359, 159 L. Ed. 2d 226 (2004)). "The district court has large discretion to model its judgments to fit the exigencies of the particular case and all doubts about the remedy are to be resolved in the Government's favor." *Id.* (quoting *E. I. du Pont de Nemours & Co.*, 366 U.S. at 334).

In New York, pursuant to the Donnelly Act, the Attorney General may seek and obtain an order on behalf of the State "to restrain and prevent the doing in this state of any act herein declared to be illegal, or any act in, toward or for the making or consummation of any contract, agreement, arrangement or combination

herein prohibited." N.Y. Gen. Bus. Law § 342. Pursuant to § 63(12) of the Executive Law, New York may seek "an order enjoining the continuance of [illegal or fraudulent] business activity or of any fraudulent or illegal acts." N.Y. Exec. Law § 63(12). Upon finding a violation under Executive Law § 63(12), a court may exercise its discretion to issue a permanent and plenary ban in a particular industry. *See*, *e.g.*, *People v. Imported Quality Guard Dogs, Inc.*, 88 A.D.3d 800, 930 N.Y.S.2d 906, 907 (2nd Dep't 2011) (permanently enjoining the appellant "from selling, breeding, or training dogs, or advertising or soliciting the sale, breeding, or training of dogs").

The Plaintiffs seek a lifetime ban against Shkreli participating in the pharmaceutical industry.[38] Banning an individual from an entire industry and limiting his future capacity to make a living in that field is a serious remedy and must be done with care and only if equity demands. Shkreli's egregious, deliberate, repetitive, long-running, and ultimately dangerous illegal conduct warrants imposition of an injunction of this scope.

The Plaintiffs presented a wealth of evidence that Shkreli conducted a comprehensive scheme that violated the antitrust laws of the United States and the competition laws of the seven States. The FTC and the States are empowered by federal and State law to seek comprehensive equitable relief. The Plaintiffs have

[38] In their memorandum, filed with the Pretrial Order, the Plaintiffs requested that Shkreli be banned for twenty years from the pharmaceutical industry.

demonstrated that a lifetime ban against Shkreli's future participation in the pharmaceutical industry will protect the public from suffering a repetition of the unlawful schemes proven in this case.

Without a lifetime ban, there is a real danger that Shkreli will engage in anticompetitive conduct within the pharmaceutical industry again. Shkreli established two companies, Retrophin and Vyera, with the same anticompetitive business model: Acquiring sole-source drugs for rare diseases so that he could profit from a monopolist scheme on the backs of a dependent population of pharmaceutical distributors, healthcare providers, and the patients who needed the drugs. The Daraprim scheme was particularly heartless and coercive. Daraprim must be administered within hours to those suffering from active toxoplasma encephalitis.

Moreover, 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.

The context in which Shkreli conducted his schemes cannot be ignored. He cynically took advantage of the requirements of a federal 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. He recklessly disregarded the health of a particularly vulnerable population, those with compromised immune systems. His scheme burdened those patients, their loved ones, and their healthcare providers.

A lifetime ban would not deprive Shkreli of the opportunity to practice a profession or to exercise a lawful skill for which he trained. In his trial testimony Shkreli does not even express a clear desire to return to the pharmaceutical industry. He reports that he is considering pursuing opportunities "within and outside" the pharmaceutical industry upon his release from prison.

The risk of a recurrence here is real. Shkreli has not expressed remorse or any awareness that his actions violated the law. While he takes full responsibility in his direct testimony for the increase of Daraprim's price from $17.50 to $750 per pill, he denies responsibility for virtually anything else. He argues in his testimony that he is not responsible for Vyera's anticompetitive contracts because he did not negotiate or sign the exclusive supply agreements or the restrictive distribution agreements. He has also denied that what happened here was egregious, arguing that the Plaintiffs have not proven that any patient died due to the price he set for Daraprim. He chose to not even attend the trial.

Shkreli presents several legal arguments against a lifetime industry ban. He contends that it amounts to a penalty beyond the proper scope of a court's power in equity. He argues that an industry ban is uncommon and reserved only for the most egregious cases and for cases of fraud. He argues that a ban of this scope is not narrowly tailored to match the challenged conduct. For the reasons laid out above, these arguments are unavailing. This is an egregious case; death is not the only

relevant metric. If 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 well-being has been adequately weighed.

Shkreli appears to suggest that any injunction could be limited to banning him from acquiring commercial assets or engaging in the "day-to-day affairs of commercializing medicine." There is no reason to believe that a narrowly crafted injunction will succeed in providing adequate protection against a repetition of illegal conduct. Shkreli has demonstrated that he can and will adapt to restrictions. With help at times from a contraband phone, Shkreli managed to control his company even from federal prison.

Shkreli's anticompetitive conduct at the expense of the public health was flagrant and reckless. He is unrepentant. Barring him from the opportunity to repeat that conduct is nothing if not in the interest of justice. "If not now, when?" *Mishnah, Pirkei Avot* 1:14.

### B. Disgorgement

The State Plaintiffs seek disgorgement in the amount of $64.6 million to return to victims nationwide.[39] Disgorgement is "a remedy tethered to a wrongdoer's net unlawful profits" and "has been a mainstay of equity courts." *Liu v. Sec. & Exch. Comm'n*, 140 S. Ct.

[39] The FTC is precluded from seeking disgorgement. *Vyera*, 2021 U.S. Dist. LEXIS 183303, 2021 WL 4392481, at *2.

1936, 1943, 207 L. Ed. 2d 401 (2020). "The district court has broad discretion not only in determining whether or not to order disgorgement but also in calculating the amount to be disgorged." *S.E.C. v. First Jersey Sec., Inc.*, 101 F.3d 1450, 1474-75 (2d Cir. 1996) (federal securities laws violations). "The amount of disgorgement ordered need only be a reasonable approximation of profits causally connected to the violation. . . . So long as the measure of disgorgement is reasonable, any risk of uncertainty should fall on the wrongdoer whose illegal conduct created that uncertainty." *S.E.C. v. Razmilovic*, 738 F.3d 14, 31 (2d Cir. 2013), *as amended* (Nov. 26, 2013).

The Second Circuit has "adopted a two-step burden-shifting framework for calculating equitable monetary relief. That framework requires a court to look first to the [plaintiff] to show that its calculations reasonably approximated the amount of the defendants' unjust gains and then shift the burden to the defendants to show that those figures were inaccurate." *Fed. Trade Comm'n v. Moses*, 913 F.3d 297, 310 (2d Cir. 2019) (citation omitted).

New York Executive Law § 63(12) empowers the New York Attorney General to disgorge unlawfully gained profits wherever they were derived. *Vyera*, 2021 U.S. Dist. LEXIS 183303, 2021 WL 4392481, at *4. Contrary to Shkreli's contention, there is no legal distinction between equitable monetary remedies available for fraudulent conduct and other illegal conduct occurring in the State of New York. The Plaintiffs have shown that the anticompetitive conduct in this case is

at least as egregious in terms of its willfulness and harm to victims as the frauds typically subject to this equitable remedy under § 63(12).

The excess profits that Vyera gained from its sales of Daraprim amount, conservatively, to $64.6 million and must be disgorged to the States, subject to a set-off of any amount paid by the settling defendants. Shkreli is liable for this relief.

In arriving at this amount, a threshold determination is the hypothetical date or dates on which generic drug companies would have entered the market but-for Vyera's anticompetitive conduct. Here, the evidence is sufficiently robust to select those dates for two competitors, Cerovene and Fera. The record is insufficiently developed regarding the three other competitors who have entered or tried to enter the market.

**a. Cerovene and Dr. Reddy's Hypothetical Entry Date**

Cerovene's president Shah estimates that his company's FDA-approved generic pyrimethamine tablet, which entered the market in March of 2020, would have entered the market in September of 2017 if Cerovene had had unfettered access to Fukuzyu's API and the RLD. This is a thirty-month delay. This estimate was unchallenged at trial.

Plaintiff's economic expert Hemphill calculated Vyera's excess profits using two alternative hypothetical entry dates for Cerovene: October 2018 and

December 2018. The October 2018 entry date is an extremely conservative date on which to base the calculations, and is adopted for the calculation of excess profits. The difference between October 2018 and March 2020 represents an eighteen-month delay.

### b. Fera's Hypothetical Entry Date

Fera's DellaFera estimates that his FDA-approved pyrimethamine tablet, which entered the market soon after it received FDA approval in July of 2021, would have entered the market in August of 2019 if Fera had unfettered access to Fukuzyu's API and to the RLD. This is a delay of roughly twenty-four months. His estimate was unchallenged at trial.

Hemphill calculated Vyera's excess profits on the assumption that Fera's generic drug would have entered the market in October 2019, representing a twenty-three month delay. The October 2019 date is a conservative estimate and is adopted for the calculation of excess profits.

### c. Vyera's Excess Profits

Hemphill's model for calculating these counterfactual profits involves four steps. First, he calculated Daraprim's actual revenue from October 2018 to December 2020. Conservatively, it was $130.6 million.

Next, he calculated Vyera's revenue in the but-for world during that same period under a number of conditions, including different generic entry dates, the

numbers of generic competitors, and the effect from Vyera launching its own authorized generic earlier. Those calculations based on the October 2018 entry date for Cerovene's drug and the October 2019 entry date for Fera's drug are the relevant calculations here.

Third, using simple arithmetic, Hemphill calculated the difference between Vyera's actual profit and its profits in the but-for world in which competitive entry was not impeded by Vyera's conduct. Hemphill determined that, but-for Vyera's illegal conduct, it would have earned $67.6 million less in Daraprim revenue during that period.

Finally, taking into account that in the counterfactual world Vyera's incremental costs would have been lower because it would be selling less Daraprim, Hemphill deducted an estimated $3 million in costs that Vyera would have avoided. This four-step process yields a conservative estimate of $64.6 million in excess profits.

Shkreli has offered no different calculation of excess profits, including any opposing calculation based on later generic entry dates or competing assumptions. Accordingly, the Plaintiff States' calculation of $64.6 million in excess profits from the sale of Daraprim is adopted.

### C. Shkreli's Liability for Vyera's Excess Profits

Disgorgement may be imposed against multiple defendants so long as the order is consistent with equitable principles. *See Liu*, 140 S. Ct. at 1949 (remanding to the Ninth Circuit to determine whether "circumstances would render a joint-and-several disgorgement order unjust"). Joint and several liability for disgorgement is properly imposed when multiple defendants have collaborated in an illegal scheme. *S.E.C. v. Pentagon Cap. Mgmt. PLC*, 725 F.3d 279, 288 (2d Cir. 2013). In *First Jersey*, an individual defendant was required to disgorge net profits accruing to his company where he was "primarily liable" for the fraud that created these profits, was "intimately involved" in the perpetration of the fraud, and was a "controlling person" of the company. 101 F.3d at 1475 (citation omitted).

Shkreli was the prime mover in this anticompetitive scheme. It was his brainchild and he drove it each step of the way. As Vyera's founder and its largest shareholder, any excess profit gained from Shkreli's scheme directly benefited him. Shkreli explains in his direct testimony that he took the actions he did at Vyera based on his belief that the "entry of a generic alternative to Daraprim . . . would have a significant effect on my investment in the company." Liability for the sum of equitable monetary relief determined in this Opinion is, therefore, properly imposed against him.

The sum owed by Shkreli will be reduced by any monies paid by the settling defendants. A settlement payment may properly "be taken into account by the court in calculating the amount to be disgorged." *Id.*

Shkreli argues that, following the Supreme Court's decision in *Liu*, he may no longer be held jointly and severally responsible for Vyera's excess profits. Shkreli relies on *Liu*'s statement that allowing joint and several liability alongside the remedy of disgorgement "runs against the rule to not impose joint liability in favor of holding defendants liable to account for such profits only as have accrued to themselves." *Liu*, 140 S. Ct. at 1945 (citation omitted). According to Shkreli, the amount of disgorgement he may be ordered to pay is limited to any profits he actually took from the scheme, and the Plaintiffs have failed to show that Shkreli personally profited at all.

*Liu* did not categorically reject a disgorgement order imposed against multiple parties. *Liu* in fact held that joint and several liability for disgorgement orders is permissible as long as they are consistent with equitable principles. *Id.* at 1949. The Supreme Court specifically noted that, since the common law permitted "liability for partners engaged in concerted wrongdoing . . . [t]he historic profits remedy thus allows some flexibility to impose collective liability." *Id.*

In this case, imposition of a disgorgement order against Shkreli serves the interests of justice, for all the reasons explained above. Shkreli was no side player in, or a "remote, unrelated" beneficiary of,

Vyera's scheme. *See id*. He was the mastermind of its illegal conduct and the person principally responsible for it throughout the years.

**Conclusion**

Shkreli is liable on each on the claims presented in this action. An injunction shall issue banning him for life from participating in the pharmaceutical industry in any capacity. He is ordered to pay the Plaintiff States $64.6 million in disgorgement.

Dated: New York, New York
January 14, 2022

/s/ Denise Cote
DENISE COTE
United States District Judge

*Appendix D*

**UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF NEW YORK**

No. 20-cv-706

FEDERAL TRADE COMMISSION, et al.,

*Plaintiffs,*

v.

MARTIN SHKRELI,

*Defendant*.

Filed: Feb. 4, 2022

OPINION AND ORDER

DENISE COTE, District Judge:

Following trial, on January 14, 2022, this Court ordered that Martin Shkreli ("Shkreli") be banned for life from participating in the pharmaceutical industry in any capacity and pay $64.6 million in disgorgement. *Fed. Trade Comm'n v. Shkreli*, No. 20CV00706 (DLC), 2022 U.S. Dist. LEXIS 7715, 2022 WL 135026 (S.D.N.Y. Jan. 14, 2022). Having considered the injunction proposed by the plaintiffs and Shkreli's objections, an injunction and final judgment has been issued today.

This Opinion addresses Shkreli's objections to the injunction. "[I]njunctive relief should be narrowly tailored to fit specific legal violations, [and] the court must mould each decree to the necessities of the particular case." *City of New York v. Mickalis Pawn Shop, LLC*, 645 F.3d 114, 144 (2d Cir. 2011) ("*Mickalis*") (citation omitted). Rule 65(d) of the Federal Rules of Civil Procedure further provides that "[e]very order granting an injunction . . . must: (A) state the reasons why it issued; (B) state its terms specifically; and (C) describe in reasonable detail—and not by referring to the complaint or other document—the act or acts restrained or required." Fed. R. Civ. P. 65(d). "Rule 65(d) reflects Congress' concern with the dangers inherent in the threat of a contempt citation for violation of an order so vague that an enjoined party may unwittingly and unintentionally transcend its bounds." *Sanders v. Air Line Pilots Ass'n, Int'l*, 473 F.2d 244, 247 (2d Cir. 1972) (citing *International Longshoremen's Assoc., Local 1291 v. Philadelphia Marine Trade Assoc.*, 389 U.S. 64, 76, 88 S. Ct. 201, 19 L. Ed. 2d 236 (1967)); *see also Corning Inc. v. PicVue Elecs., Ltd.*, 365 F.3d 156, 157-58 (2d Cir. 2004) ("*Corning*").

Rule 65(d) is satisfied only if the party enjoined can "ascertain from the four corners of the order precisely what acts are forbidden." *All. for Open Soc'y Int'l, Inc. v. United States Agency for Int'l Dev.*, 911 F.3d 104, 112 (2d Cir. 2018), *rev'd on other grounds sub nom., Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.*, 140 S. Ct. 2082, 207 L. Ed. 2d 654 (2020) (citation omitted). An injunction may be overbroad "when it seeks to

restrain the defendants from engaging in legal conduct, or from engaging in illegal conduct that was not fairly the subject of litigation." *Mickalis*, 645 F.3d at 145. An order entering an injunction that refers to extrinsic documents or is not tailored to the specific facts of the case does not meet the standard of Rule 65(d). *See, e.g., Corning*, 365 F.3d at 157-58; *Howard Opera House Assocs. v. Urb. Outfitters, Inc.*, 322 F.3d 125, 130 (2d Cir. 2003). The specificity requirement is satisfied, however, when the terms of an injunction cannot be drawn more narrowly without "unduly complicating its enforcement and impairing its effectiveness." *Peregrine Myanmar Ltd. v. Segal*, 89 F.3d 41, 51 (2d Cir. 1996).

Shkreli first objects to components of three of the injunction's definitions. The definitions are of the terms Development, FDA Authorization, and Pharmaceutical Company. The plaintiffs have agreed to remove the term Marketing Authorization Applications, which refers to procedures in the European Union and the United Kingdom, from the definition of FDA Authorization but otherwise oppose the Shkreli objections. Shkreli's remaining objections are overruled.

In addition to the reasons given by the plaintiffs for retaining the definitions, Shkreli's objections are denied to the extent that they depend on a restrictive description of the trial record. Shkreli is wrong to suggest that pharmaceutical research and development activities and that conduct outside the United States were not among the conduct at issue in this case. Shkreli and Vyera 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 here. At trial, Shkreli sought to justify his anticompetitive conduct by his need for supracompetitive profits to fund such research and development work. Vyera and its generic drug competitors depended on a global network of API suppliers and drug manufacturers to provide pyrimethamine to American distributors, medical providers, and patients. Thus, while Shkreli's violation of our nation's antitrust laws arose from his conduct and its anticompetitive impact within our borders, it denies reality to suggest that that anticompetitive activity could have succeeded without a coordinated effort that reached into the global pharmaceutical market.

Similarly, Shkreli's objection to the definition of Pharmaceutical Company fails. He contends that the definition is vague and could prevent him from working, for example, at a university that is engaged in pharmaceutical research or at an advertising agency that assists in the marketing of drugs. The injunction defines Pharmaceutical Company as "any Entity engaged in the research, Development, manufacture, commercialization, or marketing of any Drug Product or API."[1]

In response to this and a related objection, the plaintiffs have added a mechanism for Shkreli to

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[1] Entity is defined as "means any partnership, joint venture, firm, corporation, association, trust, unincorporated organization, or other business or government entity, and any subsidiaries, divisions, groups, or affiliates thereof."

undertake employment at a Pharmaceutical Company whose total gross revenues are not primarily derived from work in the pharmaceutical industry. It provides that such Qualified Employment means employment or a consulting engagement with a Pharmaceutical Company "that is not primarily involved in the research, Development, manufacture, commercialization, or marketing of Drug Products or APIs and whose gross revenues from this activity accounts for less than 10% of the total gross revenues of the Pharmaceutical Company." The injunction requires Shkreli to provide a notice of intent to accept a written offer of such work and provides the plaintiffs with 30 working days to object. In response to Shkreli's objection, the injunction requires the plaintiffs to object within 20 working days. The Court retains jurisdiction over the injunction, and Shkreli of course may apply for relief should the plaintiffs unreasonably object to his employment.

