IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE

In re:	Chapter 11, Subchapter V
Vyera Pharmaceuticals, LLC, *et al.*,[1]	Case No. 23-10605
Debtors.	(Joint Administration Requested)

DECLARATION OF LAWRENCE R. PERKINS IN SUPPORT OF THE DEBTORS' SUBCHAPTER V PETITIONS AND FIRST DAY PLEADINGS

I, Lawrence R. Perkins, hereby declare under the penalty of perjury:

1. I am the Chief Restructuring Officer ("CRO") of the above-captioned debtors and debtors-in-possession (collectively, the "Debtors") in the above-subchapter V cases (the "Subchapter V Cases"). I was appointed CRO on or about September 8, 2022.

2. I am also the Founder and Chief Executive Officer of SierraConstellation Partners ("Sierra"). Sierra has provided financial advisory and consulting support to me in my role with the Debtors since my original appointment, and intend to continue this support during the pendency of the Subchapter V Cases.

3. I have over 20 years of management consulting and advisory experience with distressed companies or companies undergoing transition. I have held senior roles in various industries including healthcare, industrial manufacturing, retail, real estate, and financial services.

4. In my capacity as CRO of the Debtors, and, among other things, through discussions with the Debtors' employees, consultants, professionals, and Phoenixus AG's board

[1] The Debtors in these subchapter V cases, along with the last four digits of each Debtor's federal tax identification number, if applicable, are as follows: Vyera Pharmaceuticals, LLC (1758); Oakrum Pharma, LLC (3999); SevenScore Pharmaceuticals, LLC (2598); Phoenixus AG (1091); Dermelix Biotherapeutics, LLC (4711); and Orpha Labs AG. The Debtors' headquarters and the mailing address for the Debtors is 600 3rd Avenue, 19th Floor, New York, NY 10016.

of directors, I have become generally familiar with the Debtors' day-to-day operations, business and financial affairs, and books and records.

5. On the date hereof (the "Petition Date"), each Debtor filed with this Court a voluntary petition for relief under chapter 11 of title 11 of the United States Code (the "Bankruptcy Code") and elected to proceed under subchapter V thereunder. The Debtors continue to manage and operate their business as debtors-in-possession pursuant to sections 1107, 1108, and 1184 of the Bankruptcy Code. To minimize any disruption resulting from the filing of the Subchapter V Cases, as well as other possible adverse effects on their business, contemporaneously herewith, the Debtors have filed various pleadings seeking certain "first day" relief (collectively, the "First Day Pleadings"). I submit this declaration (this "Declaration") to assist the Court and parties-in-interest in understanding, among other things, an overview of the Debtors and their businesses, the circumstances compelling the commencement of these Subchapter V Cases, what the Debtors plan to achieve through these Subchapter V Cases, and in support of the Debtors' subchapter V petitions and the First Day Pleadings.

6. Except as otherwise indicated herein, all statements set forth in this Declaration are based on: (i) my personal knowledge of, and familiarity with, the Debtors' operations, finances, and restructuring efforts; (ii) my review of relevant documents and information provided to me by employees of, or advisors to, the Debtors or professionals retained by Debtors; (iii) my opinion based on my experience and knowledge of the Debtors' operations and financial and business affairs, including my general knowledge of the industry in which the Debtors operate; or (iv) information supplied to me by, and in consultation with, the Debtors' management and the Debtors' professional advisors. I have obtained this information during my tenure working with the Debtors and their professionals, including the Debtors' corporate and restructuring counsel and

investment bankers. In making this Declaration, I also have relied on information and materials that the Debtors' personnel and advisors have gathered, prepared, verified, and provided to me, in each case under my ultimate supervision, at my direction, or for my benefit in preparing this Declaration.

7. I believe all information herein to be true to the best of my knowledge. Notwithstanding, my investigation of the Debtors' operations and circumstances is ongoing. To the extent that I learn that any information provided herein is materially inaccurate, I will endeavor to update or otherwise amend this Declaration.

8. I am authorized to submit this Declaration on behalf of the Debtors and am over the age of 18. If called upon to testify, I would testify competently to the facts set forth herein.

9. This Declaration is divided into four parts:

- Part I provides an overview of the Debtors, their entry into these Subchapter V Cases;
- Part II describes the Debtors' organizational structure, business, and business segments;
- Part III provides an overview of the circumstances leading to the commencement of these Subchapter V Cases;
- Part IV provides an overview of the Debtors' proposed Plan; and
- Part V summarizes the First Day Pleadings and the bases for the relief sought therein.

PART I.

OVERVIEW OF THE SUBCHAPTER V CASES

10. The Debtors develop and commercialize branded products and launch and commercialize generic products that treat orphan diseases.

11. Historically, the Debtors' largest revenue generating product is the drug Daraprim. Daraprim provides an effective therapeutic treatment for toxoplasmosis, a devastating parasitic infection that can cause severe disease and death in patients with compromised and suppressed immune systems. Debtor Vyera owns the rights to sell Daraprim.

12. In October 2014, Martin Shkreli founded Turing Pharmaceuticals LLC—which name was later changed to Vyera—and Turing Pharmaceuticals AG—which name was subsequently changed Phoenixus.[2] Shkreli focused this new venture on acquiring sole-source drugs that were the gold standard treatment option for life-threatening disease with a small patient population. *See* SDNY Op. at 26.

13. Shkreli identified Daraprim as one such drug and, in April 2015, purchased the U.S. licensing rights to Daraprim for $55 million from a third party. Shkreli then implemented a plan to generate profits (between $55 to $74 million) by increasing the price of Daraprim over 4000%—from $17.60 to $750 per tablet—and protected this exorbitant price by choking off potential generic competition. *See id.* at 6, 32–33, 34–53. Shkreli did so through the implementation of a number of measures, including directing debtor Phoenixus AG pay $7 million to RL Fine, an overseas manufacturer, to induce it to withhold a key ingredient—pyrimethamine—from generic competitors to block their attempts to obtain FDA certification. *See id.* at 52–53. Shkreli directed this strategy over the next four years even though he was arrested by the FBI in 2015, convicted of committing federal securities fraud in 2017, and began serving time in federal prison later that year. *See id.* at 13. Undeterred by this adverse turn of events, Shkreli continued to direct this scheme from prison through directors and officers he appointed—Shkreli gave orders through a

[2] To assist the Court, attached to this Declaration as **Exhibit A** is the 135-page Opinion and Order (the "SDNY Opinion") issued by the United States District Court for the Southern District of New York in the action *Federal Trade Commission v. Shkreli*, 20-cv-00706 (DLC). The SDNY Opinion provides an exhaustive description of the Debtors' history. *See* SDNY Op. at 26.

contraband cell phone that he obtained while in prison and through other means. *See id.* at 50, n.27, 81–82, 84–86.

