

Case No.: 1:20-cv-00706-DLC

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

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

Plaintiffs,

v.

VYERA PHARMACEUTICALS, LLC;
PHOENIXUS AG; MARTIN SHKRELI,
individually, as an owner and former officer
of Vyera Pharmaceuticals, LLC and
Phoenixus AG (formerly known as Turing
Pharmaceuticals, LLC and Turing
Pharmaceuticals, AG); and KEVIN
MULLEADY, individually, as an owner and
director of Phoenixus AG and a former
executive of Vyera Pharmaceuticals, LLC,

Defendants.

Case No.: 1:20-cv-00706-DLC

**[PROPOSED] 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 133 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 (“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.

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”), “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;
 - 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 a 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.

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) 60 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;
- 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.

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 preceeding 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. Within 10 business days of entry of the Order, Defendant Shkreli shall provide his Social Security Number or Taxpayer Identification Number to the Plaintiff States.
- F. 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.
- G. 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; and
 - 2. 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 preceeding 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 _____ day of _____, _____.

The Honorable Denise Cote

CERTIFICATE OF SERVICE

I hereby certify that on January 28, 2022, I have electronically filed a true and correct copy of the **Proposed Order For Permanent Injunction and Equitable Monetary Relief** with the Clerk of the Court using the CM/ECF system, which will automatically send e-mail notification of such filing to all counsel of record.

Dated: January 28, 2022

/s/ Maren Haneberg

Maren Haneberg

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