Shkreli next objects that the Preamble to Section II of the injunction is vague and overbroad. It enjoins him from "directly or indirectly participating in any manner in the pharmaceutical industry, including by" engaging in six activities. Shkreli objects that the words participating and indirectly, and the term including by are vague. Read in context, they are not. Removing these words would undercut the effectiveness of the injunction, which is necessary to protect the public.

Shkreli objects as well to the breadth of the descriptions of the activities from which he is barred. The plaintiffs have sufficiently explained the reasons for

these bars and only the following observations will be added.

Shkreli asks whether he is barred from engaging in conversations about business decisions in a pharmaceutical company with a friend who works in the company. The injunction bars him from "[p]articipating in the formulation, determination, or direction of any business decisions of any Pharmaceutical Company." This 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 employed in the industry, as he has done while incarcerated.

Objecting that one of the prohibitions in the injunction is vague and violates his First Amendment rights, Shkreli questions whether he would be prohibited from using a blog to discuss the pharmaceutical industry by the bar against him taking any action to influence the management of a Pharmaceutical Company. This provision is not vague. It bars him from taking actions to influence the management of a Pharmaceutical Company even through publicly issued statements. While First Amendment rights deserve of great protection, Shkreli's violations of the antitrust laws have lost for him the right to speak publicly about the pharmaceutical industry when such speech is uttered to influence the management or business of a Pharmaceutical Company. *See Peregrine*, 89 F.3d at 51 (finding that an injunction restraining the defendant from communicating with the management

of a joint venture from which she was also enjoined from being involved was not overbroad).

To further respond to Shkreli's objection, the following clause will be added to provision II.D.: Shkreli's public statements about a Pharmaceutical Company will be deemed an action taken to influence or control the management or business of any Pharmaceutical Company if Shkreli intended the statement to have that effect or if a reasonable person would conclude that the statement has that effect.

Shkreli next objects to certain provisions that require him to pay the judgment and that allow for a set-off. The plaintiffs have made some revisions to the proposed judgment and no further revisions are necessary to respond to Shkreli's objections. Among his objections, Shkreli asserts that he should not be required to sell his shares in Phoenixus so long as he is prohibited from voting his shares, and should certainly not be required to do so within 180 days in the event any shares are returned to him by the receiver appointed in *Koestler v. Shkreli*, 16 Civ. 7175 (S.D.N.Y.). Shkreli objects that these requirements are vague, burdensome, and in violation of his Fifth Amendment rights. The requirements are neither vague nor unduly burdensome. Nor do they violate his constitutional rights. Shkreli used his position as the largest Phoenixus shareholder to exert control over it and Vyera's operations even after he had given up all formal role in the companies' operations. Through that control, he orchestrated their violation of the antitrust laws. The divestiture of his

ownership interest in Phoenixus arises directly from the violations of law found at trial.

Finally, Shkreli objects to aspects of the reporting requirements in the injunction and the duty to provide access to certain information to insure that he pays the monetary judgment. These objections are overruled. To the extent that Shkreli is concerned that the inspection of financial records will occur at his home, the injunction recognizes that any inspection will occur in the presence of Shkreli's counsel and during business hours. It does not dictate the location. His production of his books and records could occur at any appropriate location of his choosing, including his counsel's office.

Dated: New York, New York
February 4, 2022

/s/ Denise Cote
DENISE COTE
United States District Judge

*Appendix E*

**UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF NEW YORK**

No. 20-cv-706

FEDERAL TRADE COMMISSION, et al.,

*Plaintiffs,*

v.

MARTIN SHKRELI,

*Defendant*.

Filed: April 25, 2022

OPINION AND ORDER

Following a bench trial in this antitrust enforcement action brought by the Federal Trade Commission ("FTC") and seven States,[1] defendant Martin Shkreli was found to have engaged in illegal antitcompetitive conduct. *FTC v. Shkreli*, No. 20CV00706 (DLC), 581 F. Supp. 3d 579, 2022 U.S. Dist. LEXIS 7715, 2022 WL 135026 (S.D.N.Y. Jan. 14, 2022) ("*Shkreli I*"). A final judgment entered on February 4, 2022 imposed joint

[1] The seven state plaintiffs are the States of New York, California, Ohio, Illinois, and North Carolina, and the Commonwealths of Pennsylvania and Virginia.

and several liability on Shkreli for the sum of $64.6 million and banned Shkreli for life from participating in the pharmaceutical industry (the "Injunction"). *FTC v. Shkreli*, No. 20CV00706 (DLC), 2022 U.S. Dist. LEXIS 20542, 2022 WL 336973 (S.D.N.Y. Feb. 4, 2022) ("*Shkreli II*").

On March 7, Shkreli moved pursuant to Rule 62(d), Fed. R. Civ. P., to stay the Injunction pending appeal. For the following reasons, the motion is denied.

## BACKGROUND

The Findings of Fact and Conclusions of Law from the bench trial are contained in an Opinion of January 14, 2022, which is incorporated by reference (the "Opinion"). *Shkreli I*, 2022 U.S. Dist. LEXIS 7715, 2022 WL 135026, at *1-30. In brief, in October 2014, Shkreli founded Vyera Pharmaceuticals, LLC and its parent company Phoenixus AG ("Phoenixus"; together, "Vyera"). At Shkreli's direction, in August 2015, Vyera acquired the U.S. distribution rights to the brand-name pharmaceutical Daraprim and immediately raised the price of the drug to $750 per pill, an increase of approximately 4,000%. Daraprim is a life-saving drug whose active pharmaceutical ingredient ("API") is pyrimethamine. Pyrimethamine is the gold standard treatment for toxoplasmosis, a rare parasitic infection that can cause severe disease and death. In 2015, Daraprim was the sole-source drug for the treatment of toxoplasmosis.

Vyera implemented a scheme devised by Shkreli to block the entry of generic competition with Daraprim. Vyera's contracts with its distributors and others down the distribution chain severely restricted access to Daraprim in order to prevent generic drug companies from obtaining the quantity of Daraprim, which is the Reference Listed Drug ("RLD") for pyrimethamine, that they needed to conduct the bioequivalence testing required by the Food and Drug Administration ("FDA") for approval of generic pharmaceuticals. Through exclusive supply agreements, Shkreli and Vyera also blocked access to the two most important manufacturers of pyrimethamine. Through these combined strategies, Shkreli successfully delayed the entry of generic drug competition to Daraprim for at least eighteen months, earning Vyera at least $64.6 million in excess profits. *Shkreli I*, 2022 U.S. Dist. LEXIS 7715, 2022 WL 135026, at *46-47.

The plaintiffs filed this action on January 27, 2020, bringing claims for violations of §§ 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1-2, § 5(a) of the FTC Act, 15 U.S.C. § 45(a), and various state statutes against Shkreli, Vyera, Phoenixus, and Kevin Mulleady, former Vyera CEO and member of the Phoenixus Board of Directors. Only Shkreli proceeded to trial; on the eve of trial Vyera and Mulleady settled with both the FTC and the plaintiff States. A bench trial was held from December 14 to December 22, 2021.

The Opinion of January 14, 2022 contains the Findings of Fact and Conclusions of Law from the bench trial. Among other things, the Opinion

determined that the market for FDA-approved pyrimethamine was the relevant market for the purpose of antitrust analysis, and that Vyera's restrictive distribution and exclusive supply agreements had an anticompetitive effect on that market. *Shkreli I*, 2022 U.S. Dist. LEXIS 7715, 2022 WL 135026, at *36-43. The Opinion found Shkreli individually liable for restraint of trade and for monopolizing the FDA-approved pyrimethamine market and jointly and severally liable for the disgorgement of unlawful profits.[2] 2022 U.S. Dist. LEXIS 7715, [WL] at *43-48. Finally, the Opinion found that a lifetime ban on Shkreli's participation in the pharmaceutical industry was warranted. 2022 U.S. Dist. LEXIS 7715, [WL] at *45-46.

The Court ordered the plaintiffs to file a proposed judgment and Shkreli to file objections by January 28. On February 4, the Court entered an Order for Permanent Injunction and Equitable Monetary Relief (the "Judgment") and an Opinion addressing Shkreli's objections (the "February 4 Opinion"). *Shkreli II*, 2022 U.S. Dist. LEXIS 20542, 2022 WL 336973, at *2-3.

Shkreli filed the instant motion to stay the Injunction pending appeal on March 7, and the FTC and the

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[2] The Court ordered the disgorgement of $64.6 million in excess profits and held Shkreli jointly and severally liable for those profits, subject to a set-off of any amount paid to the seven States by the settling defendants. *Shkreli I*, 2022 U.S. Dist. LEXIS 7715, 2022 WL 135026, at *48.

seven States filed opposition on March 28. The motion became fully submitted on April 11.[3]

Shkreli filed a Notice of Appeal from the Judgment on April 5. He is currently incarcerated in the United States Bureau of Prisons Allenwood Correctional Institution located in Allenwood, Pennsylvania, and is due to be released later this year. On April 15, and with Shkreli's consent, his counsel's motion to withdraw was approved. Shkreli is now proceeding *pro se*.

## DISCUSSION

Shkreli has moved to stay the Injunction pending appeal or, in the alternative, to modify the Injunction. Federal Rule of Civil Procedure 62(d) permits a district court to stay an injunction pending the appeal of a judgment. Fed. R. Civ. P. 62(d).

A stay, however, "is an intrusion into the ordinary processes of administration and judicial review." *Nken v. Holder*, 556 U.S. 418, 427, 129 S. Ct. 1749, 173 L. Ed. 2d 550 (2009) (citation omitted). The party requesting a stay therefore bears the burden of showing that the circumstances justify the stay. *See New York v. United States Dep't of Homeland Sec.*, 974 F.3d 210, 214 (2d Cir. 2020) ("*DHS*").

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[3] On March 7, Shkreli also moved to stay execution of the $64.6 million in equitable monetary relief. That motion was denied on March 17. *FTC v. Shkreli*, No. 20CV706 (DLC), 2022 U.S. Dist. LEXIS 47725, 2022 WL 814071 (S.D.N.Y. Mar. 17, 2022) ("*Shkreli III*").

The standard for evaluating an application for a stay pending appeal is well established. A court should consider:

> (1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits;
>
> (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies.

*SEC v. Citigroup Glob. Markets Inc.*, 673 F.3d 158, 162 (2d Cir. 2012) ("*Citigroup*") (per curiam) (citation omitted). The four factors operate as a "sliding scale" where "[t]he necessary 'level' or 'degree' of possibility of success will vary according to the court's assessment of the other stay factors . . . [and] [t]he probability of success that must be demonstrated is inversely proportional to the amount of irreparable injury plaintiff will suffer absent the stay." *Thapa v. Gonzales*, 460 F. 3d 323, 334 (2d Cir. 2006) (citation omitted). In deciding whether to issue a stay, the first two of the factors listed above "are the most critical." *DHS*, 974 F.3d at 214.

Shkreli has failed to carry his burden to show that a stay of the Injunction or its modification is warranted. With few exceptions, his motion relies upon prior arguments that have been considered and rejected, or on a crimped reading of the factual record.

## I. Likelihood of Success on Appeal

In support of his application for a stay, Shkreli revives five arguments he has previously raised. Considered separately or together, Shkreli's arguments fail to demonstrate a substantial possibility that he will succeed in vacating the Judgment and its Injunction.

### A. Scope of the Injunction

Shkreli contends once more that the Injunction is overbroad, punitive, and vague. Those objections were addressed in the February 4 Opinion and Shkreli raises no new arguments to cast doubt on its rejection of those objections. *See Shkreli II*, 2022 U.S. Dist. LEXIS 20542, 2022 WL 336973, at *2-3.

### B. Anticompetitive Effects Standard

Shkreli asserts that the Court applied the wrong legal standard to conclude that Vyera's agreements had an anticompetitive effect on the relevant market. These arguments were already addressed in the Opinion. *See Shkreli I*, 2022 U.S. Dist. LEXIS 7715, 2022 WL 135026, at *42-43.

Shkreli principally contends that the Court failed to hold the plaintiffs to their burden of proof under the standard articulated in *Ohio v. American Express Co.*, 138 S. Ct. 2274, 201 L. Ed. 2d 678 (2018) ("*American Express*"), to wit, that plaintiffs must show a "substantial foreclosure of competition in the relevant market." *Id.* at 2284; *see also Tampa Elec. Co. v. Nashville Coal*

*Co.*, 365 U.S. 320, 328, 81 S. Ct. 623, 5 L. Ed. 2d 580 (1961) (applying § 3 of the Clayton Act to exclusive supply agreements in the coal industry). Shkreli argues as he did at trial that *American Express* raised the standard from that applied in *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638 (2d Cir. 2015) ("*Actavis PLC*"). *Actavis PLC* explained that the relevant test is "whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit". *Id.* at 656 (citation omitted).

As the Opinion explained, even under Shkreli's rigid view of the law, his scheme "substantially impacted competition in the market for FDA-approved pyrimethamine." *Shkreli I*, 2022 U.S. Dist. LEXIS 7715, 2022 WL 135026, at *43. Vyera's exclusive supply and restrictive distribution agreements foreclosed generic pharmaceutical companies from acquiring the API and RLD that would otherwise have been "readily available to them in the ordinary course and that were critical to their efforts to compete with Vyera." *Id.*

To further support this argument, Shkreli misstates the scope of the factual findings in the Opinion. He argues that the Opinion found that Vyera only delayed the entry of two generic drug companies into the FDA-approved pyrimethamine market. Not so. The Opinion found that Vyera's illegal conduct affected at least five generic drug manufacturers, including one of the largest manufacturers of generic drugs in the United States. 2022 U.S. Dist. LEXIS 7715, [WL] at *18-27, *47. In connection with the calculation of Vyera's excess profits, however, the trial record only

permitted a conservative measure of the length of the delay of entry for two of the five manufacturers. 2022 U.S. Dist. LEXIS 7715, [WL] at *47.

### C. Evidence of Causation

Shkreli next contends that the Opinion did not adequately consider the extent to which the generic drug companies' own business decisions delayed their market entry. He emphasizes the fact that Vyera did not actually execute its exclusive API supply contract with its Japanese supplier until after that supplier had already refused to supply pyrimethamine to a generic drug manufacturer. While Shkreli disagrees with the Opinion's findings, the Opinion considered this timeline and the other facts to which he points. *See, e.g.,* 2022 U.S. Dist. LEXIS 7715, [WL] at *15-16, *20, *42. The trial evidence was overwhelming that it was the defendant's own anticompetitive scheme that was responsible for the delay in the entry of generic competition into the FDA-approved pyrimethamine market. It is not disputed that he intended that outcome. As the Opinion explained, he succeeded in achieving his goal through the scheme he put into operation. 2022 U.S. Dist. LEXIS 7715, [WL] at *35.

### D. Joint and Several Liability

Shkreli next argues that, pursuant to *Liu v. Sec. & Exch. Comm'n*, 140 S. Ct. 1936, 207 L. Ed. 2d 401 (2020), he cannot be held jointly and severally liable with Vyera for their violations of the antitrust laws

and be held responsible to disgorge its illegally obtained profits. This argument has already been rejected. *See Shkreli I*, 2022 U.S. Dist. LEXIS 7715, 2022 WL 135026, at *48.

In this motion for a stay, Shkreli emphasizes that the evidence at trial did not show that he received any profit from his investment in Vyera; he took no salary or other compensation from Vyera. While disgorgement may only be ordered for "property causally related to the wrongdoing," the plaintiffs did not need to show that the illegal gains personally accrued to Shkreli. *See SEC v. Contorinis*, 743 F.3d 296, 305-06 (2d Cir. 2014) (citation omitted). In any event, Shkreli held the controlling stake in Phoenixus and the scheme that Shkreli devised, managed, and controlled reaped enormous profits for his company. *Shkreli I*, 2022 U.S. Dist. LEXIS 7715, 2022 WL 135026, at *27-30, *48; *see also SEC v. First Jersey Sec., Inc.*, 101 F.3d 1450, 1476 (2d Cir. 1996) ("*First Jersey*") ("[T]o the extent that the [liable company's] net worth was increased by its unlawful activities, so was [the individual shareholder's] personal wealth.").

Shkreli argues that *First Jersey*—a precedent on which the Opinion relied—has no bearing on this antitrust case because the *First Jersey* court was applying § 20(a) of the Securities Exchange Act, which authorizes controlling person liability. 101 F.3d at 1471. On the contrary, *First Jersey* approved of the imposition of joint and several liability as a proper exercise of the district court's equitable discretion to "fashion

appropriate remedies, including ordering that culpable defendants disgorge their profits." *Id.* at 1474.

### E. Relevant Product Market

Finally, Shkreli argues that he is likely to succeed on appeal because the Opinion incorrectly defined the relevant market. He has raised no novel objections unaddressed in the Opinion and fails again to show a likelihood of success on appeal. *See Shkreli I*, 2022 U.S. Dist. LEXIS 7715, 2022 WL 135026, at *37-38.

## II. Irreparable Harm

Where "likelihood of success [is] totally lacking, the aggregate assessment of the factors bearing on issuance of a stay pending appeal cannot possibly support a stay." *Uniformed Fire Officers Ass'n v. de Blasio*, 973 F.3d 41, 49 (2d Cir. 2020). At any rate, Shkreli has not met his burden to show that he will be harmed or that any harm to him is irreparable absent a stay of the Injunction.

To demonstrate irreparable harm such that a stay is necessary, a party must show that it will suffer injury which "cannot be remedied" absent a stay. *Grand River Enter. Six Nations, Ltd. v. Pryor*, 481 F.3d 60, 66 (2d Cir. 2007) (per curiam) (citation omitted). The party seeking the stay has the burden of showing "injury that is not remote or speculative but actual and imminent, and for which a monetary award cannot be

adequate compensation." *Dexter 345 Inc. v. Cuomo*, 663 F.3d 59, 63 (2d Cir. 2011) (citation omitted).