14. On January 27, 2020, the Federal Trade Commission (the "FTC") and a number of state attorneys general sued Shkreli, then CEO Kevin Mulleady, Vyera, and its Swiss parent Phoenixus AG in the United States District Court for the Southern District of New York for civil violations of federal and state antitrust laws. A class action comprised of affected purchasers soon joined the lawsuit. Soon after the commencement of the FTC action, the Debtors appointed a new board and management which then took steps to eliminate Shkreli's influence. On the eve of trial, the Debtors settled the FTC action, as set in greater detail below. *See id.* at 8; *FTC v. Vyera Pharmaceuticals, LLC* (S.D.N.Y. No. 20-cv-00706-DLC).

15. However, Shkreli refused to settle and, following a one-week bench trial, on January 14, 2022, the District Court issued its 135-page opinion and order and entered judgment against Shkreli for $64.6 million in damages. *See id.* at 135. The District Court's damages award equaled the illicit profits the Debtors purportedly obtained through their anticompetitive conduct. *See id.* at 132.

16. On August 22, 2022, the shareholders of Phoenixus, including majority shareholder, Derek C. Abbott, as receiver for Martin Shkreli's shares (discussed further below) installed a new board of independent directors to take charge of the situation (the "Board of Directors"). The Board of Directors comprises three directors: Derek Pitts, Ivona Smith, and Thomas J. Allison. Pitts, Allison, and Smith have no prior connection to any interested party to the Derivative Litigation (defined below) and no material past or present business or economic relations with the Debtors. The new Board of Directors, in turn, retained Sierra as financial advisors and myself as CRO for all of the Debtors. After conducting interviews with multiple

qualified investment banks, in December 2022, the Board of Directors retained Alvarez and Marsal ("A&M") to explore strategic alternatives and retained DLA Piper LLP (US) ("DLA Piper") as restructuring counsel.

17. Ultimately, after significant efforts by the Board of Directors to examine all available restructuring alternatives, both in-court and out-of-court, the Debtors determined that the best path to preserve and maximize the value of the businesses for the benefit of the Debtors' stakeholders was to commence an expedited in-court process under subchapter V of the Bankruptcy Code.

18. As set forth in further detail below, contemporaneously herewith, the Debtors' have filed a *Joint Subchapter V Plan of Reorganization and Liquidation* (the "Plan"). The Plan is structured to support one or more sale transactions with respect to certain of the Debtors' assets and a parallel going-concern restructuring transaction with respect to Debtor Orpha Labs AG with respect to the development of ORL-101, a promising orphan drug.

19. In conjunction therewith, the Debtors, in coordination with their advisors, have prepared a postpetition budget to adequately fund continued operations as necessary until confirmation of the Plan.

* * *

PART II.

OVERVIEW OF THE DEBTORS' BUSINESSES

A. Corporate Structure

20. Phoenixus AG ("Phoenixus"), formerly known as Turing Pharmaceuticals AG and Vyera Pharmaceuticals AG, is a privately held, for-profit, Swiss corporation founded in 2014. Phoenixus has its registered office and principal place of business located in Baar, Switzerland. Phoenixus is the direct parent and owns 100 percent of the equity in each of the following co-Debtors (collectively, the "Subsidiaries"):

i. Vyera Pharmaceuticals, LLC ("Vyera"), formerly known as Turing Pharmaceuticals, LLC, is a limited liability company organized in Delaware with its principal place of business located in New York, New York.

ii. Oakrum Pharma, LLC ("Oakrum") is a limited liability company organized in Delaware, with its principal place of business located in St Louis, Missouri.

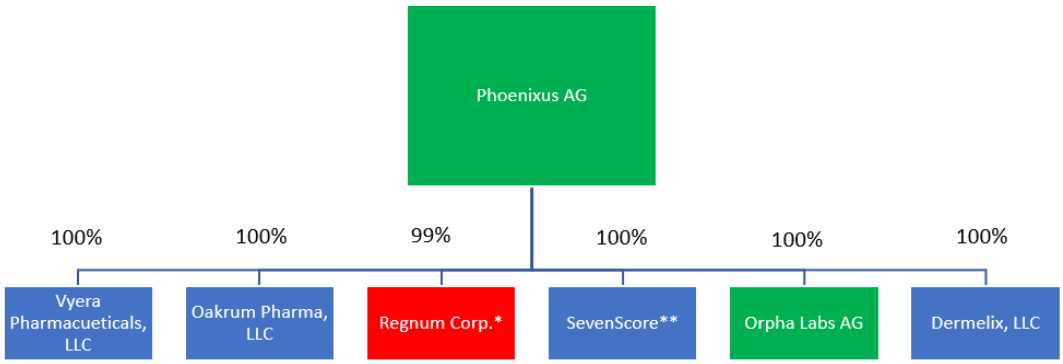
iii. SevenScore Pharmaceuticals, LLC ("SevenScore"), formerly known as Orphan Star Therapeutics, LLC, is a limited liability company organized in Delaware with its principal place of business located in New York, New York.

iv. Dermelix Biotherapeutics, LLC ("Dermelix"), formerly known as Dermelix, LLC, is a limited liability corporation and incorporated in Delaware with its registered office in Wilmington, Delaware.

v. Orpha Labs AG ("Orpha Labs") is a privately held, for-profit, Swiss corporation founded in 2020 with its registered office located in Baar, Switzerland.

21. Phoenixus also owns 18,585,977 shares of Regnum Corp ("Regnum"), a company incorporated in the State of Nevada. Regnum is not a debtor in these Subchapter V Cases and the Debtors intend to sell Phoenixus's equity interests in Regnum through a 363-sale process during the pendency of these Subchapter V Cases.[3]

[3] For the avoidance of doubt, upon information and belief, Regnum is a "voluntary filer" with the United States Securities and Exchange Commission (the "SEC"). Accordingly, while, historically, Regnum has filed certain documents with the SEC, Regnum is not subject to the reporting requirements under sections 13 or 15(d) of the Securities Exchange Act of 1934.