In support of his motion, Shkreli does not identify any actual or imminent irreparable harm that he will experience absent a stay. He does not even address the myriad reasons given in the Opinion in support of the lifetime ban defined in the Injunction, including his failure at trial to express a clear desire to return the pharmaceutical industry, the breadth of his illegal behavior, and his lack of remorse. *Shkreli I*, 2022 U.S. Dist. LEXIS 7715, 2022 WL 135026, at *45-46. To the extent Shkreli argues that the Injunction infringes his First Amendment rights, that argument has already been addressed and rejected. *Shkreli II*, 2022 U.S. Dist. LEXIS 20542, 2022 WL 336973, at *3; *see also Nat'l Soc. of Pro. Engineers v. United States*, 435 U.S. 679, 697-98, 98 S. Ct. 1355, 55 L. Ed. 2d 637 (1978); *Peregrine Myanmar Ltd. v. Segal*, 89 F.3d 41, 50-52 (2d Cir. 1996). Similarly, he has identified no irreparable harm from the Injunction's requirement that he divest any shares in Vyera that may be returned to him. *See Shkreli III*, 2022 U.S. Dist. LEXIS 47725, 2022 WL 814071, at *1-2.

## III. Injury to Interested Parties

There is a serious risk that, absent the Injunction, Shkreli will reengage in anticompetitive conduct within the pharmaceutical industry and cause injury to interested parties. *See, e.g., Shkreli I*, 2022 U.S. Dist. LEXIS 7715, 2022 WL 135026, at *46. The burdens of

his schemes fell on patients, their families, health care professionals, generic drug manufacturers, and others in the pharmaceutical industry.

Shkreli argues that there is no risk of substantial injury to these parties without a stay because of the passage in 2019 of the Creating and Restoring Equal Access to Equivalent Samples Act (the "CREATES Act"). *See* 21 U.S.C. § 355-2. The CREATES Act provides a private right of action for generic drug manufacturers to seek injunctions against pharmaceutical companies that refuse to sell them sufficient RLD on "commercially reasonable, market-based terms" for use in their efforts to obtain FDA approval of generic pharmaceuticals. *Id.* § 355-2(b)(1). The CREATES Act targets only one leg of the comprehensive scheme Shkreli implemented at Vyera, providing generic drug companies with recourse to the courts to combat a component of the scheme Shkreli perfected. It is a testament to the scale of Shkreli's impact on the industry that he attracted congressional attention and movitated legislative action. Congress's response, however, does not suggest that the risk Shkreli poses to others connected to the generic pharmaceutical industry has been eliminated.

## IV. The Public Interest

Finally, the public interest is served by maintaining the Injunction, not by staying it. *See Shkreli I*, 2022 U.S. Dist. LEXIS 7715, 2022 WL 135026, at *46. Shkreli speculates that the public may benefit should

he return to the industry and be able to develop a life-saving drug for a rare disease. That speculation does not override the record developed at trial that Shkreli's engagement in the pharmaceutical industry was not in the public interest. Nor does that record allow for optimism about any engagement with the industry that he may desire in the future. Shkreli's violations of our antitrust laws came at the expense of public health and undermined public confidence in the government's ability to control notorious predatory behavior within the pharmaceutical industry. For all of these reasons, Shkreli has not shown that the Injunction should be stayed pending appeal.

## V. Modification of the Injunction

In the event that his motion for a stay has been denied, Shkreli seeks modification of the Injunction pursuant to Rule 62(d), Fed. R. Civ. P., to prohibit him only from entering into any exclusive supply or restrictive distribution agreements in the United States pharmaceutical industry pending appeal. For the reasons explained above, Shkreli's request for a modification is denied.

## CONCLUSION

Shkreli's March 7 motion to stay or to modify the February 4 Injunction pending appeal is denied. The Clerk of Court shall mail a copy of this Opinion to Martin Shkreli and note service on the docket.

Dated: New York, New York
April 25, 2022

/s/ Denise Cote
DENISE COTE
United States District Judge

*Appendix F*

## RELEVANT STATUTORY PROVISIONS

1. **Section 13(b) of the Federal Trade Commission Act**, Pub. L. No. 203, 38 Stat. 717 (1914), codified as amended at 15 U.S.C. § 53(b), provides:

> **(b) Temporary restraining orders; preliminary injunctions**
>
> Whenever the Commission has reason to believe—
>
> (1) that any person, partnership, or corporation is violating, or is about to violate, any provision of law enforced by the Federal Trade Commission, and
>
> (2) that the enjoining thereof pending the issuance of a complaint by the Commission and until such complaint is dismissed by the Commission or set aside by the court on review, or until the order of the Commission made thereon has become final, would be in the interest of the public—
>
> the Commission by any of its attorneys designated by it for such purpose may bring suit in a district court of the United States to enjoin any such act or practice. Upon a proper showing that, weighing the equities and considering the Commission's likelihood of ultimate success, such action would be in the public interest, and after notice to the defendant, a temporary restraining order or a preliminary injunction may be granted without bond: *Provided, however*, That if a complaint is not filed within such period (not exceeding 20 days) as may

be specified by the court after issuance of the temporary restraining order or preliminary injunction, the order or injunction shall be dissolved by the court and be of no further force and effect: *Provided further*, That in proper cases the Commission may seek, and after proper proof, the court may issue, a permanent injunction. Any suit may be brought where such person, partnership, or corporation resides or transacts business, or wherever venue is proper under section 1391 of title 28. In addition, the court may, if the court determines that the interests of justice require that any other person, partnership, or corporation should be a party in such suit, cause such other person, partnership, or corporation to be added as a party without regard to whether venue is otherwise proper in the district in which the suit is brought. In any suit under this section, process may be served on any person, partnership, or corporation wherever it may be found.

2. **N.Y. Exec. Law § 63(12)** provides:

12. Whenever any person shall engage in repeated fraudulent or illegal acts or otherwise demonstrate persistent fraud or illegality in the carrying on, conducting or transaction of business, the attorney general may apply, in the name of the people of the state of New York, to the supreme court of the state of New York, on notice of five days, for an order enjoining the continuance of such business activity or of any fraudulent or illegal acts, directing restitution and damages and, in an appropriate case, cancelling any certificate filed under and by virtue of the provisions of section

four hundred forty of the former penal law or section one hundred thirty of the general business law, and the court may award the relief applied for or so much thereof as it may deem proper. The word "fraud" or "fraudulent" as used herein shall include any device, scheme or artifice to defraud and any deception, misrepresentation, concealment, suppression, false pretense, false promise or unconscionable contractual provisions. The term "persistent fraud" or "illegality" as used herein shall include continuance or carrying on of any fraudulent or illegal act or conduct. The term "repeated" as used herein shall include repetition of any separate and distinct fraudulent or illegal act, or conduct which affects more than one person. Notwithstanding any law to the contrary, all monies recovered or obtained under this subdivision by a state agency or state official or employee acting in their official capacity shall be subject to subdivision eleven of section four of the state finance law.

In connection with any such application, the attorney general is authorized to take proof and make a determination of the relevant facts and to issue subpoenas in accordance with the civil practice law and rules. Such authorization shall not abate or terminate by reason of any action or proceeding brought by the attorney general under this section.

*Appendix G*

**UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF NEW YORK**

No. 20-cv-706

FEDERAL TRADE COMMISSION, et al.,

*Plaintiffs,*

v.

VYERA PHARMACEUTICALS, LLC, et al.,

*Defendants*.

Filed: April 16, 2020

REDACTED AMENDED COMPLAINT
FOR INJUNCTIVE AND OTHER EQUITABLE RELIEF

Plaintiffs, the Federal Trade Commission ("FTC" or "the Commission"), by its designated attorneys, and the states of New York, California, Illinois, North Carolina, Ohio, Pennsylvania, and Virginia, by and through their Attorneys General, petition this Court, pursuant to Section 13(b) of the Federal Trade Commission Act, 15 U.S.C. § 53(b), Section 16 of the Clayton Act, 15 U.S.C § 26, Section 342 of the New York General Business Law, Section 63(12) of the New York Executive Law, Sections 16700 *et seq.* and 17200 *et seq.* of the

California Business and Professions Code, Section 7 of the Illinois Antitrust Act, 740 ILCS 10/1 *et seq.*, North Carolina Unfair or Deceptive Practices Act, N.C. Gen. Stat. §75-1 *et seq*., Chapter 1331 and Section 109.81 of the Ohio Revised Code, Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P.S. § 201-1 *et seq*. and Common Law Doctrine against Restraints of Trade proceeding under 71 P.S. §732-204 (c), and the Virginia Antitrust Act, Virginia Code § 59.1-9.1 *et seq*.; for a permanent injunction and other equitable relief, including equitable monetary relief, against Defendants Vyera Pharmaceuticals, LLC ("Vyera"), Phoenixus AG ("Phoenixus"), Martin Shkreli, and Kevin Mulleady to undo and prevent their anticompetitive conduct and unfair methods of competition in or affecting commerce in violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, Section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a), and state law.

* * *

137. The purpose of Defendants' extensive resale restrictions and quantity limits is to prevent generic companies from obtaining the Daraprim necessary to meet the FDA's bioequivalence testing requirements and thereby impede them from launching generic Daraprim products.

138. This purpose was publicly reported and widely known. In September 2015, the New York Times reported that "Daraprim's distribution is now tightly controlled, making it harder for generic companies to

get the samples they need for the required testing" and that this could prevent generic competition. The Times further reported that Defendant Shkreli had previously used a similar strategy "as a way to thwart generics."

139. In November 2015, the Senate Special Committee on Aging launched a bipartisan investigation into dramatic price increases on several off-patent drugs, including Daraprim. The Committee concluded that Vyera "put [Daraprim] in a closed distribution system to keep potential generic competitors from getting access to the drug to conduct required bioequivalence tests for developing generic alternatives." The Committee elaborated that "[r]estricted distribution in this case was a deliberate part of [Vyera's] plan to defend its shocking price increase and subsequent increased revenue against potential competition."

140. As part of the Senate investigation, multiple Vyera executives testified that the purpose of the distribution restrictions was to prevent competition from generic companies by denying them access to the samples they needed for bioequivalence testing.

141. The restrictions preventing distributors or purchasers from selling Daraprim to generic companies do not have any legitimate business rationale.

* * *

## VIII. Vyera Has Monopoly Power in a Relevant Market for FDA-Approved Pyrimethamine Products

295. From 2015 until at least March 2020, Vyera exercised monopoly power in the United States with respect to Daraprim.

296. Vyera's monopoly power can be observed directly. In 2015, Vyera raised the price of Daraprim by more than 4,000%. This massive price increase was extremely profitable: prior to the acquisition, Daraprim had annual revenues of approximately [redacted]. After raising the price 4,000%, Vyera's annual Daraprim revenues were approximately [redacted]—an increase of more than [redacted].

* * * *

*Appendix H*

**UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF NEW YORK**

No. 20-cv-706

FEDERAL TRADE COMMISSION, et al.,

*Plaintiffs,*

v.

VYERA PHARMACEUTICALS, LLC, et al.,

*Defendants*.

Filed: Feb. 4, 2022

PLAINTIFFS' RESPONSES TO
DEFENDANT SHKRELI'S OBJECTIONS TO
PLAINTIFFS' PROPOSED ORDER FOR
PERMANENT INJUNCTION AND
EQUITABLE MONETARY RELIEF

* * *

**4. Section II Permanent Injunction**

Section II of the Proposed Order properly orders "that Defendant Shkreli is hereby banned and enjoined for life from directly or indirectly participating in any manner in the pharmaceutical industry. . . ." (ECF 867-1 at 4). Shkreli objects to this language,

questioning how "one 'indirectly' participates in the pharmaceutical industry" and whether this prohibition might prevent him that "discussing pharmaceuticals with friends or colleagues in the industry." (ECF 867-2 at 5). These objections are unfounded. A lifetime ban from the pharmaceutical industry must clearly prohibit Shkreli from having any involvement in the pharmaceutical industry. This includes discussions with pharmaceutical executives, such as Shkreli's friend and Vyera executive Akeel Mithani, or the type of indirect participation Shkreli has been engaged in since being incarcerated. Without such prohibitions, Shkreli will have license to repeat the very conduct giving rise to this case.

* * *

**7. Paragraph II.D**

Shkreli objects to this provision prohibiting him from taking any action to influence or control the management of any pharmaceutical company on the basis that it could prohibit him from tweeting or blogging about the pharmaceutical industry. Given that the Court has ordered Shkreli banned from the pharmaceutical industry for life, he indeed should be prohibited from tweeting or blogging about the pharmaceutical industry, as an obvious goal and effect would be to influence or control the management of a pharmaceutical company.

* * * *

*Appendix I*

**UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF NEW YORK**

No. 20-cv-706

FEDERAL TRADE COMMISSION, et al.,

*Plaintiffs,*

v.

VYERA PHARMACEUTICALS, LLC, et al.,

*Defendants*.

Filed: Dec. 20, 2021

DIRECT TESTIMONY OF MARTIN SHKRELI

Due to a transcription error, the citation in Paragraph 67 should reference Trial Exhibit DX497, rather than DX126. Plaintiffs do not object to this revision.

**UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF NEW YORK**

No. 20-cv-706

FEDERAL TRADE COMMISSION, et al.,

*Plaintiffs,*

v.

VYERA PHARMACEUTICALS, LLC, et al.,

*Defendants*.

DECLARATION OF MARTIN SHKRELI

I, Martin Shkreli, declare that I have personal knowledge of the facts set forth herein and state as follows:

## I. Background

1. My name is Martin Shkreli. I am 38 years old.

2. I am a first generation American citizen. I am the second of four children of Pashko and Katrina Shkreli, who immigrated to the United States from Albania and settled in the Midwood section of Brooklyn, New York, where I was raised.

3. From a young age, and throughout my high school years, I was fascinated by science and the financial industry, and in particular, biotech companies.

While still in high school, at the age of 17, I was hired as an intern by the investment fund Cramer, Berkowitz & Co., founded by famed investor Jim Cramer, the host of "Mad Money" on CNBC. I continued working there through my college years, until April 2004.

4. I attended Baruch College, where I continued to pursue my interest in finance and biotech. I graduated from Baruch in 2004 with a Bachelor's Degree in Business Administration.

5. From 2004-2006, I worked as a healthcare and technology analyst for an established hedge fund, Intrepid Capital Management.

6. In 2006, I left Intrepid Capital Management to found my own firm, Elea Capital Management LLC.

7. In 2009, along with a friend and colleague, Marek Biestek, I founded a hedge fund called MSMB Capital Management.

8. MSMB Capital Management's business focused on managing client assets, primarily in the healthcare investment field, including in the areas of drug discovery and development. As President and Chief Investment Officer, I was responsible for stock selection, portfolio management, investor communications, trading analysis, and other management-related matters.

9. I have always had a passion for finding cures for rare diseases, and spent years after college studying drug trials, chemistry, and biopharmaceutical stocks. In late 2010, I began creating a start-up

biopharmaceutical company aimed at developing pharmaceutical drugs to treat and cure rare diseases often ignored by large pharmaceutical companies.

10. Around this time, I learned about a young boy who died from a form of muscular dystrophy. I began to focus on Duchene Muscular Dystrophy (DMD). DMD is a rare genetic disease that causes significant progressive muscle degeneration and weakness. It is caused by the absence of dystrophin, the protein that keeps muscle cells intact. Inspired by this story, I decided to call the new biopharmaceutical company "Retrophin," combining the words recombinant and dystrophin.

11. Despite having little formal training in biology, after reading volumes of academic publications and having discussions with leading experts in neurology and pharmacology, I wrote the genetic sequence for a new fusion protein incorporating recombinant dystrophin, hoping that it could one day be used to help people suffering from muscular dystrophy. Based on my work, Retrophin worked to develop a new treatment for DMD.

12. While at Retrophin, I served as CEO. I was also a co-inventor of a pharmaceutical candidate to treat a disease called pantothenate kinase-associated neurodegeneration, or "PKAN." PKAN is a rare neurological disorder characterized by the progressive degeneration of specific regions of the central nervous system. It is normally diagnosed in early childhood and can lead to death. Along with two other colleagues, Dr.

Andrew Vaino and Marek Biestek, I was awarded several issued patents for this treatment. Retrophin conducted a Phase III trial for this candidate. Our effort was the first-ever drug candidate discovered and developed for PKAN.

13. During my tenure as CEO, Retrophin acquired the pharmaceutical Chenodal, a drug used to treat gallstones, and licensed the rights to Thiola, a drug used to prevent kidney stones in patients suffering from cystinuria, an inherited condition characterized by a buildup of the amino acid, cystine, in the kidneys and bladder.

14. Retrophin raised the prices of both Chenodal and Thiola to bring them in line with other pharmaceuticals that offered comparable benefits, and to generate revenue for new drug development and discovery, including the potential treatment for PKAN.

## II. Turing/Vyera

### A. Founding of Turing

15. I resigned from Retrophin in September of 2014, and, along with several other former Retrophin employees, founded a new pharmaceutical company, which we named Turing Pharmaceuticals LLC. I personally invested approximately $18 million into Turing. At around the same time, we also formed Turing Pharmaceuticals AG, which was Turing Pharmaceuticals LLC's parent company.

16. Turing Pharmaceuticals LLC has since been renamed Vyera Pharmaceuticals LLC, and Turing Pharmaceuticals AG has been renamed Phoenixus AG. I will refer to these companies as Vyera and Phoenixus throughout this declaration.

17. From the date of Vyera's and Phoenixus' founding until December of 2015, I was the CEO of Vyera and a Director and Chairman of the Board of Phoenixus AG. I never received a salary or any form of compensation from either company.

18. Early on, I advised the Phoenixus Board of Directors that while I had been acting as Vyera' s CEO, it was not a role that I planned or wanted to fill much longer, and urged the company to identify and hire a new CEO with greater pharmaceutical industry experience than I had.

19. I recruited well-credentialed and experienced scientists at Vyera to conduct research and development ("R&D"). I personally recruited and hired Vyera's head of R&D, Eliseo Salinas, M.D. Prior to coming to Vyera, Dr. Salinas had had 22 years of experience in the pharmaceutical industry, including as head of global R&D for Shire Pharmaceuticals, Chief Medical Officer at Adolor, and Chief Medical Officer-Head of Development at Elan Pharmaceuticals. Dr. Salinas was assisted by approximately 8-9 scientists with Ph.Ds, including, to name just a few, Dr. Adam Brockman, a parasitologist with two decades of experience in the biopharmaceutical industry; Dr. Matthew Welsch, a medicinal chemist; Dr. Steven Thomas, also

a medicinal chemist and currently Chief Scientific Officer for ValenzaBio; and Dr. Wendy Cousin, who holds a Ph.D in life sciences and molecular and cellular aspects of biology, and is currently the lead scientist at Spring Discovery.