- Remaining 1% is public float

Key:
Swiss Entity
Delaware Entity
Nevada Entity

B. The Debtors' Businesses and Operations

22. The Debtors are engaged primarily in the development, commercialization, and sale of pharmaceutical products with a focus on developing therapies for patients suffering from serious and neglected diseases, often referred to as "orphan" diseases. In 1983, the United States Food and Drug Administration (the "FDA") passed the Orphan Drug Act in an effort to push the industry to pursue the treatment of rare diseases that afflict less than 200,000 patients a year in the United States. It is estimated that around 10% of the population in the United States (approximately 30 million individuals) suffer from rare diseases, many of which are life-threatening. Since the passage of the Orphan Drug Act, there have been over 1,000 orphan drug designations approved by the FDA. Still, treatments for orphan diseases are rare.

23. The Debtors develop and commercialize both generic and branded products that treat orphan diseases. Generic products are off-patented drugs that are bioequivalent to branded medications in terms of dosage, strength, quality, form, effect, intended use, side effects, and route of administration. Generic drugs reduce the cost of medicines by entering the market at

substantially lower prices than the branded drugs for which they are substituted, creating savings for patients, payers, and the healthcare system as a whole. Historically, companies were eligible for several extra years of marketing exclusivity, without generic competition, if they were able to obtain FDA approval for qualifying rare diseases. These are referred to as "branded" drugs.

24. The Debtors' main product lines are (i) Daraprim, a prescription medication for the treatment of toxoplasmosis; (ii) Vecamyl, for the management of moderately severe to severe hypertension and in uncomplicated cases of malignant hypertension; (iii) Nitisinone, used to treat a rare genetic condition called hereditary tyrosinemia type 1 ("HT-1"); and (iv) Pyrimethamine, which is the generic version of Daraprim (collectively the "Products").

i. ***VYERA***

25. Vyera conducts the majority of the operations of Phoenixus in the United States. Vyera and Phoenixus have entered into formal distribution terms (the "Distribution Agreement") whereby Phoenixus supplies Vecamyl and Daraprim to Vyera to be distributed to customers in the United States. Additionally, Vyera also provides Phoenixus and its subsidiaries with support services including research and development, preclinical support, and clinical operations, and provides certain Subsidiaries with back-office services (i.e., human resources, accounting, and information technology.

26. Vyera primarily develops and commercializes two branded products: (i) Daraprim and (ii) Vecamyl. Daraprim is used to treat toxoplasmosis, a common parasitic infection typically transmitted through undercooked meat and infected cat feces. On August 7, 2015, the Debtors acquired the rights to Daraprim for $55 million from the then-owner Impax Laboratories. Vyera has since established a partnership with ANI Pharmaceuticals Inc. for the manufacture and packaging of Daraprim. Fukuzyu Pharmaceutical Company, Ltd., a Japanese company, supplies Vyera with the active pharmaceutical ingredients ("APIs") for Daraprim. Vyera distributes

Daraprim to two major customer groups, specialty distributors and specialty pharmacies, as further detailed in the Customer Programs Motion (defined below).

27. Vecamyl is indicated for the management of severe hypertension and uncomplicated malignant hypertension. The active ingredient of Vecamyl is mecamylamine, which is a potent, oral antihypertensive agent and ganglion blocker.

28. LGM Pharma Solutions, LLC ("LGM") holds certain rights to manufacture and develop generic pharmaceutical products including mecamylamine hydrochloride in oral form (2.5 mg tablet) including the abbreviated new drug application rights. Phoenixus entered into a license and manufacturing agreement with LGM, whereby Phoenixus was granted the exclusive right to market and sell mecamylamine. The API for Vecamyl is supplied by Piramal Enterprises Ltd, which is a company incorporated in India that has technical expertise in process development and manufacturing of API and related pharmaceutical products. Phoenixus acquired certain world-wide rights to Vecamyl from Waldun Pharmaceuticals, LLC ("Waldun") pursuant to a purchase agreement dated February 13, 2015 (the "Vecamyl Purchase Agreement").

29. Under the Vecamyl Purchase Agreement, each quarter, Phoenixus is required to pay Waldun certain royalty payments contingent on the net sales of Vecamyl. However, the Debtors only distribute Vecamyl to one specialty pharmacy customer, Optime Care Inc., to be dispensed to patients. Accordingly, as at the Petition Date, Vecamyl has only generated $84,767 in 2023 net sales. Additionally, LGM recently informed the Debtors that due to pending FDA approvals, they would not be ready to re-supply Vecamyl until July 2023, which has caused major disruptions in the Debtors' supply of Vecamyl to its customers. Not only that, but LGM has also requested the Debtors contribute $191,000 towards the cost of manufacturing in order to continue

their production efforts. As a result, Vecamyl has been out of the market and has not generated any revenue for the Debtors since March 2023.

ii. ***OAKRUM***

30. Oakrum's primary business strategy is to target specialty pharmaceuticals and build a diversified portfolio of on-market commercial products, focusing on generic products.

31. Oakrum has established partnerships with networks of development and manufacturing companies including a partnership with Phoenixus to distribute Pyrimethamine and with Biophore Pharma Inc. to launch Nitisinone.

32. In 2022, Oakrum had a portfolio of twelve (12) products, both on-market commercial pharmaceuticals and a robust pipeline of late-stage assets to be launched. Following a sale of certain assets in the Oakrum portfolio, however, as of the Petition Date, Nitisinone and Pyrimethamine are Oakrum's main products.

33. Pyrimethamine is an authorized generic version of Daraprim, indicated for the treatment of toxoplasmosis when used conjointly with a sulfonaminde. Oakrum launched Pyrimethamine in March 2020 as the exclusive United States distributor in accordance with a profit-sharing agreement with Phoenixus. Oakrum distributes Pyrimethamine through AmerisourceBergen Corporation which is a specialty distributor and two specialty pharmacies. Pyrimethamine continues to generate revenue for the Debtors with estimated 2023 year to date net sales of $66,633 as at the Petition Date.