20. Vyera also worked with WuXi AppTec, a global leader in contract research used by large and small biopharmaceutical companies. WuXi assisted Vyera with research and development related to toxoplasmosis, and WuXi and Vyera researchers worked to create the first x-ray crystallography images for pyrimethamine and toxoplasma gondii dihydrofolate and reductase (DHFR). Achieving this milestone was a fundamental step that had never been undertaken before, and was instrumental in creating a superior medicine to pyrimethamine.

21. My co-founders and I envisioned that Vyera would engage in drug discovery, from the very basics of inventing new drugs to developing drugs that had been licensed from universities but had not yet reached human stage or developing drugs that pharmaceutical companies had put in human stage and then had abandoned.

22. We also envisioned that Vyera would acquire pharmaceuticals that were established and older, or manufacture generic versions of established pharmaceuticals.

23. In short, we believed that Vyera had the capability to do virtually anything in the pharmaceutical

space that would benefit patients and create shareholder value.

24. We observed that medium and large-sized pharmaceutical manufacturers often neglect older drugs. We saw opportunities to add shareholder value through licensing or purchasing these drugs and then improving distribution networks, focusing on patient outreach and education, and investing in R&D to improve these drugs or devise new and better treatments for the diseases they treat.

25. Vyera's business development group focused on identifying lifesaving drugs in which Vyera should invest. This group, which consisted of between 10 and 15 people, was tasked with finding under-valued drugs that provided significant patient benefits for neglected disease states. The business development group cast a wide net, and was not focused on any one disease or pharmaceutical.

26. Vyera's business development group was led by Patrick Crutcher and Michael Smith.

27. Mr. Crutcher and Mr. Smith reported to me, but I was not involved in the day-to-day activities of the group.

### B. Acquisition of Daraprim

28. In March of 2015, Patrick Crutcher reported that in his research he had discovered a drug called Daraprim that was prescribed to treat a rare disease known as toxoplasmosis encephalitis. Mr. Crutcher

suggested that Vyera consider acquiring the rights to the drug. At the time, I had never heard of Daraprim.

29. Toxoplasmosis encephalitis (which, for purposes of this declaration, I will refer to simply as "toxoplasmosis") is an infection caused by the Toxoplasma gondii parasite. Many people are infected with this parasite, and never know it. That is because, in healthy individuals, the immune system keeps the parasite in an inactive state and prevents it from causing illness. But in immunocompromised individuals, toxoplasmosis can cause serious illness and even death.

30. I agreed with Mr. Crutcher's suggestion that we seek to acquire Daraprim, because I believed that Vyera could develop a better version of Daraprim with less severe side effects, while at the same time providing shareholder value. It was clear to me that Daraprim was significantly undervalued, and that if Vyera could acquire the drug at the right price, the acquisition made sense.

31. Vyera proceeded to engage in negotiations with the owner of Daraprim, Core Pharma, a subsidiary of Impax Laboratories.

32. In August of 2015, Vyera bought Daraprim for $55 million from Core Pharma. Through that transaction, Vyera obtained the exclusive rights to manufacture and sell Daraprim in the United States.

### C. The Price Increase and R&D

33. After Vyera purchased Daraprim, it increased its price from $17.50 to $750 per pill. I authorized the price increase because I believed that Daraprim was significantly underpriced relative to other lifesaving medications such as drugs that treat hepatitis C (*e.g.,* Sovaldi and Harvoni), and HIV drugs. Much of the media attention following the price increase focused on the price of one pill. But when comparing drug prices, it is more instructive to compare the cost of an entire course of treatment. At $750 per pill, Daraprim compared very favorably to hepatitis C and HIV drugs when one considers the cost of a course of treatment. For example, a full course of treatment for hepatitis C costs approximately $80,000, whereas, at $750 per pill, a full course of treatment for toxoplasmosis costs approximately $40,000. And of those three diseases—hepatitis C, HIV, and toxoplasmosis—only one, toxoplasmosis, is rapidly fatal.

34. I also believed that the price increase would allow Vyera to invest in R&D to create a new and better version of Daraprim. At that time, Daraprim had been commercially available for over 60 years. And, as far as I am aware, no research had been conducted to improve upon the drug or its delivery mechanism during those 60-plus years. This is significant because Daraprim, on its own, is highly toxic and must be taken in combination with another drug called leucovorin. Adding a second drug to the treatment regimen can result in reduced adherence to the regimen. My vision

was to make a combination pill containing both Daraprim and leucovorin.

35. I believed that if Vyera were going to increase the price of the drug, it had an obligation to the patient community to invest the revenues from the price increase into research and development. This is why I never took a salary from Vyera or Phoenixus.

36. I urged the company to invest revenues from the price increase into new drug development, including either a drug with an entirely new chemical composition, effective against toxoplasmosis, or a combination pill combining Daraprim and leucovorin. Led by a team of four-five doctors in the R&D department, Vyera focused its research and development efforts on making a better form of Daraprim. We were the first company to develop new toxoplasmosis drugs, including a new drug (TUR-006) that would obviate the need for sulfa drugs and thus remove the allergic complications that most HIV patients experience. We also had two papers published in the Journal of Medicinal Chemistry about these innovations. *See* Hopper, Allen T., et al., *Discovery of Selective Toxoplasma gondii Dihydrofolate Reductase Inhibitors for the Treatment of Toxoplasmosis,* J. Med. Chern. 2019, 62, 1562-1576; Janetka, James W., et al., *Optimizing pyrazolopyrimidine inhibitors of calcium dependent protein kinase 1 for treatment of acute and chronic toxoplasmosis,* J. Med. Chern. 2020 June 11, 63(11), 6144-6163.

37. I am proud of the fact that while I was at Vyera, the company developed the first ever

toxoplasmosis-specific inhibitor of the enzyme DHFR. In fact, Vyera began work on this project even before the company acquired Daraprim. The drug even entered Phase 1 clinical development, a stage that few research projects attain.

38. But I must accept the blame for the media firestorm that ensued following the price increase. Many people criticized Vyera, and me personally, for raising the price so dramatically. In the course of defending the price increase, I gave interviews and made statements that reflected poorly on Vyera and its mission of curing rare diseases. During my time in prison, I have had a lot of time to reflect upon my decisions and conduct during this time period, and regret many of my actions and statements. I accept full responsibility for the price increase—which I still believe was the right decision for the company and the patient community—and also for the unfortunate negative publicity that Vyera received as a result.

39. Daraprim was just one of over a dozen drugs that Vyera acquired or developed. These include: leronlimab, an antibody used to treat HIV (licensed from CytoDyn Inc.); intranasal Ketamine, which treats acute suicidality; Stiripentol, used for Dravet Syndrome, a severe encephalapothy affecting children; oxytocin, which treats autism; Vecamyl, used for malignant hypertension and spinal cord injury; two new toxoplasmosis drugs; four new medicines and new nucleic acid therapies for various rare diseases; and new, cheaper generic drugs.

### D. Vyera's Sourcing of API

40. The active pharmaceutical ingredient (API) in Daraprim is a substance known as pyrimethamine.

41. In order to manufacture Daraprim, it was necessary for Vyera to contract with an API supplier to manufacture and sell it pyrimethamine.

42. I do not recall Vyera entering into any supply agreements while I was CEO of Vyera.

43. After I left the company, I learned that Vyera signed a supply contract with a Japanese company called Fukuzyu. I did not negotiate or sign, and am not familiar with any of the terms of, Vyera's contract with Fukuzyu.

[paragraphs 44 and 45 redacted]

46. API supply is an area where I and the other founders of Vyera believed that Vyera could outperform Daraprim's prior owners. A company such as Core Pharma, and its parent company Impax Laboratories, have hundreds of drugs. Our view was that the larger pharmaceutical companies such as Core Pharma tend not to pay attention to details for certain of their drugs, such as ensuring API supply through a secondary supplier. For Vyera, which depended on Daraprim sales to generate revenue, having a back-up supplier was important to ensure both that it could continue to offer and make sales of Daraprim and that there would be no interruption in the supply of Daraprim to the patients who depend upon it.

47. For these reasons, while I served as CEO of Vyera, I asked the manufacturing team to look into contracting with not only a primary supplier, but also a secondary supplier.

48. That process was not completed by the time I left the company. Prior to my resignation, there had been discussions with an Indian company, Neuland Laboratories, about supplying Vyera with pyrimethamine. However, those discussions did not progress very far. In addition, Vyera's head of manufacturing, Dr. Hasmukh Patel, approached a second company, Ipca Laboratories, about supplying API in the United States, during the time that I was CEO. However, those efforts were ultimately unsuccessful, as Dr. Patel left the company in November or December of 2015.

49. Two years later, in 2017, when I was no longer an employee of Vyera or director of Phoenixus, I became aware of another potential API manufacturer of pyrimethamine, an Indian company named RL Fine.

50. A representative of RL Fine approached a former Vyera employee, Edwin Urrutia, and informed him that RL Fine was working towards manufacturing pyrimethamine. That information was passed on to me through my attorney.

51. Around that same time, I fortuitously learned in conversations with either Mr. Mulleady or Mr. Mithani—I cannot recall which one—that Vyera was already engaged in discussions with RL Fine.

52. I informed Mr. Mulleady of what I had learned from Mr. Urruita, namely that RL Fine was working towards the manufacture of pyrimethamine.

53. It was unknown to me then, and remains unknown to me now, whether Mr. Mulleady and Mr. Mithani already knew that RL Fine was working towards the manufacture of pyrimethamine.

54. Regardless, I believed that it was important to inform Vyera management of this fact because I thought that it could mean that entry of a generic alternative to Daraprim was imminent, which would have a significant effect on my investment in the company. As a shareholder, I felt that my role was limited to conveying the information to management so that they could project when that entry might occur and make whatever decisions they thought appropriate to prepare for it—such as reducing the sales force. But any decision about what to do with the information was for Vyera management, not me, to make.

55. RL Fine represented a potential secondary or back-up source of pyrimethamine for Vyera. I also thought that RL Fine could be a potential partner with Vyera in creating a combined drug containing pyrimethamine and leucovorin.

56. I do not know what, if anything, Mr. Mulleady did with the information I provided him about RL Fine. I later learned that Vyera approached RL Fine about purchasing pyrimethamine, and I counseled Mr. Mithani, who was inexperienced in such

matters, on how to approach RL Fine on this subject and the possible partnership for a combination pill.

57. I also know that at some point Vyera entered into an API supply agreement with RL Fine. However, I did not negotiate that agreement, did not sign it, and have never seen it.

### E. Vyera's Distribution of Daraprim

58. I also have very little knowledge concerning the specifics of Vyera's distribution of Daraprim, other than the fact that it is offered through specialty distribution, just as it was under its previous owner, Core Pharma.

59. The distribution of Daraprim was handled by other Vyera executives who understood specialty distribution.

60. I did not negotiate, did not sign, and am not familiar with any of the terms of any of the distribution contracts that Vyera entered into with distributors.

### F. The Proxy Fight

61. In 2016, I was not satisfied that Vyera was moving in the right direction, and became concerned about the future of the company, which at that time was my largest investment. I was particularly frustrated by the way that Ron Tilles, who had been named interim CEO, was managing Vyera. As a result, I organized a proxy fight to remove members of the Board of

Directors of Phoenixus that I did not think were doing a good job, including Mr. Tilles. The proxy fight was successful, and my slate of directors, which included Kevin Mulleady and Akeel Mithani, was elected.

62. The proxy fight was totally unrelated to Vyera's sale and distribution of Daraprim.

63. Despite the fact that my share ownership in Vyera allowed me to make changes to the Board of Phoenixus, I never used that power to affect in any way Vyera's distribution of Daraprim, its acquisition of pyrimethamine API for Daraprim, or its policies and practices related to reporting of data.

### G. Generic Competition

64. As a shareholder of Phoenixus, I viewed, and continue to view, my role as being limited to making suggestions to the company's management, and I understand that my suggestions need not be followed. Indeed, my suggestions to Vyera management often go ignored.

65. One significant example of Vyera management ignoring my suggestions after I left the companies is their failure to follow my suggestion that Vyera develop an alternative to or a better form of Daraprim to treat toxoplasmosis.

66. Ever since Vyera purchased Daraprim, I have anticipated the development of a generic competitor. My view, as I expressed to my Vyera colleagues, is

that the only way to mitigate the impact of generic competition is to develop a new or better drug.

67. In fact, I stated as much in a September 26, 2015 email to Vyera employee Ed Painter, who had asked me if an annual price reduction commitment might discourage generics from entering the market. As I told Mr. Painter, I do not think there is much that can be done to prevent generics from entering the market other than to introduce a new drug. Trial Ex. DX 126.

68. As a result, when I was CEO of Vyera, I made sure that R&D was a core focus for the company. And Vyera employees spent a lot of time thinking about how to make a better version of Daraprim, which would block the DHFR enzyme. Specifically, a "new Daraprim" would block toxoplasma's DHFR enzyme but not the patient's DHFR enzyme, which is necessary for life. Daraprim does not do this now. Vyera successfully created such a molecule under my watch, and this discovery was published in the prestigious peer-reviewed journal for discovery research, the Journal of Medicinal Chemistry.

69. I explained my philosophy about R&D in a 2017 email to Tracy Seckler, the Chief Visionary Officer for Charley's Fund, a charity dedicated to developing life-saving treatments for DMD. As I told Ms. Seckler, if a company increases the price of a pharmaceutical, as Vyera did, it needs to use the profits to fund lab research and develop a better drug. Trial Exhibit DX 481. No company had ever focused on new drugs

for toxoplasmosis before Vyera. I envisioned using Daraprim as a platform to create drugs for a variety of neglected infectious diseases, including schistosomiasis, Chagas and viral diseases.

70. After my resignation, I repeatedly advised and implored Vyera employees to continue this research. But unfortunately, my advice went unheeded. For several years after I left the company, the management had very little interest in R&D. As a result, Vyera has not developed a new or better drug to treat toxoplasmosis.

71. I am not aware of any plan by Vyera—which owned Daraprim for only four months before I resigned as CEO—to stop or slow a generic pharmaceutical company from manufacturing and selling a generic version of Daraprim, which I do not believe is possible.

### H. Involvement in Vyera After February 2016

72. I only served as CEO of Vyera for approximately four months following Vyera's purchase of Daraprim. I resigned as CEO of Vyera on December 17, 2015, following my arrest. I resigned as Chairman of the Board of Vyera on January 20, 2016, and as director on February 10, 2016.

73. Since February 10, 2016, the only role I have had in Vyera or Phoenixus is Phoenixus shareholder.

74. I am currently the largest shareholder in Phoenixus. I own approximately 32% of Phoenixus'

outstanding shares, and have approximately a 43% voting interest. As a large shareholder in Phoenixus, I am an active investor, and regularly ask questions of Vyera management and make suggestions to management on the direction of the company.

75. Since leaving the companies, I have had very little knowledge of Vyera's manufacture, distribution, and sale of Daraprim, other than information I have received in my role as a large shareholder. For example, I would often ask Vyera executives such as Nancy Retzlaff and Ron Tilles about sales figures for Daraprim, which were and are critical to my investment. But I have received only the type of information that any other large shareholder would be expected to receive.

76. Since leaving the companies, I have not had the authority to make, and have not made, any decisions for Vyera or Phoenixus in any way relating to Daraprim (or for that matter, any other drug).

77. As an active investor, I initially sought to have a continuing role in the direction of Vyera and Phoenixus after I had left the Board. But Vyera's management made it clear that it did not want me to have any such role.

78. In early 2016, Vyera management did not allow me to participate in meetings of Vyera's Senior Leadership Team (SLT). Later that year, management denied my request for a consulting contract with Vyera, and completely shut me out of any role in the day-to-day operations of Vyera.

79. Since leaving Vyera and Phoenixus in February 2016, I have been in contact with former Vyera employee Kevin Mulleady and current employee Akeel Mithani and, more recently, with Vyera's current CEO and General Counsel, Averill Powers.

80. I have known Mr. Mulleady and Mr. Mithani for years and have considered both of them friends. Following my resignation from Vyera, I have had many discussions and communications with both of them on various topics ranging from pop culture to personal matters to matters affecting Vyera. From the time that Mr. Powers was promoted to interim CEO in December 2018, I have had a limited number of conversations with him, beginning in 2020.

81. In the course of the many discussions I have had with Messrs. Mulleady, Mithani and Powers, I have made suggestions to each of them about Vyera, primarily relating to business development, in my role as a major shareholder in Phoenixus. But no Vyera employee, including Mr. Mulleady, Mr. Mithani, and Mr. Powers, is required or bound to follow my suggestions. In fact, more often than not they ignore, or at least do not follow, those suggestions. This has been a continuing source of frustration for me.

## III. The Future

82. I do not know what the future holds for me after I am released from prison. However, I expect that my conviction will significantly limit my future employment options. I have considered pursuing

opportunities both within and outside of the pharmaceutical industry.

83. I am aware that I will need to work to rehabilitate my public image, so if I do pursue employment within the pharmaceutical industry, I am not interested in acquiring commercial assets or the day-to-day affairs of commercializing medicine. Instead, I hope to continue playing a role in the discovery of cures and treatments for rare and life-threatening diseases. I would like to return to the type of work I did when working on cures for DMD and PKAN, and focus on experimental and research-based opportunities related to discovery of new medicines and new uses for existing medicines.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on October 15th, 2021

/s/
Martin Shkreli

*Appendix J*

**UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF NEW YORK**

No. 20-cv-706

FEDERAL TRADE COMMISSION, et al.,

*Plaintiffs,*

v.

VYERA PHARMACEUTICALS, LLC, et al.,

*Defendants*.

Filed: Dec. 7, 2021

JOINT MOTION FOR ENTRY OF
STIPULATED ORDER FOR
PERMANENT INJUNCTION

Plaintiffs Federal Trade Commission ("FTC), by its designated attorneys, and the states and commonwealths of New York, California, Illinois, North Carolina, Ohio, Pennsylvania, and Virginia (collectively the "Plaintiff States"), by and through their Attorneys General (collectively "Plaintiffs") and Defendants Vyera Pharmaceuticals, LLC, Phoenixus AG, and Kevin Mulleady (collectively "Settling Defendants"), by their respective attorneys, respectfully move this

Court to enter the accompanying Stipulated Order for Permanent Injunction and Equitable Monetary Relief ("Stipulated Order"). Entry of the Stipulated Order will end the litigation against the Settling Defendants. The litigation will proceed against Defendant Martin Shkreli. A copy of the Stipulated Order is attached as Exhibit A. As grounds for this request, the parties state as follows:

1. On April 16, 2021, Plaintiffs filed an Amended Complaint against the Settling Defendants and Mr. Shkreli, pursuant to Section 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b), Section 16 of the Clayton Act, 15 U.S.C § 26, Section 342 of the New York General Business Law, Section 63(12) of the New York Executive Law, Sections 16700 *et seq.*, 17200 *et seq.* of the California Business and Professions Code, Section 7 of the Illinois Antitrust Act, 740 ILCS 10/1 *et seq.*, North Carolina Unfair or Deceptive Practices Act, N.C. Gen. Stat. §75-1 *et seq.*, Chapter 1331and Section 109.81 of the Ohio Revised Code, Pennsylvania, Unfair Trade Practices and Consumer Protection Law, 73 P.S. § 201-1 *et seq.* and Common Law Doctrine against Restraints of Trade proceeding under 71 P.S. § 732-204 (c) and the Virginia Antitrust Act, Virginia Code §59.1-9.1 *et seq.*, alleging unfair methods of competition, monopolization, and agreements in restraint of trade to prevent generic competition to Daraprim, an antiparasitic used to treat toxoplasmosis.

2. The Settling Defendants deny the allegations and claims against them in the Amended Complaint,

and that Plaintiffs are entitled to any relief sought therein.

3. In their Amended Complaint, Plaintiffs seek a permanent injunction to prevent the continuation of the conduct at issue and to prevent similar and related conduct in the future and to prevent Defendants Shkreli and Mulleady (the "Individual Defendants") from owning in part or whole, or working for, a pharmaceutical company. The State Plaintiffs also seek equitable monetary relief under Section 342 of the New York General Business Law, Section 63(12) of the New York Executive Law, Sections 16700 *et seq.*, 17200 *et seq.* of the California Business and Professions Code, Section 7 of the Illinois Antitrust Act, 740 ILCS 10/1 *et seq.*, North Carolina Unfair or Deceptive Practices Act, N.C. Gen. Stat. §75-1 *et seq.*, Chapter 1331and Section 109.81 of the Ohio Revised Code, Pennsylvania, Unfair Trade Practices and Consumer Protection Law, 73 P.S. § 201-1 *et seq.* and Common Law Doctrine against Restraints of Trade proceeding under 71 P.S. § 732-204 (c) and the Virginia Antitrust Act, Virginia Code §59.1-9.1 *et seq*.

4. The Settling Defendants have reached a settlement with Plaintiffs. In doing so, the Settling Defendants admit only the facts necessary to establish the personal and subject matter jurisdiction of the Court in this matter.

5. The Settling Defendants agree to be bound by the terms of the Stipulated Order upon its entry by the Court.

6. The Stipulated Order applies for a period of 10 years and provides for the parties to bear their respective costs in this action.

7. The Stipulated Order includes injunctive relief in the form of conduct prohibitions that prevent the Corporate Defendants from engaging in conduct similar to that challenged in the Amended Complaint for a period of 10 years, as set forth in Section II.A.

8. The Stipulated Order also includes (a) injunctive relief in the form of conduct prohibitions that prevent Mr. Mulleady (or any company owned or controlled by him) from engaging in conduct similar to that challenged in the Amended Complaint for a period of 10 years, as set forth in Section II.F; and (b) injunctive relief that bans, restrains, and enjoins Mr. Mulleady from participating in various activities relating to, exercising control over, and serving as an officer or director of, any pharmaceutical company, and from acquiring, holding, or voting more than 8% of any pharmaceutical company, with two exceptions, for a period of 7 years, as set forth in Section II.C and D of the Stipulated Order.

9. The Stipulated Order also provides for the following equitable monetary relief payable to the Plaintiff States:

- The Corporate Defendants shall pay a guaranteed amount of $10 million upfront and up to $30 million more in contingent payments over 10 years as set forth in Paragraphs V.A-G of the Stipulated Order;

- A suspended judgment of $250,000 is entered against Mr. Mulleady that is payable only after a final unappealable court ruling that he has violated the Order as set forth in Paragraph V.H. of the Stipulated Order.

10. By December 6 2021 all Plaintiffs and the Settling Defendants had signed the Stipulated Order. On December 7 2021 the Commission voted 4-0 to accept the proposed Stipulated Order. On December 6 2021 the Attorneys General of all Plaintiff States accepted the proposed Stipulated Order. All Plaintiffs and the Settling Defendants jointly request that the Court enter the attached Stipulated Order and place it on the public record thereby bringing this litigation to an end as to the Settling Defendants and retain jurisdiction for the purposes of construction modification and enforcement of the Proposed Order.

Respectfully submitted,

*/s/ Markus H. Meier*
Markus H. Meier
Federal Trade Commission
600 Pennsylvania Ave., NW
Washington, DC 20580
Tel: (202) 326-3759
mmeier@ftc.gov

*Counsel for Plaintiff Federal Trade Commission*

*/s/ Elinor R. Hoffmann*
Elinor R. Hoffmann
Chief, Antitrust Bureau
Office of the New York Attorney General
28 Liberty Street
New York, NY 10005
Tel: (212) 416-8269
elinor.hoffmann@ag.ny.gov

*Counsel for Plaintiff State of New York*

*/s/ Michael D. Battaglia*
Michael D. Battaglia
Deputy Attorney General
Office of the Attorney General of California
455 Golden Gate Avenue, Suite 11000
San Francisco, CA 94102
Tel: (415) 510-3769
michael.battaglia@doj.ca.gov

*Counsel for Plaintiff State of California*

*/s/ Richard S. Schultz*
Richard S. Schultz
Assistant Attorney General
Office of the Attorney General of Illinois
100 W. Randolph Street, 11th Floor
Chicago, IL 60601
Tel: (312) 814-3000
rschultz@ilag.gov

*Counsel for Plaintiff State of Illinois*

*/s/ K.D. Sturgis*
K.D. Sturgis
Special Deputy Attorney General
Jessica V. Sutton
Special Deputy Attorney General
North Carolina Department of Justice
Consumer Protection Division
114 West Edenton Street
Raleigh, NC 27603
Tel: (919) 716-6000
ksturgis@ncdoj.gov

*Counsel for Plaintiff State of North Carolina*

*/s/ Beth A. Finnerty*
Beth A. Finnerty
Assistant Chief, Antitrust Section
Derek M. Whiddon
Assistant Attorney General
Ohio Attorney General
30 E. Broad Street, 26th Floor
Columbus, OH 43215
Tel: (614) 466-4328
beth.finnerty@ohioattorneygeneral.gov

*Counsel for Plaintiff State of Ohio*

*/s/ Joseph S. Betsko*
Joseph S. Betsko
Senior Deputy Attorney General
Stephen M. Scannell
Deputy Attorney General
Pennsylvania Office of Attorney General
Antitrust Section
Strawberry Square, 14th Floor
Harrisburg, PA 17120
jbetsko@attorneygeneral.gov

*Counsel for Plaintiff Commonwealth of Pennsylvania*

*/s/ Tyler T. Henry*
Tyler T. Henry
Assistant Attorney General
Office of the Attorney General of Virginia
202 North Ninth Street
Richmond, VA 23219
thenry@oag.state.va.us

*Counsel for Plaintiff Commonwealth of Virginia*

*/s/ Steven A. Reed*
Steven A. Reed
Morgan Lewis & Bockius LLP
1701 Market St.
Philadelphia, PA 19103
Tel: (215) 963-5603
steven.reed@morganlewis.com

*Counsel for Defendants Phoenixus AG and Vyera Pharmaceuticals, LLC*

*/s/ Kenneth R. David*
Kenneth R. David
1633 Broadway
New York, NY 10019
Tel: (212) 506-1893
kdavid@kasowitz.com
Kasowitz Benson Torres LLP
*Counsel for Defendant Kevin Mulleady*

*Appendix K*

**UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF NEW YORK**

No. 20-cv-706

FEDERAL TRADE COMMISSION, et al.,

*Plaintiffs,*

v.

VYERA PHARMACEUTICALS, LLC, et al.,

*Defendants*.

Filed: Dec. 7, 2021

STIPULATED ORDER FOR
PERMANENT INJUNCTION AND
EQUITABLE MONETARY RELIEF

Plaintiffs the Federal Trade Commission ("FTC" or "Commission"), by its designated attorneys, and the states or commonwealths of New York, California, Illinois, North Carolina, Ohio, Pennsylvania, and Virginia (collectively "Plaintiff States"), by and through their Attorneys General (collectively "Plaintiffs"), pursuant to Section 13(b) of the Federal Trade Commission Act, 15 U.S.C. § 53(b), Section 16 of the Clayton Act, 15 U.S.C § 26, Section 342 of the New York General

Business Law, Section 63(12) of the New York Executive Law, Sections 16700 *et seq.*, 17200 *et seq.* of the California Business and Professions Code, Section 7 of the Illinois Antitrust Act, 740 ILCS 10/1 *et seq.*, North Carolina Unfair or Deceptive Practices Act, N.C. Gen. Stat. §75-1 *et seq.*, Chapter 1331 and Section 109.81 of the Ohio Revised Code, Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P.S. § 201-1 *et seq.* and Common Law Doctrine against Restraints of Trade proceeding under 71 P.S. § 732-204 (c) and the Virginia Antitrust Act, Virginia Code §59.1-9.1 *et seq.*, filed their Amended Complaint for Permanent Injunctive and Other Equitable Relief, against Defendants Vyera Pharmaceuticals, LLC, Phoenixus AG, Martin Shkreli, and Kevin Mulleady to remedy and prevent their alleged anticompetitive conduct and unfair methods of competition in or affecting commerce in violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, Section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a), and state law. The Plaintiffs and Defendants Vyera Pharmaceuticals, LLC, Phoenixus AG, and Kevin Mulleady (collectively "Settling Defendants") have agreed to resolve this case through settlement, without trial or final adjudication of any issue of law or fact, and stipulate to entry of this Stipulated Order for Permanent Injunction and Equitable Monetary Relief ("Order") to resolve all matters against the Settling Defendants in dispute in this action.

## FINDINGS

1. This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331, 1337(a), and 1345, as well as under the principles of supplemental jurisdiction codified in 28 U.S.C. § 1367(a).

2. This Court has personal jurisdiction over the Settling Defendants because each has the requisite constitutional contacts with the United States of America pursuant to 15 U.S.C. 53 §(b) and with the state of New York pursuant to N.Y. CPLR §§ 301, 302.

3. Venue for this matter is proper in this Court under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), 15 U.S.C. § 22, and 15 U.S.C. § 1391(b) and (c).

4. The Amended Complaint alleges that the Settling Defendants engaged in anticompetitive conduct and unfair methods of competition in violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), and state law.

5. The Settling Defendants admit the facts necessary to establish the personal and subject matter jurisdiction of this Court in this matter.

6. The Settling Defendants deny the allegations and claims in the Amended Complaint and dispute that Plaintiffs are entitled to obtain relief.

7. The Settling Defendants waive any claim they may have under the Equal Access to Justice Act, 28 U.S.C. § 2412, concerning the prosecution of

this action through the date of this Order, and agree to bear their own costs and attorney fees.

8. Entry of this Order satisfies the requests for relief made by the Plaintiffs in their Amended Complaint and is in the public interest.

**STIPULATIONS**

1. The Settling Defendants stipulate that venue for this matter is proper in this Court under 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) and (c), and under Section 13(b) of the FTC Act, U.S.C. § 53(b).

2. The Settling Defendants waive all rights to appeal or otherwise challenge or contest the validity of this Order.

3. The Plaintiffs and the Settling Defendants have agreed that entry of this Order fully and finally resolves all claims and litigations between them arising from or based primarily on the allegations described in the Amended Complaint and precludes further litigation against Phoenixus, Vyera, and/or Mulleady, as defined herein, arising from or based primarily on the allegations except for purposes of enforcing or modifying this Order.

4. The Plaintiffs and Settling Defendants stipulate that they will each bear their own costs in this matter and shall not make any claims against the other for attorneys' fees or costs.

## ORDER

**IT IS HEREBY ORDERED:**

## I. DEFINITIONS

As used in this Order, the following definitions apply:

A. "Phoenixus" means Phoenixus AG, its directors, officers, employees, agents, attorneys, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Phoenixus AG, and the respective directors, officers, employees, agents, attorneys, representatives, successors, and assigns of each.

B. "Vyera" means Vyera Pharmaceuticals, LLC, its directors, officers, employees, agents, attorneys, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Vyera Pharmaceuticals, LLC, and the respective directors, officers, employees, agents, attorneys, representatives, successors, and assigns of each. Vyera Pharmaceuticals, LLC is a subsidiary of Phoenixus.

C. "Kevin Mulleady" or "Mulleady" means Defendant Kevin Mulleady, an individual defendant. Mulleady was Chairman of the Board of Directors of Phoenixus AG and Chief Executive Officer of Vyera Pharmaceuticals, LLC. Mulleady is also the Executive Chairman and Chief Executive Officer of Prospero Pharmaceuticals, LLC.

D. "Commission" means the United States Federal Trade Commission.

E. "Plaintiff States" mean the states or commonwealths of New York, California, Illinois, North Carolina, Ohio, Pennsylvania, and Virginia.

F. "API" means any active pharmaceutical ingredient that is used in the manufacture of a Drug Product.

G. "Biosimilar" means any biologic Drug Product that is highly similar to, and has no clinically meaningful difference from, an existing FDA-approved biologic Drug Product or that otherwise meets the FDA's criteria for classification as a biosimilar.

H. "Corporate Asset" means any asset of a Corporate Named Defendant or any successor, assign, joint venture, subsidiary, partnership, division, group, or affiliate controlled by a Corporate Named Defendant. Corporate Asset expressly excludes any inventory, goods or products that are sold or to be sold in the ordinary course of business, including without limitation, any APIs, raw materials, or finished product. Corporate Asset also expressly excludes any unissued shares of equity interests, capital stock, partnership interest, membership or limited liability company interest or similar equity right in one or both of the Corporate Named Defendants or any successor, assign, joint venture, subsidiary, partnership, division, group, or affiliate controlled by any of them.

I. "Corporate Defendants" means Phoenixus and Vyera.

J. "Corporate Named Defendants" means Phoenixus AG and Vyera Pharmaceuticals, LLC.

K. "Customer or Supplier" means a counter-party to a distribution, wholesale, resale, API supply, or Drug Product purchase agreement with a Corporate Defendant.

L. "Daraprim" means any Drug Product authorized for marketing or sale in the United States pursuant to FDA Authorization NDA 008578, and any supplements, amendments, or revisions to this NDA.

M. "Designated State Representatives" mean the following named individuals or another representative identified by each respective Plaintiff State:

1. Elinor R. Hoffmann, Chief, Antitrust Bureau, Office of the New York State Attorney General, 28 Liberty Street, New York, NY 10005, elinor.hoffmann@ag.ny.gov;

2. Michael D. Battaglia, Deputy Attorney General, California Department of Justice, 455 Golden Gate Avenue, Suite 11000, San Francisco, CA 94102, michael.battaglia@doj.ca.gov;

3. Richard S. Schultz, Assistant Attorney General, Antitrust Bureau, Office of the Illinois Attorney General, 100 West Randolph Street, Chicago, IL 60601, richard.schultz@ilag.gov;

4. K. D. Sturgis, Special Deputy Attorney General, North Carolina Department of Justice, 114 West Edenton Street, Raleigh, NC 27603, ksturgis@ncdoj.gov;

5. Beth A. Finnerty, Assistant Chief, Antitrust Section, Office of the Ohio Attorney General,

30 East Broad Street, 26th Floor, Columbus, OH 43215, Beth.Finnerty@ohioAGO.gov;

6. Joseph S. Betsko, Senior Deputy Attorney General, Pennsylvania Office of Attorney General, Strawberry Square, Harrisburg, PA 17120, jbetsko@attorneygeneral.gov; and

7. Tyler T. Henry, Assistant Attorney General, Office of the Attorney General of Virginia, 202 North Ninth Street, Richmond, VA 23219, thenry@oag.state.va.us.

N. "Development" means all preclinical and clinical research and development activities related to a Drug Product, including discovery or identification of a new chemical entity, test method development, all studies for the safety or efficacy of a Drug Product, toxicology studies, bioequivalence and bioavailability studies, pharmaceutical formulation, process development, manufacturing scale-up, development-stage manufacturing, quality assurance/quality control development, stability testing, statistical analysis and report writing, for the purpose of obtaining any and all FDA Authorizations necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, labeling, distribution, and sale of a Drug Product, and regulatory affairs related to the foregoing.

O. "Drug Product" means any product that is the subject of an FDA Authorization.

P. "Exempted Company" means any Pharmaceutical Company owned or controlled by Mulleady (including Prospero) whose business is limited to a

Therapeutic Equivalent of Thiola and/or the PKAN Product.

Q. "FDA" means the United States Food and Drug Administration.

R. "FDA Authorization" means any of the following applications:

1. An application filed or to be filed with the FDA pursuant to 21 C.F.R. Part 314 *et seq.*, including "New Drug Application" ("NDA"), "Abbreviated New Drug Application" ("ANDA"), "Supplemental New Drug Application" ("SNDA"), or "Marketing Authorization Application" ("MAA"), and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto; or

2. A "Biologic License Application" ("BLA") filed or to be filed with the FDA pursuant to 21 C.F.R. 601.2, *et seq.*, and Section 351 of the Public Health Service Act, and any NDA deemed to be a BLA by the FDA, and all supplements, amendments, revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto.

S. "GPO" means any group purchasing organization, an entity that negotiates prices of Drug Products on behalf of member healthcare providers, including hospitals, ambulatory care facilities, physician

practices, nursing homes, and home health agencies.

T. "Net Proceeds" means proceeds after deducting direct transaction costs paid to Third Parties (i.e., sales commissions, advisor fees, and other costs incurred solely due to the underlying transaction).

U. "Ownership Interest" means any voting or nonvoting stock, share capital, or equity in a Person (other than an individual). Ownership Interest shall not include any unexercised options or other unexercised instruments that are convertible into any voting or nonvoting stock.

V. "Person" means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, or other business or government entity, and any subsidiaries, divisions, groups, or affiliates thereof.

W. "Pharmaceutical Company" means any Person (other than an individual) that is engaged in the research, Development, manufacture, commercialization, or marketing of any Drug Product.

X. "PKAN Product" means the chemical compound that, as of the date this Order is entered, Prospero is involved in the Development of as a potential treatment for pantothenate kinase-associated neurodegeneration ("PKAN").

Y. "Priority Review Voucher" means a voucher issued by the FDA that entitles a Drug Product to receive expedited regulatory review.