34. Nitisinone is used to treat a rare genetic condition called HT-1 which is a metabolic disorder that occurs when the body does not produce enough of an enzyme that breaks down proteins from certain foods. Historically, HT-1 was treated with the branded form of Nitisinone—Orfadin—marketed by SOBI-Swedish, which received FDA approval in 2002. Par Pharmaceuticals followed suit and received FDA approval of their generic form of Nitisinone in

2019, with other generics also following suit in 2020. Oakrum expected to launch Nitisinone, its own generic version of Orfadin, in May 2022 following FDA approval, which Oakrum now expects to receive in June 2023.

iii. ***SEVENSCORE AND DERMELIX***

35. SevenScore and Dermelix were founded on behalf of Phoenixus by Dr. Nicholas France, who has expertise in rare disease clinical drug development with extensive experience leading clinical and regulatory activities for novel therapeutics. The purpose of SevenScore and Dermelix is to pursue business objectives and new projects while avoiding the reputational damage that Phoenixus and Vyera had incurred as a result of their association with Shkreli (discussed further below). Dermelix's operations focused on the development of innovative treatments for rare genetic skin diseases. However, as of the Petition Date, Dermelix does not hold any assets or conduct any operations.

36. On or about October 29, 2020, SevenScore entered into that certain Assignment and Assumption Agreement with Vyera and CytoDyn, Inc ("CytoDyn"), whereby Vyera's rights, title, interest, and duties to a joint-development and licensing agreement with CytoDyn (the "Commercialization Agreement") were assigned to SevenScore. In January 2022, SevenScore assigns its rights, title, interest, and duties to the Commercialization Agreement to Regnum. The Commercialization Agreement grants an exclusive license to develop, market and distribute leronlimab (PRO 140) an anti-CCR5 humanized monoclonal antibody in the United States for the treatment of human immunodeficiency virus (HIV). CytoDyn maintained the responsibility for the development and FDA approval of leronlimab for all HIV-related and other indications. In October 2022, CytoDyn announced the voluntary withdrawal of its pending biologics license application for leronlimab due to various factors including feasibility of achieving FDA approval without significant additional investment.

37. While both SevenScore and Dermelix made specific expenditures geared toward certain research and development projects, the majority of the expenditures were made by Vyera or Phoenixus. Accordingly, Phoenixus and Vyera reported these entities on their consolidated financial statements.

iv. ***ORPHA LABS***

38. Orpha Labs is a clinical stage biopharmaceutical company focused on developing first-in-class therapies for ultra-rare diseases that do not have existing therapies in the market. Currently, the clinical operations of Orpha Labs are focused on the development of ORL-101 for the treatment of Leukocyte Adhesion Deficiency Type II ("LAD II"), an ultra-rare congenital immunodeficiency disorder with only 10-20 patients estimated to have LAD II worldwide.

39. LAD II is an autosomal recessive mutation in the SLC35C1 gene impacting uptake of fucose into golgi vessels, leading to the loss of E- and P-selectin ligands on leukocytes. Patients with LAD II suffer recurrent infections as the immune system is unable to combat microbes in the same way as an average person.

40. ORL-101 is an investigational pharmaceutical-grade L-fucose manufactured according to the Current Good Manufacturing Practice. ORL-101 is believed to act by improving the fucosylation of various plasma membrane glycoproteins including E- and P-selectin ligands. ORL-101 is a pure form of L-Fucose manufactured at a GMP-compliant facility,

41. The Debtors have a robust supply chain including a reliable supplier of the API for ORL-101. Orpha Labs maintains a supply contract with a 5-year term with current API supplier, Laboratorium Ofichem BV. Orpha Labs partners with Losan Pharma GmbH for the development, manufacturing, and packaging of ORL-101.

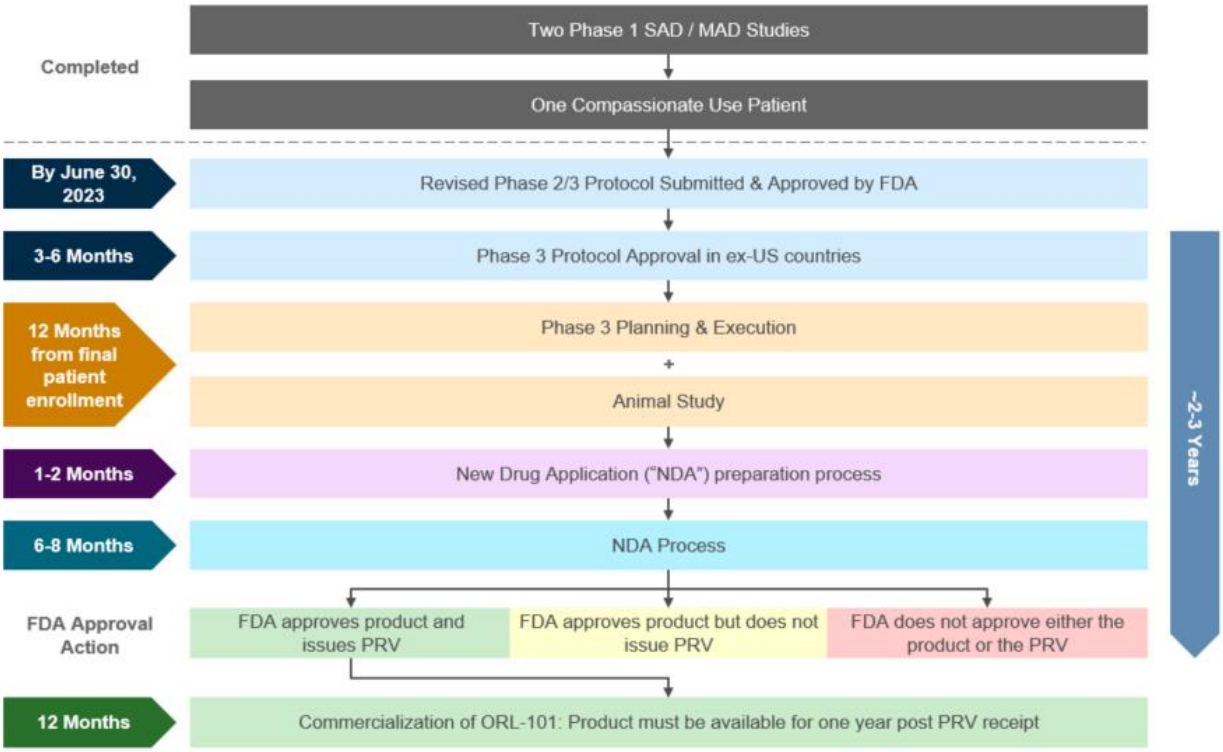
42. In 2007, the FDA passed the Food and Drug Administration Amendments Act that permits the issuance of "priority review" vouchers (a "PRV"), which allows drug manufacturers

to expedite the review of any one of its new drug products, thereby reducing the standard drug submission review time from a target of ten (10) months to an expedited six (6) month review cycle.