Z. "Prospero" means Prospero Pharmaceuticals, LLC, its directors, officers, employees, agents,

representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Prospero Pharmaceuticals, LLC, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

AA. "Therapeutic Equivalent" means a Drug Product that is classified by the FDA as being therapeutically equivalent to another Drug Product because, among other criteria, both Drug Products contain identical amounts of an API in the identical dosage form and route of administration, meet compendial or other applicable standards of strength, quality, purity, and identity, and they are classified by the FDA as bioequivalent.

BB. "Thiola" means the Drug Products authorized for marketing or sale in the United States pursuant to FDA Authorizations NDA 019569 or NDA 211843, and any supplements, amendments, or revisions to these NDAs.

CC. "Third Party" means any Person that is not a Corporate Defendant or an entity under common management, direction, or control of a Corporate Defendant.

## II. PROHIBITED BUSINESS ACTIVITIES

**Corporate Defendants**

A. The Corporate Defendants, directly or through any Person, are hereby restrained and enjoined from entering into or enforcing any contract, arrangement, mutual understanding, or agreement

that prohibits, or in any manner interferes with or restricts the ability of:

1. Any purchaser (including hospitals and pharmacies), reseller, wholesaler, or distributor of a Drug Product to provide that Drug Product to a Pharmaceutical Company or its agent(s) or representative(s) for the purposes of the Development of a Therapeutic Equivalent or Biosimilar of that Drug Product by that Pharmaceutical Company,

   *Provided, however,* this provision does not prohibit the Corporate Defendants from entering an agreement with a distributor that restricts that distributor to certain channels of sale so long as it permits the distributor to sell the Drug Product to a Pharmaceutical Company or its agent(s) or representative(s) for the purposes of the Development of a Therapeutic Equivalent or Biosimilar of the Drug Product;

2. Any manufacturer, seller, supplier, or distributor of an API to sell or provide that API to a Pharmaceutical Company,

   *Provided, however*, this provision does not prohibit a Corporate Defendant from entering a contract to purchase all of its needs for a particular API from any Person so long as the contract does not require the Person to supply the API exclusively to the Corporate Defendant or restrict the Person's freedom to sell the API to any other Person, and

   *Provided further,* if the Corporate Defendants have no other supply agreement for a

particular API, this provision will not apply to any arrangement to obtain API from a Person who has not previously manufactured the API if the Corporate Defendants bear at least 50% of the direct costs of developing the API; or

3. Any distributor, wholesaler, pharmacy, or GPO of a Drug Product to sell or otherwise provide data related to the sales or distribution of any Drug Product, such as sales numbers and volume, or other sales variables such as ordering trends, to a Person engaged in the business of purchasing, aggregating, and selling sales and distribution data on Drug Products.

B. The Corporate Defendants shall not hire, appoint as an officer or director, or otherwise do business with Mulleady in any manner that violates Paragraph II.C of this Order and shall not hire, appoint as an officer or director, or otherwise do business with Defendant Martin Shkreli in any manner that violates any provision or restriction in an order issued by this Court.

**Defendant Kevin Mulleady**

C. For a period ending 7 years after this Order is entered, Mulleady is hereby banned, restrained, and enjoined from, directly, or through any other Person:

1. Participating in the research, Development, manufacture, commercialization, distribution, marketing, importation, or sale of a Drug Product or API, including participating in the

formulation, determination, or direction of any business decisions of any Pharmaceutical Company;

2. Exercising control over the activities, conduct, board, or management of any Pharmaceutical Company;

3. Serving as an officer or director of any Pharmaceutical Company;

4. Entering into any agreements, whether oral or written, concerning how to vote his shares in any Pharmaceutical Company; and

5. Calling an Extraordinary General Meeting at Phoenixus or Vyera either on his own or as part of a group doing so,

*Provided, however,* Mulleady may exercise all other rights to which he is entitled as a shareholder of an Exempted Company and/or any Pharmaceutical Company to the extent such shareholding is permitted by Paragraph II.D. Nothing in this Paragraph II.C shall preclude Mr. Mulleady from expressing his own views on his own behalf as a shareholder concerning the business of any such Pharmaceutical Company,

*Provided, further,* it is not a violation of this Paragraph II.C for Mulleady to be employed by, consult with, or act as an officer or director of Phoenixus or Vyera, and in so doing take the actions set forth in Paragraphs II.C.1 to 3, so long as:

a) Mulleady does not own or control any Ownership Interest in Phoenixus or Vyera, either directly or through any other Person, and

b) Mulleady provides prior notification to the Commission and the Plaintiff States of any proposed involvement in or engagement with Phoenixus or Vyera pursuant to Paragraph VI.C, and

*Provided, finally*, that it is not a violation of this Paragraph II.C for Mulleady to be employed by, consult with, or act as an officer or director of an Exempted Company and/or take the actions set forth in Paragraphs II.C.1 to 4 at an Exempted Company, so long as:

a) The Exempted Company's business is limited to (i) a Therapeutic Equivalent of Thiola and/or (ii) the PKAN Product, and the Exempted Company does not have an interest or role in, and is not engaged in any activities related to, any other Drug Product;

b) The Exempted Company's financial interest in any Therapeutic Equivalent of Thiola is limited to a passive royalty right;

c) The Exempted Company does not have any authority, control, or other role in, or engage in any activities related to, the commercialization, marketing, sales, distribution, or pricing of any Therapeutic Equivalent of Thiola;

d) Prior to the filing of an FDA Authorization, the Exempted Company fully divests itself of any control or authority to commercialize, market, sell, distribute, or price any PKAN Product; and

e) Mulleady complies with the prior notification provisions set forth in Paragraphs VI.D and VIII.B.

D. Mulleady is hereby restrained and enjoined from acquiring, holding, or voting more than 8% of the Ownership Interest (based on the latest information available to shareholders from the issuer) in any Pharmaceutical Company (other than an Exempted Company), either directly or through any other Person,

*Provided, however,* it shall not be a violation of this Paragraph II.D if Mulleady passively obtains more than 8% of the Ownership Interest in a Pharmaceutical Company through means other than exercising options or otherwise purchasing the Ownership Interest so long as Mulleady (i) reduces his Ownership Interest in such Pharmaceutical Company to 8% or lower within 10 months, and (ii) in the interim only votes up to 8% of the Ownership Interest in the Pharmaceutical Company,

*Provided, further,* this Paragraph II.D does not permit Mulleady to acquire, hold, or vote any Ownership Interest in Phoenixus or Vyera while Mulleady is employed by, consulting with, or acting as officer or director for Phoenixus or Vyera, and

*Provided, finally,* Mulleady may exercise the rights to which he is entitled as a shareholder of a Pharmaceutical Company (other than those prohibited by Paragraphs II.C.4 and 5) so long as his Ownership Interest in such company does not exceed the limits in this Paragraph II.D.

E. If Phoenixus or Vyera is found in violation of Section II of this Order, it shall be presumed that Mulleady has also violated the terms of this Order, but only if he is employed by, consulting with, or acting as officer or director for Phoenixus or Vyera at the time the violation occurs. Mulleady may rebut this presumption by proving to the Court by a preponderance of the evidence that he did not have any knowledge of, involvement in, or in any manner facilitate, the violation of this Order.

F. Mulleady, any Exempted Company, and any other company Mulleady controls, is restrained and enjoined from proposing, negotiating, reviewing, entering into, being a party to, or enforcing, either directly or through any other Person, any contract, arrangement, mutual understanding, or agreement that prohibits, or in any manner interferes with or restricts the ability of:

    1. Any purchaser (including hospitals and pharmacies), reseller, wholesaler, or distributor of a Drug Product to provide that Drug Product to a Pharmaceutical Company or its agent(s) or representative(s) for the purposes of the Development of a Therapeutic Equivalent or Biosimilar of that Drug Product by that Pharmaceutical Company,

*Provided, however,* this provision does not prohibit Mulleady, any Exempted Company, or any other company Mulleady controls from entering an agreement with a distributor that restricts that distributor to certain channels of sale so long as it permits the distributor to sell the Drug Product to a Pharmaceutical Company or its agent(s) or representative(s) for the purposes of the Development of a Therapeutic Equivalent or Biosimilar of the Drug Product;

2. Any manufacturer, seller, supplier, or distributor of any API to provide that API to a Pharmaceutical Company,

*Provided, however,* this provision does not prohibit Mulleady, any Exempted Company, or any other company Mulleady controls from entering a contract to purchase all of its needs for a particular API from any Person so long as the contract does not require the Person to supply the API exclusively to the company or restrict the Person's freedom to sell the API to any other Person, and

*Provided further,* if Mulleady, any Exempted Company, or any other company Mulleady controls has no other supply agreement for the particular API, this provision will not apply to any arrangement to obtain API from a Person who has not previously manufactured the API if Mulleady, the Exempted Company, or any company he owns or controls bears at least 50% of the direct costs of developing the API; or

3. Any distributor, wholesaler, pharmacy, or GPO of a Drug Product to sell or otherwise provide data related to the sales or distribution of any Drug Product, such as sales numbers and volume, or other sales variables such as ordering trends, to a Person engaged in the business of purchasing, aggregating, and selling sales and distribution data on Drug Products.

## III. NOTIFICATIONS TO AFFECTED PERSONS

**Corporate Defendants**

The Corporate Defendants shall provide, within 21 days of the entry of this Order, written notification in the form of Appendix A to this Order to all their Customers and Suppliers, and going forward shall provide such notification to any Customer or Supplier to whom the Corporate Defendants have not previously provided notification under this Section III,

*Provided, however,* the Corporate Defendants need not provide notice to Customers entering into an agreement to purchase generic prescription drugs so long as the agreement does not also include branded prescription drugs or an API.

## IV. SUPPLY OF DRUG PRODUCTS

**Corporate Defendants**

A. So long as a Corporate Defendant markets a Drug Product, they shall, at the request of a Pharmaceutical Company, sell the Drug Product to that

Pharmaceutical Company for use in Development of a Therapeutic Equivalent or Biosimilar of the Drug Product in accordance with the following:

1. The quantity sold shall be at least as much as the Pharmaceutical Company, in its reasonable judgment, needs to conduct its Development of a Therapeutic Equivalent or Biosimilar of the Drug Product;

2. The Drug Product is delivered no later than 30 days after the Corporate Defendant receives a purchase order; and

3. The Corporate Defendants shall charge the Pharmaceutical Company a price that is no greater than the wholesale acquisition cost of the Drug Product.

B. The Corporate Defendants shall continue to market and sell Daraprim until the earliest to occur of the following:

1. At least three Pharmaceutical Companies that are Third Parties have obtained FDA Authorization to market and sell a Therapeutic Equivalent of Daraprim and each has made at least one commercial sale of the Therapeutic Equivalent;

2. At least two Pharmaceutical Companies that are Third Parties have obtained FDA Authorization to market and sell a Therapeutic Equivalent of Daraprim and each of these Pharmaceutical Companies has made uninterrupted commercial sales of the Therapeutic Equivalent for a period of at least 9 months;

3. The Corporate Defendants exhaust their supply of pyrimethamine API, the API is no longer available, or the API is only available at a cost or in quantities that make it unprofitable to continue marketing and selling Daraprim, and the Corporate Defendants notify the Commission and the Designated State Representatives of their inability to secure a supply of pyrimethamine and the reasons therefore;

4. An independent auditor, selected by the Corporate Defendants and approved by the Plaintiffs, verifies that the operating expenses (including variable and fixed costs) for Daraprim exceeded net revenues generated through the sale of Daraprim for at least two consecutive quarters;

5. The Corporate Defendants lose FDA Authorization to continue marketing Daraprim;

6. Three years after this Order is entered; or

7. The Corporate Defendants (a) notify the Commission and the Plaintiff States of their intent to discontinue marketing Daraprim; (b) sell their Daraprim business to an acquirer ("Acquirer") and in a manner that is acceptable to the Commission and the Plaintiff States; (c) maintain the viability, marketability, and competitiveness of the Daraprim business until the sale of the Daraprim business is completed; and (d) provide the Acquirer with the assistance and information necessary to enable the Acquirer to obtain the necessary approvals to manufacture, market, and sell

Daraprim in commercial quantities, and to supply the Acquirer with sufficient quantities of Daraprim to meet the Acquirer's commercial needs until the Acquirer is independently able to manufacture and market commercial quantities of Daraprim.

C. The Corporate Defendants shall provide notifications required under this Section IV to the Commission and the Plaintiff States by sending electronic copies to the Secretary of the Commission at ElectronicFilings@ftc.gov and to the Compliance Division at bccompliance@ftc.gov, and by sending electronic copies to each Designated State Representative.

## V. EQUITABLE MONETARY RELIEF

**Corporate Named Defendants**

A. The Corporate Named Defendants shall pay up to $40 million to the Settlement Fund (defined below), comprised of a guaranteed payment of $10 million, and contingent payments of up to $30 million pursuant to Paragraph V.C.

B. The Corporate Named Defendants shall pay $10 million as equitable monetary relief, which shall be used for a settlement fund in accordance with the terms of this Order ("Settlement Fund"). The Corporate Named Defendants will make this payment within 30 business days of the entry of this Order by electronic fund transfer into the Settlement Fund in accordance with instructions provided by the Plaintiff States. The money deposited into the Settlement Fund shall be held in escrow

and distributed in the manner prescribed in Paragraph V.D herein.

C. The Corporate Named Defendants are ordered to make additional payments of equitable monetary relief, not to exceed $30 million in the aggregate, to the Settlement Fund as described below:

1. For any Corporate Asset other than a Priority Review Voucher, Corporate Named Defendants will:

a) Pay 20% of the total Net Proceeds from the sale, license, transfer, or other monetization of an asset that results from a transaction that is executed within 5 years after this Order is entered; and

b) Pay 20% of the total Net Proceeds from a transaction monetizing the remaining royalty stream related to Ketamine assets that is executed prior to entry of this Order or within 5 years after this Order is entered.

Corporate Named Defendants must transfer monies related to transaction into the Settlement Fund within 30 days of its receipt; for example, in a transaction with an upfront payment and royalty stream, the Corporate Named Defendants would pay 20% of the net upfront payment within 30 days of receiving the upfront payments and would pay 20% of any additional royalties within 30 days of when the royalties are received by either Corporate Named Defendant,

*Provided, however,* the Corporate Named Defendants shall not be required to make payments under this Paragraph V.C.1 after (a) their total payments to the Settlement Fund under this Paragraph V.C.1 equal $15 million, or (b) their total combined payments to the Settlement Fund under Paragraphs V.C.1 and V.C.2 equal $30 million.

2. For any Priority Review Voucher that is a Corporate Asset, the Corporate Named Defendants will pay 20% of the Net Proceeds received from the the sale, license, transfer or other monetization of the Priority Review Voucher that results from a transaction executed during the term of this Order,

   *Provided, however,* the Corporate Named Defendants shall not be required to make payments under this Paragraph V.C.2 after their total payments to the Settlement Fund under Paragraphs V.C.1 and V.C.2 equal $30 million.

3. No later than 30 days after any transaction for which the Corporate Named Defendants are required to make additional payments under this Paragraph V.C, the Corporate Named Defendants shall provide notice to the Designated State Representatives of the transaction. The notice shall include a description of the transaction and its financial terms, contact information for each party to the transaction (including the name, phone number and email address of a representative of the party

with knowledge of the transaction), and a copy of all agreements regarding the transaction.

D. All money deposited in the Settlement Fund pursuant to this Section V shall be used for equitable relief, including consumer redress and other equitable relief that the Plaintiff States determine to be related to the Corporate Named Defendants' alleged violative practices and injury, any attendant expenses for the administration of such fund, and repayment of out-of-pocket expenses, and to satisfy the amount of any settlement reached in the related case, *BCBSM, Inc. v. Vyera Pharmaceuticals, LLC, et al.,* No. 21-cv-01884-DLC (SDNY) (the "Class Action"). Any money remaining in the fund after such distributions shall be deposited by the Plaintiff States as disgorgement to be used consistently with their respective state laws. Any interest earned on amounts deposited into the fund will remain in the fund and become a part of the fund.

E. Within 10 business days of entry of the Order, the Corporate Named Defendants shall submit their Taxpayer Identification Numbers (Employer Identification Numbers) to the Plaintiff States.

F. The Corporate Named Defendants shall have no right to challenge any actions the Plaintiff States or their representatives may take pursuant to this Section V of this Order.

G. In consideration for the settlement of this matter and Plaintiff States' agreement to receive equitable monetary relief over a period of 10 years, one or both Corporate Named Defendants, on behalf of themselves and their successors, and any

subsidiaries, and affiliates controlled by them, whether private or publicly-traded, shall sign within 30 days of entry of this Order a collateral agreement (in the form contained in Appendix B or as otherwise agreed to by the Plaintiff States and the Corporate Named Defendants) to secure the contingent debt described in Paragraph V.C as follows: (1) the Corporate Named Defendants give and grant the Plaintiff States a secured interest in all of the assets that are Corporate Assets (other than as set forth in Appendix B and other than any right, title, or interest in any Priority Review Voucher) of the Corporate Named Defendants until the obligation in Paragraph V.C.1 has been fully satisfied or the prescribed period of time has expired; and (2) the Corporate Named Defendants give and grant the Plaintiff States a secured interest in the Priority Review Voucher that is a Corporate Asset until the obligations of Paragraph V.C.2 have been fully satisfied or the prescribed period of time has expired. The Corporate Named Defendants shall promptly provide information requested by a Designated State Representative to facilitate the perfection or enforcement of the security interest granted under the collateral agreement. If Corporate Named Defendants file for bankruptcy protection, within this 10 year period, the Corporate Named Defendants shall not object to the Plaintiff States asserting the appropriate security interest as a Secured Creditor with the appropriate court.

**Defendant Kevin Mulleady**

H. Judgment in the amount of two hundred and fifty thousand dollars ($250,000) is entered in favor of the Plaintiff States against Mulleady as equitable monetary relief in connection with a negotiated resolution of this action and not as part of any final adjudication of any issue of fact or law. The judgment is suspended unless and until there is a final unappealable judgment of contempt against Mulleady (i.e., all parties have exhausted their rights to appeal the judgment of contempt or the time for all such appeals has lapsed). A final unappealable judgment of contempt against Mulleady shall lift the suspension of the judgment and Mulleady shall be required to pay the judgment within 90 days of delivery of instructions by a Designated State Representative. Neither party will contest the other party's right to appeal any order or judgment of contempt or other violation of this Order.

## VI. PRIOR NOTIFICATION REQUIREMENTS

**Corporate Defendants**

A. The Corporate Defendants shall not, directly or indirectly, through subsidiaries, partnerships, or otherwise, acquire from a Third Party:

   1. Any Pharmaceutical Company;

   2. Any rights or interest in any Pharmaceutical Company; or

   3. Any exclusive rights to market, distribute, or sell any FDA-approved Drug Product;

without providing prior written notification to the Commission and each of the Designated State Representatives.

The prior notification required by this Section VI shall be given on the Notification and Report Form set forth in the Appendix to Part 803 of Title 16 of the Code of Federal Regulations as amended (hereinafter referred to as the "Notification"), and shall be prepared and transmitted in accordance with the requirements of that part, except that no filing fee will be required for any such Notification. Notification shall be filed with the Secretary of the Commission at ElectronicFilings@ftc.gov, and copies provided to the Compliance Division of the Commission at bccompliance@ftc.gov, and each Designated State Representative. Notification need not be made to the Department of Justice. Notification is required only of the Corporate Defendants and not of any other party to the transaction. The Corporate Defendants shall provide Notification to the Commission and to each of the Designated State Representatives at least 30 days prior to consummating any such transaction (hereafter referred to as the "first waiting period"). If, within the first waiting period, representatives of the Commission make a written request for additional information or documentary material (within the meaning of 16 C.F.R. § 802.20), the Corporate Defendants shall not consummate the transaction until 30 days after substantially complying with such request. Early termination of the waiting periods in this Paragraph VI.A may be requested by the Corporate Defendants and, where appropriate, granted by a letter from the Commission's Bureau of Competition,

*Provided, however,* that prior notification to the Commission shall not be required by this Order for a transaction for which notification is required to be made, and has been made, pursuant to Section 7A of the Clayton Act 15 U.S.C. § 18a; however, notification shall still be made to the Designated State Representatives, and

*Provided further,* that prior notification shall not be required by this Order for a transaction valued at less than $25 million, as adjusted annually on the anniversary of the date this Order is entered based on the yearly increase or decrease of the Producer Price Index for Pharmaceutical Preparation Manufacturing.

**Defendant Kevin Mulleady**

B. If Mulleady, directly or through any other Person, acquires more than 1% of Ownership Interest in a Pharmaceutical Company (other than indirectly through a mutual fund, exchange-traded fund, or other diversified, investment vehicle that is not specifically focused on Pharmaceutical Companies), Mulleady shall provide written notification to the Commission and to each of the Designated State Representatives within 30 days of acquiring such interest,

*Provided, however,* Mulleady need not provide notice of his Ownership Interest in Phoenixus, Vyera, or Prospero as of the date this Order is entered. As part of his notification, Mulleady shall describe, by number of shares and percentage of total ownership, based on the latest information available to shareholders from the issuer (which

source Mulleady shall identify in the referenced notification), the size of his Ownership Interest in the relevant Pharmaceutical Company before the transaction, and the size of the Ownership Interest he acquired in the transaction.

C. Mulleady shall not be employed by, consult with, or act as an officer or director for Phoenixus or Vyera pursuant to Paragraph II.C without providing 30 days' prior written notification to the Commission and each of the Designated State Representatives. As part of his notification, Mulleady must identify and describe in detail his position and responsibilities, provide a copy of any employment or consulting agreement, identify and provide contact information for his immediate supervisor, and certify that he has provided a copy of the Order to his immediate supervisor. If, in response to the notification required pursuant to this Paragraph VI.C, representatives of the Commission or the Plaintiff States make a written request for additional information or documentary material, Mulleady will not commence any such work for Phoenixus or Vyera until 30 days after substantially complying with the request.

D. If Mulleady is employed by, consulting with, or acting as an officer or director of an Exempted Company, then the Exempted Company may not divest itself of control or authority to commercialize, market, sell, distribute, or price the PKAN Product without providing 30 days' advance written notice of the closing of any such transaction to the Commission and the Plaintiff States. The written notification must identify the intended counterparty and value and date of the proposed transaction. No

filing fee shall be required for such notification. If, in response to a notification required pursuant to this Paragraph VI.D, representatives of the Commission or the Plaintiff States make a written request for additional information or documentary material, the Exempted Company shall not consummate the transaction until 30 days after submitting such additional information or documentary material. The Commission and Plaintiff States are collectively limited to a single such request for additional information.

## VII. COMPLIANCE REPORTING REQUIREMENTS

**All Settling Defendants**

A. Each Settling Defendant shall submit to the Commission and to each of the Designated State Representatives verified written reports ("Compliance Reports") setting forth in detail the manner and form in which each Settling Defendant intends to comply, has complied, and is complying with this Order, in accordance with the following:

1. Each Settling Defendant shall submit an initial Compliance Report within 60 days of the entry of this Order;

2. On the first anniversary of the entry of this Order, and annually thereafter for 9 years on the anniversary date of the entry of this Order, each Settling Defendant shall submit an annual Compliance Report; and

3. Each Settling Defendant shall submit additional Compliance Reports as the Commission

or its staff or a Designated State Representative may request.

B. Each Compliance Report shall contain sufficient information and documentation to enable the Commission and the Plaintiff States to determine whether the Settling Defendants are in compliance with the Order. Conclusory statements that the Settling Defendant has complied with its or his obligations under this Order are insufficient.

C. The Corporate Defendants shall include in their Compliance Reports, among other information or documentation that may be necessary to demonstrate compliance with this Order:

1. A full description of the measures the Corporate Defendants have implemented or plans to implement to ensure that they have complied, are complying, or will comply with each paragraph of this Order;

2. A certified accounting of all proceeds from the sale, license, transfer, or other monetization of any Corporate Asset (other than an asset related to a Priority Review Voucher) and the monetization of the remaining royalty stream related to Ketamine; and

3. A certified accounting of all proceeds from the sale, license, transfer, or other monetization of any Priority Review Voucher.

D. Mulleady shall include in his Compliance Reports, among other information or documentation that may be necessary to demonstrate compliance with this Order:

1. A full description of the measures he has implemented or plans to implement to ensure that he has complied, is complying, or will comply with each paragraph of this Order, and

2. Information that identifies and describes all ballots cast by him, directly or indirectly, in the exercise of his voting interest in any Pharmaceutical Company. Upon request by the Commission or a Designated State Representative, Mulleady shall provide copies of such ballots.

E. Each Settling Defendant shall retain all material written communications with each party identified in its or his Compliance Report and all internal memoranda, reports, and recommendations concerning fulfilling its or his obligations under this Order, and shall provide non-privileged copies of these documents to Commission staff and the Designated State Representatives upon request.

F. Each Settling Defendant shall submit its or his Compliance Report to the Commission and the Plaintiff States by submitting the report electronically to the Secretary of the Commission at ElectronicFilings@ftc.gov, to the Compliance Division of the Commission at bccompliance@ftc.gov, and to each Designated State Representative.

## VIII. CHANGE OF CORPORATE CONTROL

**Corporate Defendants**

A. The Corporate Defendants shall notify the Commission and each Designated State Representative at least 30 days prior to:

1. The dissolution of a Corporate Named Defendant;

2. Any proposed acquisition, merger, or consolidation of a Corporate Named Defendant; or

3. Any other change in a Corporate Named Defendant, including assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Order.

**Defendant Kevin Mulleady**

B. If Mulleady is employed by, consulting with, or acting as an officer or director of an Exempted Company, then Mulleady shall notify the Commission and each Designated State Representative at least 30 days prior to:

1. The dissolution of the Exempted Company;

2. The closing of any proposed acquisition, merger, or consolidation of the Exempted Company;

3. The closing of any proposed change of ownership, control, or authority of the PKAN Product; or

4. Any other change in the Exempted Company, including assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Order.

## IX. ACCESS TO INFORMATION

**All Settling Defendants**

For purposes of determining or securing compliance with this Order, subject to any legally recognized privilege, upon written request, and upon 10 business days' notice to a Corporate Defendant (made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address), or to Mulleady (if Mulleady is employed at, consulting with, or acting as officer or director of an Exempted Company in accordance with Paragraph II.C), the notified Corporate Defendant or Mulleady shall, without restraint or interference, permit any duly authorized representative of the Commission or of a Designated State Representative:

A. Access, during business office hours of the Corporate Defendant or the Exempted Company, and in the presence of counsel, to all facilities and access to inspect and copy all non-privileged books, ledgers, accounts, correspondence, memoranda, and all other records and documents ("Books and Records") in the possession or under the control of that Corporate Defendant or Mulleady related to compliance with this Order, which copying services shall be provided by the Corporate Defendant or Mulleady at the request of the authorized

representative(s) of the Commission or of a Designated State Representative and at the expense of the Corporate Defendant or Mulleady,

*Provided*, *however*, that if the Exempted Company does not have dedicated facilities of its own (including rented office space in a multipurpose building), Mulleady may make such Books and Records available at an alternative location within the Southern District of New York; and

B. To interview officers, directors, or employees of the Corporate Defendant or the Exempted Company, who may have counsel present, regarding such matters.

## X. COOPERATION

**Corporate Defendants**

A. In connection with litigation in this matter against Defendant Martin Shkreli, the Corporate Defendants shall:

1. Agree not to object or move to quash service of process of trial subpoenas to Anne Kirby and Nicholas Pelliccione issued by the Commission or the Plaintiff States under Rule 45 of the Federal Rules of Civil Procedure; and agree to seek their authorization to accept service on their behalf; and

2. Negotiate in good faith with the Commission and a Designated State Representative to provide a declaration, affidavit or, if necessary, a sponsoring witness to establish the authenticity and admissibility of any documents or data

that the Corporate Defendants produce or have produced to the Commssion or the Plaintiff States.

**Defendant Kevin Mulleady**

B. In connection with litigation in this matter against Defendant Martin Shkreli, Mulleady shall:

1. Agree to service of process of a trial subpoena to Mulleady issued by the Commission or the Plaintiff States under Rule 45 of the Federal Rules of Civil Procedure; and

2. Negotiate in good faith with the Commission and a Designated State Representative to provide a declaration, affidavit or, if necessary, act as a sponsoring witness to establish the authenticity and admissibility of any documents or data as to which he has personal knowledge or can provide evidence as to its reliability.

## XI. RETENTION OF JURISDICTION

This Court shall retain jurisdiction of this matter for the purposes of construction, modification, and enforcement of this Order.

## XII. EXPIRATION OF ORDER

This Order shall expire 10 years after the date it is entered.

## XIII. DISMISSAL AND COSTS

This action is hereby dismissed with prejudice as to the Settling Defendants. Each party to bear its own costs.

SO ORDERED this 7th day of December, 2021.

/s/ Denise Cote
The Honorable Denise Cote

**[Counsel signature pages and appendices omitted]**

*Appendix L*

**UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF NEW YORK**

No. 20-cv-706

FEDERAL TRADE COMMISSION, et al.,

*Plaintiffs,*

v.

MARTIN SHKRELI,

*Defendant*.

Filed: Dec. 30, 2021

TRANSCRIPT OF PROCEEDINGS, DEC. 22, 2021

[1176] McFARLANE: Good morning, your Honor. And may it please the Court, I'm Amy McFarland, from the New York State Attorney General's Office. I'm also speaking today on behalf of the government plaintiffs.

I'd like to briefly address our authority to seek injunctive relief and the state's authority to seek equitable monetary relief in this case.

Your Honor, ever since New York initiated the Daraprim investigation in 2015, we and the other plaintiff states have worked closely with our sister enforcers at

the Federal Trade Commission to address the conduct that allowed defendant, in 2015, to implement a 4,000 percent increase in the price of Daraprim, a lifesaving drug, and to unlawfully maintain that 4,000 percent increase by engaging in anticompetitive practices.

The evidence clearly shows that Martin Shkreli, through the company that he controlled, directed and [1177] participated in a comprehensive scheme to prevent generic competition for Daraprim to protect his massive price hike. This scheme, designed to maintain a monopoly on Daraprim, violated the antitrust laws.

As your Honor knows from our papers, the FTC and the states, particularly New York, have strong independent federal and state law bases for the equitable relief sought in this case. Here, I'll be touching on those legal bases and on the appropriateness of three aspects of that relief:

First, permanently banning Mr. Shkreli from working in the pharmaceutical industry, consulting in the pharmaceutical industry, or having any meaningful ownership interest in a pharmaceutical company.

Second, the disgorgement of unjust gains.

And, third, the application of joint and several liability in relation to the disgorgement of unjust gains.

So, first, with respect to an injunction: The FTC act, the Clayton Act, and state law authorize the plaintiffs to seek strong injunctive relief, including industry bans against individuals when equity demands it.

The New York Attorney General has the ability to seek broad equitable relief under Section 63.12 of the New York executive law, which is a remedial statute, not a penal statute.

Through Section 63.12, the Attorney General has [1178] secured lifetime bans against individuals who repeatedly or persistently violate the law. In litigated cases, our state courts have exercised their equitable discretion to issue industry bans against lawbreakers in a variety of industries.

As noted in our papers, the Attorney General has secured injunctions banning individuals from everything from the business of equipment leasing, to the business of mortgage foreclosure consultation, to the business of selling, breeding, or training of dogs.

These industry bans were not time limited, and they did not provide carve-outs for certain activities. They were permanent, plenary injunctions.

Here, federal law and New York law should be used to ban Martin Shkreli from the pharmaceutical industry for life.

To be sure, banning an individual from working in an industry is a serious remedy, but where egregious conduct demands it, it is the proper remedy. And, here, the defendant's conduct warrants a permanent industry ban. He has repeatedly undertaken to profit by grossly distorting competition in pharmaceutical markets and will do it again unless he is banned from the industry.

Mr. Shkreli's chose not to attend this trial and offer his testimony live, but we know from the—

THE COURT: You have to slow down—

MS. McFARLANE: Okay.

[1179] THE COURT: —so that the reporter can catch every word you say and so I can catch every word you say.

MS. McFARLANE: Thank you very much, your Honor, and I apologize.

THE COURT: Thank you.

MS. McFARLANE: Mr. Shkreli chose not to attend this trial and offer his testimony live, but we know, from the many facts in evidence at this trial, that Mr. Shkreli participated in, and directed, the illegal scheme at issue in this case.

While at his prior pharmaceutical company, Retrophin, Mr. Shkreli pioneered his strategy of restricting distribution to foreclose generic—to foreclose potential generic competitors from getting the drug samples necessary to conduct FDA testing for generic approval.

At Retrophin, he bragged to investors that putting drugs into closed distribution has protected virtually every single company that has it from generic competition. He used this strategy at Retrophin to protect price increases after he raised the price of Chenodal from $100,000 to $515,000 a year, and raised the price of Thiola from $4,000 to $80,000 per year.

Then Mr. Shkreli started Vyera. His business development team that had implemented his strategies at Retrophin followed him to Vyera. Vyera, under Mr. Shkreli's control, acquired Daraprim from Impax. As we've heard from Dr. Hardy, Daraprim is used to treat central nervous system [1180] toxoplasmosis, a disease that most frequently afflicts immunocompromised individuals, such as those with uncontrolled HIV.

Under the control of Shkreli, Vyera acquired Daraprim and immediately increased the price 4,000 percent, a price that we've heard former Vyera executive, Dr. Salinas, call excessive, crazy, irresponsible, and the poster child of everything that is considered wrong about the pharmaceutical industry.

Dr. Salinas testified that this kind of massive price hike was Mr. Shkreli's business model. To be able to protect and maintain this grossly excessive price, Vyera imposed restrictions on API suppliers, distributorships, and information flows. Mr. Shkreli, the largest shareholder of Vyera's parent corporation, directed and participated in the scheme continuously from 2015 to the present, even from prison. Because of that conduct, generic entry was impeded, and Vyera was able to force patients to pay its exorbitant price for Daraprim.

As Dr. Hardy testified, and as we've seen in emails from Massachusetts General Hospital, Shkreli's scheme to inflate the price of Daraprim forced physicians and vulnerable patients in life-threatening situations to turn to second-best treatments. Mr. Shkreli

has testified that he contemplates some sort of return to the pharmaceutical industry when he is [1181] released from prison. This must not happen.

Equity demands that Mr. Shkreli be permanently banned from the pharmaceutical industry. 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.

We ask the Court to use the federal and New York State law to issue the strong injunctive relief to ensure that Mr. Shkreli cannot repeat this or any other kind of reprehensible conduct in the pharmaceutical industry when he is released from prison.

Banning Mr. Shkreli from the pharmaceutical industry would also send a powerful signal to corporate executives in the pharmaceutical industry that they cannot engage in illegal schemes to reap monopoly profits at the expense of vulnerable patients.

Turning now to the equitable monetary relief, sought by the state plaintiffs in this case. As your Honor knows, following the Supreme Court's decision in the AMG case, monetary relief here is the unique province of the states.

Your Honor has already found in this case that the plaintiff states have parens patriae standing to bring this action for equitable relief. Your Honor determined, in your partial summary judgment ruling, that the New York Attorney [1182] General has the authority

to seek disgorgement of defendant's net profits. Your Honor also ruled that New York has authority to seek disgorgement of unjust gains from the defendant based on the entirety of U.S. sales of Daraprim because the locus of the wrongful activity was in New York State.

Case law counsels that the district court has broad discretion in calculating the amount to be disgorged. In the Second Circuit, *FTC v. Bronson* provides the guiding principles for calculation of disgorgement. *Bronson* tells us that the plaintiffs bear the burden of showing that the disgorgement calculation reasonably approximated the amount of defendants' unjust gain.

[1183] MS. McFARLANE: *Bronson* specifies that this should be the calculation of the profits resulting from the unlawful conduct less any direct costs incurred by the defendant. If plaintiffs make this showing, the burden then shifts to the defendants to show that the figures were inaccurate.

*SEC v. First Jersey Securities* counsels that any risk of uncertainty in calculating disgorgement should fall on the wrongdoer whose illegal conduct created the uncertainty.

Here, Professor Hemphill has calculated the amount of unjust gain resulting from the illegal activity. He has reasonably approximated that unjust gain to be $64.6 million. As we heard from Professor Hemphill, he was assigned to construct a model that calculates the amount of excess profits under a variety of counterfeit factual scenarios that reflect the likely timing and extent of entry, absent Vyera's unlawful

conduct. In order to make this calculation, Professor Hemphill undertook four steps, each of which I will briefly address.

First, Professor Hemphill calculated Vyera's net Daraprim revenue in the actual world over the relevant period, October 2018, when Professor Hemphill assumed the first generic would have entered, through December 2020. This is a relatively straightforward calculation.

Revenues for the relevant period, less discounts, rebates, and chargebacks paid to distributors, purchasers and payors, Professor Hemphill calculates this figure to be $130.6 [1184] million. This is actually a conservative estimate, since he only considered data through the end of 2020, even though Shkreli's scheme continued to yield unjust gains after that date.