43. To date, the FDA has granted a Rare Pediatric Disease Designation to ORL-101 for the treatment of patients with LAD II, which is a precursor requirement to obtaining PRV. If the FDA approves a new drug application ("NDA") for ORL-101 for patients with LAD II, Orpha Labs may be eligible to receive a PRV from the FDA, which can be redeemed by any company to obtain priority review for any subsequent marketing application. The PRV reduces the FDA review process allowing for faster commercialization of a product.

44. The FDA may grant approval for a PRV in conjunction with approving an NDA, according to the processes set out in figure 1 ("PRV Stages"):

Figure 1: the PRV Stages



45. Upon completion of the PRV Stages, Orpha Labs can submit an NDA to the FDA for approval, and request that the FDA grant the Orpha Labs a PRV. Thereafter, Orpha Labs will need to commercialize ORL-101 within 365 days for the PRV to remain valid. A company that receives a PRV can determine whether to keep it or sell it to a third party, which can accelerate the approval process for *any* drug, not only the drug that was granted the PRV. In addition, there is no limit on the number of times a PRV can change hands, and no expiration date to the voucher. Upon information and belief, recent industry transactions have valued PRVs, on average, at $105 million with a range of $95–120 million.

46. As of the date hereof, ORL-101 has undergone a two-stage phase one trial and demonstrated that it is safe at a single ascending dose level up to 500 mg/kg and multiple ascending doses up to 10,000 mg/kg under both fed and fasted conditions. Orpha Labs conducted a single dose clinical trial from January 2020 to April 2020 and conducted a multiple dose trial from October 2021 to March 2022.

Figure 2: Phase 1 Single Ascending Dose (SAD) Trial

Dates	Jan 2020 – Apr 2020
Trial Phase & Design	Phase 1 Randomized, double-blind, placebo-controlled, single-dose study under fasting conditions
Dosing	Single oral dose of 500 mg/kg
# Patients	N = 12 healthy volunteers, • 10 received ORL-101 • 2 received placebo
Safety Results	No deaths No serious adverse events No discontinuations due to adverse events
PK Results	Serum L-fucose peaked and declined rapidly • Median T_{max}: 1.5 h • Mean $t_{1/2}$: 1.3 h

Figure 3: Phase 1 Multiple Ascending Dose (MAD) Trial

	Part A	Part B
Dates	Oct 2021 – Mar 2022	
Trial Phase & Design	• Phase 1, Part A • Randomized, double-blind, placebo-controlled, multiple-dose study	• Phase 1, Part B • Cross-over study under fasted and high-fat meal conditions
Dosing	4 cohorts: 250, 500, 750, 1000 mg/kg/day	250 mg/kg dose
# Patients	N = 32, 8 at each dosing level	N = 15
Safety Results	• Mild to moderate GI TEAEs in multiple subjects, including 1 discontinuation due to TEAE • No AEs in 250 mg/kg/day group • No apparent differences in tolerability under fasted or fed conditions	
PK Results	• Little to no accumulation in serum L-fucose AUCs and C_{max} in all doses • Median T_{max} similar across all doses	• Median T_{max} similar under both fasted and fed conditions • AUC_{0-t} and C_{max} were 10% and 40% lower, respectively, under fed conditions compared to fasted

47. Additionally, Orpha Labs conducted a compassionate use program in Israel following approval from the Israeli Ministry of Health. The patient was a 3.5-year-old girl who was diagnosed with LAD II at age five months (the "ORL Patient"). The ORL Patient was treated with ORL-101 for ten weeks under the program. The results were positive; they demonstrated a reduction in the leukocyte count from the baseline and no infections or side effects were evident.

48. Orpha Labs will need to successfully complete two more stages with respect to ORL-101 before filing an NDA with the FDA. This includes (i) a pivotal phase 2/3 registration and trial; and (ii) an animal study. In order to progress the phase 2/3 study, the FDA will need to approve Orpha Labs' proposed protocol for the trial (the "Proposed Protocol"). On April 17, 2023, the FDA provided further helpful guidance to refine the Proposed Protocol which will enable Orpha Labs to progress efficiently through the PRV Stages. Orpha Labs is updating the Proposed Protocol accordingly.

49. Once Orpha Labs amends and re-submits the Proposed Protocol to FDA, Orpha Labs will still need to obtain additional regulatory approval from each country where the trials will be conducted, which may take two (2) to four (4) months from submission. In connection therewith, in order to identify the patients, Orpha Labs will need to hire and work with local clinical research organizations that will undertake a short-term contract to conduct the trials in each of the local jurisdictions. In parallel, Orpha Labs will continue to identify any other countries that may have potential patients for the trials. The Debtors estimate that the PRV Stages will take two to three years and cost approximately $7.8 million. The majority of these estimated costs will only accrue if the Debtors deem continued investment worthwhile based on patient enrollments and results of the clinical trials.

C. The Debtors' Prepetition Capital Structure

50. As of the Petition Date, the Debtors believe that they have no secured debt. Rather, the Debtors' capital structure is made up solely of unsecured debt and equity interests.

51. As of the Petition Date, the Debtors have less than $7.5 million outstanding in noncontingent liquidated unsecured claims. As more fully described below, there are also a number of unliquidated and contingent claims that have been asserted against the Debtors that are not included in this calculation.

52. Additionally, at times throughout the Debtors' history, including in the months leading up to the filing of these subchapter V cases, certain Debtors have made Intercompany Transfers by way of subordination agreements. In general, Swiss law requires a company to report to the Swiss government a year-end balance sheet showing over-indebtedness pursuant to Art. 725b para 1 of the Swiss Code of Obligations. Notification will typically lead to the initiation of bankruptcy proceedings under Swiss law. Accordingly, entry into various subordination agreements over the years has safeguarded an involuntary bankruptcy proceeding against the

Debtors in Switzerland. To that end, on March 13, 2023, Vyera and Phoenixus entered into a subordination agreement, pursuant to which Vyera subordinated claims against Phoenixus totaling CHF $14,096,577 to all other existing and future claims against Phoenixus. Additionally, on June 10, 2021, Phoenixus and Orpha Labs entered into a subordination agreement, pursuant to which Phoenixus subordinated claims against Orpha Labs totaling USD $2,511,855.67 to all other existing and future claims against Orpha Labs.