Second, he calculated Vyera's revenue in the counterfactual but-for world associated with a number of different scenarios for generic and authorized generic entry.

Now, one issue that is always central to the construction of the counterfactual is whether the assumptions that were made to construct the counterfactual were reasonable.

Here, Professor Hemphill has said that he relied on the testimony and documents from the generic drug makers, Cerovene and Fera. We have heard from the generic manufacturers, Cerovene and Fera, that they were delayed from entering the market because of

restraints on their ability to source API and obtain samples for FDA testing. This is despite the fact that they doggedly pursued every avenue to overcome the roadblocks erected by Mr. Shkreli and Vyera.

We heard from Manish Shah, the president of Cerovene. Mr. Shah testified that in a world where Fukuzyu agreed to supply Cerovene with API in October 2016, and in a world where Cerovene had no trouble sourcing Daraprim RLD, Cerovene could have filed its amended ANDA in February 2017. Mr. Shah told us that if Cerovene were using Fukuzyu API, the FDA likely would have approved the ANDA in six months, in August of 2017. [1185] Cerovene then would have completed validation batches and would have entered in November 2017. This is actually earlier than Professor Hemphill had anticipated in the very conservative but-for world that he constructed.

We also heard from Frank Della Fera, the CEO of Fera. Mr. Della Fera said that in a normal world, without the restraints imposed by the defendant, he would have expected to source API from Fukuzyu in November 2017. In a normal world, he would have been able to easily acquire RLD and test it against sample batches in June 2018. In a normal world, he would have filed his ANDA in January of 2019 with approval in September, and he would have launched within 30 days, that is to say, in October 2019.

This is consistent with Professor Hemphill's scenarios that assume Fera entry in the fourth quarter of 2019. As we have heard in the testimony, there is a

strong evidentiary basis for Professor Hemphill's scenario that assumes Cerovene entry on or before October 2018 and Fera entry in October 2019.

I should note that, as Professor Hemphill testified, this is a very conservative model. First, it's conservative in that it does not model potential entry from two other firms that sought to enter the market, InvaTech and Mylan, because at the time we constructed the models there was not sufficient information to reasonably determine when these companies might have entered. It's always conservative in that we project [1186] Cerovene entry in October 2018, although we now have testimony from Manish Shah at Cerovene saying that without the illegal conduct, Cerovene might have been able to enter as early as 2017.

Professor Hemphill considered just Cerovene and Fera and assumed Cerovene entry in October 2018 and Fera entry in October 2019 to calculate Vyera's Daraprim revenues, absent the illegal conduct.

The third step of Professor Hemphill's model is a simple mathematical calculation. In this step, he assesses the difference between Vyera's real-world revenues and the revenues that they would have made in the counterfactual world, where there was no illegality. By doing this, he determines the incremental revenue attributable to Vyera's conduct. Professor Hemphill calculates this access revenue, revenue but for the illegal conduct, to be $67.6 million.

Which brings us to the fourth and final step of Professor Hemphill's excess profits calculation. In the

counterfactual world, where generics entered earlier, Vyera would have sold less Daraprim. Vyera's incremental costs, costs associated with the manufacturing of tablets and sales force costs, therefore, would have been lower in the but-for world.

So as a final adjustment, Professor Hemphill deducts the cost that Vyera would have avoided if Vyera were making and [1187] selling less Daraprim. After deducting those costs, Professor Hemphill recently approximates that 64.6 million in excess profits were attributable to the illegal conduct.

Professor Hemphill's model incorporated assumptions that are well rooted in fact, so he has reasonably approximated the amount of unjust gain. Plaintiffs have met their burden under *Bronson*. As I mentioned, under *Bronson*, the burden then shifts to the defendants to show that our approximation of unjust gains is inaccurate.

Defendant's expert, Professor Jena, has done nothing to establish that Professor Hemphill's approximation is unreasonable. He raises no issue with Professor Hemphill's methodology. Instead, he notes generally, without any specifics, that Professor Hemphill has not provided a sound basis for determining the date of generic entry in the but-for world.

He also quibbles with Professor Hemphill's volume assumption, even though Professor Hemphill based those assumptions on the real-world data and on Vyera's own forecast. His thin and uncompelling criticisms do nothing but cast doubt on the accuracy of

Professor Hemphill's analysis. Defendant's have, therefore, failed to meet their burden under *Bronson*.

Professor Hemphill has presented a reasonable approximation of ill-gotten gains, and we ask the Court to award at least $64.6 million of disgorgement to the plaintiffs.

[1188] As a last issue, should the Court award disgorgement in this case, Martin Shkreli should be held jointly and severally liable for the award. It is well established that the Court can exercise its discretion to impose joint and several liability in disgorgement cases. This discretion is properly exercised when defendants in a case have collaborated on the illegal scheme.

For example, in *SEC v. Pentagon Capital Management*, the Second Circuit found that joint and several liability was appropriate because defendants collaborated on a common scheme.

This principle also holds under state law. In *212 Investors Corporation v. Kaplan*, a New York state court observed that there is a significant body of authority holding that when apportioning liability for disgorgement, courts have the discretion to find joint and several liability when two or more individuals collaborate in the illegal conduct. Where joint and several liability applies in the disgorgement context, as it should here, there is no requirement to show that the ill-gotten profits personally accrued to the defendant.

As the Second Circuit noted in *SEC v. Contorinis*, where there is joint and several liability for disgorgement, the amount a court may order a wrongdoer to disgorge may not exceed the total amount of gain from the illegal action, but that does not entail that the gain must personally accrue to [1189] the wrongdoer.

Whether an award of several and joint liability is appropriate is a fact-specific inquiry. The facts here clearly establish that the defendant should be held jointly and severally liable for the total amount of disgorgement.

Since Martin Shkreli hatched this monopolistic scheme, he has been a primary shareholder of Vyera's parent company and has significant voting rights. Any increased revenues that have benefited shareholders have benefited Mr. Shkreli first and foremost.

As we have heard from Ms. Haneberg, Mr. Shkreli also continuously exercised functional control over the company, even after he was in prison. Shkreli stayed in regular contact with Kevin Mulleady while Shkreli was in prison, collaborating with him regarding the operation and management of Vyera.

As your Honor knows, Shkreli's foliation of messages sent from Shkreli's illegal prison phone have prejudiced our ability to fully understand the scope of those discussions. But we do know, according to Kevin Mulleady's log, that Mulleady had over 1500 communications with Shkreli just in the seven-month period from December 2019 until July 2020, some of which pertained to the operation of Vyera.

And we know, from reported prison conversations, that Shkreli thought, as recently as 2020, that being on the board of Phoenixus means you're on the Martin and Kevin board. He [1190] understood himself to be and in fact was controlling the company from prison. He was personally integrally involved in decision making at Vyera and was collaborating with Vyera executives to continue implementation of the illegal scheme that he had designed. If defendants have collaborated in an illegal scheme, imposition of joint and several liability is consistent with equitable principles. The Supreme Court recognized this in *SEC v. Liu* and remanded to the trial court there to determine whether the facts were such that Liu and his wife could be held jointly and severally liable. On remand, the trial court found that Liu's wife of was an active partner and accomplice in the scheme and imposed joint and several liability.

Here, Shkreli designed and maintained an illegal scheme that harmed not only competition but also consumers, the patients who are unable to obtain or afford Daraprim and those who were forced to pay its inflated price.

For his role in this scheme Martin Shkreli should be permanently banned from the pharmaceutical industry and should be held jointly and severally liable for a disgorgement award of at least $64.6 million.

Thank you, your Honor, for your time and consideration.

THE COURT: There has been a settlement publicly disclosed with respect to the codefendants in this action. So [1191] how does that settlement agreement affect, if at all, the award that you seek here of disgorgement?

MS. McFARLANE: Sure, your Honor. Should your Honor find $64.6 million of disgorgement appropriate in this case and declare Mr. Shkreli jointly and severally liable, we do believe that equitable principles may require some setoff in the amount of what the settling defendants actually pay in the settlement.

THE COURT: Thank you.

MS. McFARLANE: Thank you, your Honor.

* * *

[1196] MR. CASEY: Thank you, your Honor.

One other thing I wanted to address, your Honor. The plaintiffs said that Mr. Shkreli is blaming others, blaming the generic companies, blaming the FDA.

Your Honor, that's not what is happening here. Mr. Shkreli is not blaming anybody. In fact, he has taken responsibility in his affidavit for some conduct, including the price increase, which he takes responsibility for, and for some of the fallout after that.

But what our argument is is simply holding the plaintiffs to their burden of proof. They have a burden to establish causation. They have a burden to establish that there was a substantial anticompetitive effect in

the market. Our argument is they have not met that burden.

That's what I plan to go into with the Court today, is to discuss some of those pieces of record evidence that suggest, we think strongly—I wouldn't say suggest—that [1197] show that plaintiffs haven't met their burden.

It's not debatable that under the rule of reason plaintiffs bear the initial burden—and I'm quoting from *Ohio v. American Express*, Supreme Court decision, 2018—the initial burden to prove that the challenged restraint has a substantial anticompetitive effect that harms consumers in the relevant market.

That's plaintiffs' burden. They have to show that these restrictions and this scheme, as they put it, actually delayed the generics in entering the market. The record evidence does not show that, your Honor.

MR. CASEY:

* * *

[1228] At this point, your Honor, I would like to move on to the relief issues, injunctive relief and equitable monetary relief. Plaintiffs have asked for an industry ban. This morning it appeared that they were asking for a lifetime ban.

It's not clear to me whether that's in fact what they are seeking. In their pretrial memo they asked for at least a 20-year ban. But, in any event, they are asking for a significant industry ban from the Court.

Here, your Honor, this obviously is an issue for your discretion. This is an equity court. In our view, any injunctive relief, if the Court disagreed with us and believed that Mr. Shkreli should be held liable, the question is, what is the consequence of that? Any injunctive relief should be narrowly tailored to the specific violations and avoid unnecessary burden on lawful commercial activity. That's a quote from a case called *Syntel Sterling Best Shores Mauritius Ltd. v. Trizetto Group, Inc.*, 2021 WL 1553926 at page 14 (S.D.N.Y. April 20, 2021)

Your Honor, the plaintiffs concede in their pretrial brief that an industry ban is "uncommon and reserved for the most egregious cases." That's a direct quote from their pretrial memorandum at page 49.

But this is not the type of case in which the FTC or the states have pursued industry bans. For this Court to issue [1229] an industry ban, we submit would simply constitute punishment, which is not the purpose of an equity court.

For that, your Honor, I can refer you to the Liu case, which was cited earlier by plaintiffs in the Supreme Court. *Liu v. SEC*, 140 S. Ct. 1936 at page 1945 (2020). The plaintiffs have cited a number of cases in their pretrial memorandum, some of those we saw this morning, maybe all of them, in which courts have issued industry bans. In every single one of those cases there was fraudulent conduct by the defendant. And there has been no fraud alleged here.

This is a civil rule-of-reason antitrust case. It's not about, we would humbly submit, whether the price increase was a wise decision and whether we agree or if the Court agrees with that decision. This is about antitrust. They have not shown why in this particular case, on these facts, with these allegations, the defendant should be banned from an industry for the remainder of his life. The cases where they have done that have been fraud cases akin to criminal cases. Whatever else Mr. Shkreli has done, which I would submit is not relevant to what he did in this case, there is no justification for an industry ban in this particular case.

I don't want to discuss those cases that they have cited in any detail, but I would mention one that is worth mentioning. It's a case called *FTC v. Ross*, 897 F.Supp.2d 369. It's from the District of Maryland in 2012. The Court in *Ross* [1230] specifically declined to issue an industry ban. Instead, the defendant was permitted to continue working in the industry with conduct restrictions. This was so despite that the defendant's fraudulent marketing scheme generated large sums of money and resulted in the filing of over 3,000 consumer complaints with the FTC.

Plaintiffs point to no case where the government has sought or the Court has imposed an industry ban in an antitrust case without any allegations of fraud. The Court should not take the apparently unprecedented step of imposing an industry ban in an antitrust case when conduct restrictions would be sufficient to restrain and prevent the challenged conduct from recurring.

THE COURT: What conduct restrictions do you recommend?

MR. CASEY: Your Honor, I don't think you should impose any. Our position is you should not. We don't think you should find liability. But if the Court were to find liability, restrictions that are tailored to the allegations in the complaint: Exclusive supply agreements, restricted distribution agreements, data blocking agreements. Those are the allegations in the complaint. And what they are doing now is going well beyond those.

I know the Court has lots of criminal cases. It's as if the defendant was ready to plead to every count of the [1231] indictment but yet that's not enough. There has got to be some extra sanction imposed on the defendant.

In this case the FTC and the states are enforcing the antitrust laws and they do a very good job of it. I used to be at the FTC many years ago. I respect what they do. But what they do is, they are there to protect the market and to make sure that this kind of conduct—again, I don't agree with their theory of the case, but I respect their right to bring the case. They bring the case. They get relief and the market—they fix the market harm. In my view, that's what they should be doing instead of expelling an individual from an industry for the rest of his life. I don't think that's appropriate here, particularly in an equity court. I don't think there has been anything presented by them other than—obviously, there has been a lot of negative

publicity associated with Mr. Shkreli. He has acknowledged that. He takes responsibility for that. He did in his affidavit.

THE COURT: He didn't take responsibility for violating the antitrust laws.

MR. CASEY: Correct.

THE COURT: He has not admitted liability here.

MR. CASEY: He has not, your Honor. We are defending the case.

THE COURT: When you say he took responsibility, he admitted that he's the one who set the price for the drug, for [1232] Daraprim. He admitted he set it at 750. He is not denying he said he should have set it higher. I'm not quite sure what you are saying, he admitted.

MR. CASEY: I didn't mean to suggest that he's admitting the conduct.

THE COURT: OK.

MR. CASEY: What I'm saying is, from the tenor, I will say, of the discussion about what their relief should be, it seems like it's a little bit beyond what they have charged in the complaint and what they should be seeking. That is my view. I would submit to the Court that whatever the Court does—and I respect that this is the Court's decision. You have discretion to do it. But my only point is, this is an equity court and the Court should find an equitable resolution, if the Court finds liability, that advances the legitimate law

enforcement purposes of the plaintiffs. I don't know that they have made a case, at least I haven't heard it made, for why they would need to ban Mr. Shkreli from this industry for the rest of his life.

THE COURT: Is it or is it not relevant, from your point of view, for me to consider that he was the author of the strategy?

MR. CASEY: Your Honor, I don't know that I would necessarily agree—it depends on what you mean by author, but certainly there is record evidence to support the fact—

[1233] THE COURT: No. I'm sorry. Let me put my question more directly. If I find he is liable for a violation of the antitrust laws and am now considering what kind of injunctive relief is appropriate, which is what I think you're addressing now.

MR. CASEY: Yes.

THE COURT: On the assumption that I have found him liable and have turned to the issue of formulating injunctive relief, is it—in your view, should I find it to be true that I consider, in shaping the injunctive relief, that I have found he is the author of the anticompetitive strategy?

MR. CASEY: I think that's a valid consideration for the Court to make.

THE COURT: Would it be relevant, from your point of view, as a legal matter, for me to consider that it was a strategy, again, directed to the pharmaceutical

industry and the role that the pharmaceutical industry plays in providing life-saving remedies to the public?

MR. CASEY: Certainly. That's certainly a consideration that's appropriate.

THE COURT: Would it be relevant for me to consider in this decision making that the specific drug that's at the heart of this is in fact a life-saving drug for which the decision about its administration must be made generally within 24 hours of symptoms?

[1234] MR. CASEY: Well, certainly, your Honor, that's something you could consider.

My point only, your Honor, is that you have to fashion and mold the relief to stop this from occurring again. I think that's an appropriate role for the Court. But a narrowly tailored injunction for a reasonable period of time would be an appropriate resolution rather than a ban. I don't know why they need a ban in this case. They have said there is an enforcement problem with something less than a ban. I am not sure I understand that. But I just ask the Court to consider that, what is appropriate and necessary, again, given that the issue here is whether there has been a violation of the antitrust laws and whether the Court needs to put in place an injunction to prevent that from happening again. That's I think the role of the Court. I respect the Court's discretion to come up with an appropriate injunction, if the Court decides to do that.

In terms of equitable monetary relief, your Honor, the *Liu* case from the Supreme Court says that disgorgement should not be a joint and several remedy. In *Liu*, the Supreme Court said the rule against joint and several liability for profits that have accrued to another appears throughout equity cases awarding profits. That's in the *Liu* case, 140 S. Ct. at page 1945. In other words, allowing joint and several liability "runs against the rule to not impose joint liability in favor [1235] of holding defendants liable to account for such profits only as have accrued to themselves."

*Liu* also held that the amount of disgorgement must be limited to profits the defendant took from the alleged scheme. Here, the plaintiffs have failed to meet their burden to prove that Mr. Shkreli profited at all from Vyera sales of Daraprim. Mr. Shkreli testified in his written direct testimony that he invested approximately $18 million into Vyera, and plaintiffs have not rebutted this testimony.

The only asset Mr. Shkreli has from Vyera is his Vyera stock. He took no salary from the company. The plaintiffs have not proven the value of that stock. Professor Hemphill's calculation is flawed because even if the Court is inclined to hold Mr. Shkreli jointly and severally liable for Vyera's profits from Daraprim, the plaintiff has failed to show that those profits should be in the range of 53 to $64.6 million, as Professor Hemphill claims.

Professor Hemphill admitted on cross-examination that in performing his calculation he did not take

into account the numerous business decisions that the generic companies made that I have talked about here today that contributed to their delay in entering the market. Therefore, the assumptions on which his excess profits model is based are flawed.

Your Honor, I just wanted to mention a few things about Mr. Shkreli and his future plans. I know it was [1236] referenced in plaintiffs' presentation, and he addresses it in his affidavit.

Again, the Court has the discretion to decide, if the Court finds him liable, what the appropriate relief is. I will just say this. He does hope to change the public's perception of him following his release from prison and his return to civilian life. He said in his written direct testimony at page 83 that he hopes to "continue playing a role in the discovery of cures and treatments for rare and life-threatening diseases."

In conclusion, your Honor, we would ask that the Court find that Mr. Shkreli is not liable for any of the counts in the amended complaint. In the alternative, should the Court disagree, we ask the Court to impose relief that is narrowly tailored to the allegations of the amended complaint, such as an injunction to not engage in the alleged conduct for a reasonable period of time and to deny any monetary relief. Thank you very much, your Honor.