53. As of the Petition Date, there are approximately 8,287,562 shares of Phoenixus issued of which approximately 6,563,818 shares are outstanding (the "Outstanding Shares"), approximately 564,693 treasury shares and approximately 1,204,051 warrants/options/restricted shares. Of the Outstanding Shares, approximately (i) 1,960,984 shares are ordinary shares; and (ii) 4,557,834 shares are preferred A shares (the "Preferred A Shares"). The Debtors issue the Preferred A Shares in 2015 as part of a $75 million equity raising, the only one to date and have a liquidation preference of $15 per share or $68.4 million.

54. As of May 9, 2023, on a consolidated basis, the Debtors have cash on hand of approximately $10.5 million, exclusive of retainers totaling approximately $2.6 million held by the Debtors' professionals and additional deposits held by certain of the Debtors' landlords and vendors.

* * *

PART III.

CIRCUMSTANCES LEADING TO THE SUBCHAPTER V CASES

55. The Debtors can group the circumstances leading to these Subchapter V Cases into the following categories: (i) introduction of general alternatives and declining sales; (ii) the impact of Martin Shkreli's actions, and the resulting litigation, on the Debtors; (iii) the impact of the related FTC Litigation stemming therefrom; and (iv) the impact of certain litigation brought, or threatened, against the Debtors.

A. Introduction of Generic Alternatives and Declining Sales

56. The Debtors operate in a highly competitive and regulatory-intensive industry. The success of the Debtors' businesses and operations is predicated upon its ability to generate sales from the marketed Products successfully commercialize new products. From 2016 through 2019, the Debtors grossed between $55 million and $74 million from sales of Daraprim, the Debtors' main revenue generating product. Since 2019, however, net sales have declined to $21.2 million in 2021 and $9.5 million in 2022, primarily caused by the entrance of several generic alternatives into the market. The net sales of Daraprim have continued this downward trend with 2023 year to date net sales of approximately $1,350,000. Generic drugs enter the market at a discount, therefore, the entry of the first generic competitor generally results in price erosion. As of the Petition Date, on a consolidated basis, the Debtors incurred a net income loss of $6,300,000 and current cash balances are insufficient to fund the operations of the Debtors and pay liquidated and unliquidated claims against them.

B. The Impact of Martin Shkreli's Actions

57. In 2015, Vyera acquired the U.S. licensing rights to Daraprim from the then-owner, Impax Laboratories, for $55 million. At the time of Vyera's acquisition, Daraprim had a list price of $17.60 per tablet. After purchasing the rights to Daraprim, then-CEO Martin Shkreli raised the

price of the drug from $17.60 to $750.00 per tablet, effective August 11, 2015. From 2016 to 2019, it was estimated that the average net price of Daraprim ranged between $228.00 and $305.00 per tablet (price per tablet after subtracting discounts, chargebacks and rebates). Vyera faced swift backlash from health care providers, patients, medical societies, the general public, and Congress. Furthermore, Shkreli was found to have initiated a scheme to block the entry of generic drug competition into the market in order to maintain the sales of Daraprim (detailed further in the FTC Litigation (defined below)). Through exclusive supply agreements, Shkreli had blocked access to the two most important manufacturers of the API for Daraprim to other manufacturers. Shkreli refused to apologize and stated that he wished he had raised the price even higher. He had engaged in similar practices at a previous company he had co-founded, namely, Retrophin Inc. ("Retrophin"), a publicly traded biopharmaceutical company where Shkreli had served as the CEO from December 2012 to September 2014. At Retrophin, Shkreli had closed the distribution systems of two branded drugs, Chenodal and Thiola, to reduce access to the product samples needed for testing and impeded the generic drug competition and substantially increased the drug prices.

58. On December 18, 2015, Shkreli was arrested and charged with securities fraud in connection with prior dealings that were unrelated to the Debtors. In August 2017, following a six-week trial, a federal jury convicted Shkreli of two counts of securities fraud and one count of securities fraud conspiracy. Shkreli served as the chairman of the Board of Phoenixus until January 20, 2016, resigning on February 10, 2016. Although Shkreli's incarceration began in September 2017, he remained Phoenixus's largest shareholder, and he continued to attempt to direct the Debtors' business from prison. Shkreli obtained a contraband cell phone and was found to have

used it to communicate with certain directors of the Debtors. *See* SDNY Opinion. These directors are no longer members of, or associated with, the current Board of Directors in any capacity.

59. On August 16, 2021, following an arbitration between Shkreli and a former business partner, the United States District Court for the Southern District of New York entered an order (the "Receivership Order") appointing Derek Abbott as a receiver (the "Receiver") to collect and sell Shkreli's Phoenixus stock. *See Koestler v. Shkreli,* 1:16-cv-07175-DLC (S.D.N.Y. Aug 16, 2021). Specifically, the Court instructed the Receiver to use the proceeds of the sale of Shkreli's shares to pay the judgment. In June 2022, the Court further authorized the Receiver to act in Shkreli's place with respect to all shares of Phoenixus stock that he owned (a total of 2,251,923 shares, equaling approximately 34.31% of the outstanding shares), including by voting the shares in Shkreli's stead.[4] The Court instructed that, when voting Shkreli's shares, the receiver should vote "consistent with his independent view of the facts and circumstances, but may consider the input of all interested parties," *see id.,* and that the Board of Directors is authorized to accept the receiver's direction, vote, or other input "as if he were the owner of" Shkreli's shares. *Id.*

60. Upon information and belief, Shkreli's actions have caused serious reputational harm to the Debtors and have hampered the Debtors' ability to, among other things, open certain bank accounts, successfully commercialize new products, and either raise capital or consummate the sale of various Debtor assets.

i. ***The Impact of the FTC Litigation***

61. As noted above, on January 27, 2020, the Federal Trade Commission ("FTC") and the state of New York sued Vyera, Phoenixus, Shkreli, and Mulleady (the "Antitrust Defendants") in the U.S. District Court for the Southern District of New York (the "FTC Litigation"). On April

[4] Notwithstanding the foregoing, upon information and belief, Shkreli may still hold certain proxy founder rights, which do not appear to have been collected by the Receiver pursuant to Receivership Order.

14, 2020, six more states joined the case. *See FTC v. Vyera Pharmaceuticals, LLC, et al.* (S.D.N.Y. No. 20-cv-00706-DLC).

62. On December 7, 2021, Vyera, Phoenixus, and Mulleady reached a settlement agreement (the "FTC Consent Order") with the FTC and the States. The FTC Consent Order required, (i) Mulleady to pay a fine of $250,000 subject to certain exceptions, (ii) Vyera to pay $10 million into a settlement fund in January 2022, and (iii) contingent payments of up to $30 million to be paid upon the monetization of any assets of Phoenixus and Vyera within 5 to 10 years following the date of the FTC Consent Order (the "Contingent FTC Payments").

63. As Shkreli did not reach a settlement with respect to the FTC Litigation, the FTC and Shkreli proceeded to a bench trial in December 2021. On January 14, 2022, the Court found Shkreli liable on all counts, enjoined him from the pharmaceutical industry for life, and ordered him to pay $64.6 million in disgorgement. Shkreli's appeal is currently pending before the U.S. Court of Appeals for the Second Circuit.

C. The Impact of Actual and Threatened Litigation

i. *Antitrust Related Litigation*

64. On March 4, 2021, BCBSM Inc. d/b/a Blue Cross and Blue Shield of Minnesota, filed a class action lawsuit against Phoenixus, Vyera, Martin Shkreli, and Kevin Mulleady. The class plaintiffs alleged that BCBSM Inc. and other members of the class reimbursed the purchase of Daraprim at artificially inflated prices which were maintained through anti-competitive conduct addressed in the FTC Litigation. *See BCBSM, Inc. v. Vyera Pharmaceuticals*, No. 21-cv-1884-DLC (S.D.N.Y March 4, 2021) (the "BCBSM Litigation"). On May 6, 2021, the Court granted an order consolidating the BCBSM Litigation as a related case in the FTC Litigation. Thereafter, the parties entered into a settlement pursuant to the FTC Consent Order. On February 8, 2023, the

class plaintiffs' representative filed a UCC-1 financing statement was filed against each of Phoenixus and Delaware for the benefit of the class plaintiffs.

ii. ***Derivative Litigation***

65. On November 23, 2020, while the FTC Litigation was ongoing, Wormwood Capital LLC ("Wormwood"), SPQR Capital (Cayman) Limited, Sabine Gritti, Andrew Pizzo, and Antoine Verglas (collectively, the "Derivative Plaintiffs") filed a derivative action (the "Derivative Litigation") against four (4) of Phoenixus's then officers and directors—Mulleady, Akeel Mithani, Jordan Walker, and Averill Powers (the "Individual Defendants") in New York state court. *See Wormwood Capital LLC v. Kevin P. Mulleady*, No. 656481/2020 (N.Y. Sup. Ct. Nov. 23, 2020). The Derivative Plaintiffs alleged derivative claims on behalf of Phoenixus and named Phoenixus as a nominal defendant.

66. At base, the Derivative Plaintiffs alleged that the defendants conspired with each other and Shkreli to engage in self-dealing and took actions to enrich themselves at the expense of Phoenixus via SevenScore and Dermelix. The Derivative Plaintiffs allege that the SevenScore and Dermelix served no legitimate business purpose and were instead allegedly created to transfer money out of Phoenixus and Vyera to Shkreli and some combination of the Individual Defendants. In connection therewith, the Derivative Plaintiffs allege that Phoenixus's 2018 and 2019 financial statements are false and misleading. The Derivative Plaintiffs also claim that the purported inaccuracies in the 2018 and 2019 financial statements made it difficult for Phoenixus's shareholders to assess its performance or otherwise evaluate the value of their shares.

67. In February 2021, the Individual Defendants moved to dismiss the Derivative Litigation. While initially successful, the dismissal was reversed on appeal, and the case was remanded to the trial court on March 10, 2022. The Derivative Plaintiffs have not taken any further steps in these proceedings.

iii. ***Duane Morris Litigation***

68. On February 27, 2020, Shkreli retained Duane Morris LLP for the limited scope of representing him in connection with the FTC Litigation. Upon information and belief, Duane Morris had an hourly-rate arrangement and received a retainer of $75,000. Subsequently, on August 27, 2021, Shkreli retained Duane Morris to represent him in connection with the BCBSB Litigation. The fees in respect to the BCBSB Litigation were capped at $600,000 plus expenses, based on certain assumptions. Duane Morris issued a final request to pay $2.1 million in professional fees in the FTC Litigation against the Debtors on October 14, 2022. On October 31, 2022, the Debtors received an order, issued by the Zug debt enforcement agency, to pay the such professional fees. The Debtors dispute the validity of the Duane Morris fee claim on the basis, among other reasons, that Shkreli is not entitled to indemnification of fees due to his intentional wrongful conduct.

iv. ***Cerovene and Dr. Reddy Threatened Litigation***

69. On September 16, 2022, Vyera and Phoenixus received a draft complaint from Cerovene, Inc. ("Cerovene") and Dr. Reddy's Laboratories, Inc. ("DRL"), who partnered in 2017 to develop a generic form of the drug Daraprim. The complaint is premised largely on the same conduct that was the subject of the FTC Litigation and asserted a significant claim, albeit contingent, unliquidated, and disputed, which could dwarf the other liabilities and cash balances of the Debtors. Specifically, Cerovene and DRL allege that Vyera and Phoenixus's restricted distribution system inhibited their ability to obtain Daraprim and that Vyera and Phoenixus's exclusive API supply agreements delayed their ability to find an API supplier. Cerovene and DRL allege that, consistent with the District Court's finding in the FTC Litigation, this conduct delayed

them from bringing their generic Daraprim to market. Cerovene and DRL have yet to bring this action formally.

70. In the face of these ever-growing challenges, among other things, the Debtors made several strategic organizational changes, including the installment of an independent Board of Directors, the thorough investigation of various litigation claims brought against the Debtors, and the retention of professionals to pursue both in-court and out-of-court sale possibilities as well as professionals to analyze other potential restructuring alternatives, all as described further below. After considering all of the strategic alternatives, the Board made the difficult determination that an expedited in-court process under subchapter V of the Bankruptcy Code was the best path to preserve and maximize the value of the business for the benefit of the Debtors' stakeholders. Accordingly, the Debtors have commenced these Subchapter V Cases to (i) preserve the value of the Debtors' assets, (ii) maximize value for the Debtors' stakeholders through a sale of assets under section 363 of the Bankruptcy Code, if possible, and (iii) progress the development of the ORL-101 PRV process which, if successful, would result in all creditors being paid in full and provide substantial recovery for the Debtors' equity holders. Toward that goal, the Debtors have filed their proposed Plan contemporaneously herewith, which is discussed in greater detail below.

D. Strategic Organizational Changes

i. *Appointment of Independent Board*

71. In August 2022, the shareholders of Phoenixus elected a new independent Board of Directors, consisting of Derek Pitts, Ivona Smith, and Thomas J. Allison. Pitts, Allison, and Smith have no prior connection to any interested party to the Derivative Litigation and no material past or present business or economic relations with the Debtors. The Board of Directors has since acted consistently and in good faith to explore every feasible avenue to maximize the value of the Debtors' estates for the benefit of stakeholders and has held regular board meeting to that end.

ii. ***Litigation Committee / Derivative Action***

72. On September 6, 2022, the Independent Board formed the litigation committee (the "Litigation Committee") with Derek Pitts appointed to lead its investigation and act as liaison. The Litigation Committee investigated the claims raised with respect to the Derivative Litigation thoroughly and ultimately reported to the Board of Directors that it did not discover any evidence in support of the claims made in the Derivative Litigation. The Litigation Committee further advised the Board of Directors that it was not in the best interest of the Debtors to pursue the claims any further.

iii. ***Cost Reductions***

73. In an effort to reduce the Debtors' liquidity constraints, prior to the Petition Date, the Debtors terminated a number of officers and field-based employees in the Subsidiaries, cutting the budget by approximately $1 million. Additionally, the Debtors further terminated relationships with certain suppliers and service providers to further reduce expenses. The Debtors continue to evaluate their vendor relationships with an eye toward maximizing value.

iv. ***Retention of Professionals, Strategic Review, and Marketing Process***

74. In May 2022, the Debtors engaged Bourne Partners to explore a sale of the Oakrum product portfolio, and in June 2022, Oakrum sold four (4) products from its portfolio to ANI Pharmaceuticals for $8 million.

75. In light of the declining sales and ongoing financial and capital constraints, the Board of Directors began a strategic review process to explore potential alternatives to maximize value, including a sale of assets and the restructuring of the Subsidiaries. To assist in that process, on September 8, 2022, I was engaged as CRO for the Debtors and Sierra was engaged as financial advisor. On November 22, 2022, the Debtors engaged DLA as restructuring counsel, and on December 1, 2022, the Debtors engaged A&M as investment banker. In consultation with their

advisors, the Board of Directors immediately implemented a framework aimed at maximizing and preserving liquidity by shutting down non-core operations and pursuing a broad marketing process for the sale of assets led by A&M. In accordance with this strategy, the Debtors disposed of the 248,615 common stock of Seelos Therapeutics, Inc. for $2.2 million in January 2023 and terminated certain contractual relationships with suppliers to reduce expenses.

76. Upon instruction by the Board of Directors, in January and February 2023, A&M commenced a marketing process in respect of the assets of Vyera and Orpha Labs (the "Marketing Process"). As part of the Marketing Process, A&M established a virtual data room containing extensive information about the Debtors' businesses and operations and financial data for those parties who had entered into non-disclosure agreements and requested such information. In connection therewith, A&M contacted 151 parties, of which eight (8) executed non-disclosure agreements. The Debtors received varying non-binding proposals for certain of their assets from four (4) bidders: (collectively the "Bidders"). However, the Board did not deem any of these non-binding proposals to be actionable and would resolve the Debtors' liquidity constraints in any meaningful way. Upon information and belief, among other things, declining revenue trends, continued brand legacy issues with respect to Daraprim, and supplier issues have negatively impacted the sales process.

77. Accordingly, as of the Petition Date, the Debtors have not entered into any binding or otherwise definitive documentation with respect to the non-binding proposals from any of the Bidders. Through discussions with parties engaged in the Marketing Process, including the Bidders, the Debtors it was determined that the best available option to maximize value and/or reasonably execute a strategic transaction was through an in-court sale pursuant to section 363 of Bankruptcy Code. Accordingly, in light of the precarious financial situation, potential litigation

claims and the Marketing Process failing to furnish any actionable proposals that would resolve the Debtors' liquidity constraints in any meaningful way and address the potential liabilities, the Debtors commenced these Subchapter V Cases to maximize value for the benefit of its estate and creditors.

E. Recent Developments

i. *Shareholder Request*

78. On March 29, 2023, the Independent Board received a letter (the "Shareholder Letter") from Mangeat Attorneys at Law LLC, as representatives of a group of minority shareholders of Phoenixus owning approximately 886,951 shares, or 12.44%, of the outstanding share capital (the "Requesting Shareholders"). Wormwood Capital is the largest member of the minority shareholder group holding 5.39% of the outstanding share capital. The Shareholder Letter requested a general shareholder meeting to vote on the following items (the "Shareholders' Request"):

a) An increase in the share capital of Phoenixus by a minimum of a sum in CHF equivalent to a minimum of $1 million and a maximum of $1.5 million, by the issuance of new preferred shares. The newly issued shares shall first be offered to the current shareholders and then to Akkadian; and

b) The appointment of four (4) new directors to the Board of Directors.

79. The proposal is highly dilutive to current shareholders. If approved, the proposed investment would result in existing shareholders being diluted to 23.5% and 31.5% of total shares (preferred and ordinary) and 17.6% and 24.2% of preferred shares.

80. In contrast, under the Plan, existing shareholders will suffer no dilution with respect to any distribution to shareholders after existing creditor claims have been paid in full.

81. The Debtors' advisors responded on April 19, 2023, setting out the additional information that was required from the Requesting Shareholders to facilitate the Shareholders' Request including: clarification of the nominal amount by which the share capital is to be increased, class of shares to be issued, issue price per share, the form of contribution i.e. cash, acceptance letter from the proposed new board members. The Requesting Shareholders subsequently provided the requested clarification.

ii. ***Employee Bonuses***

82. In an effort to stymie the departure of employees immediately prior to and after the Petition Date, shortly before the Petition Date, the Debtors entered into certain retention agreements with six (6) of the Debtors' employees. The aggregate amount of such retention bonuses was approximately $163,000. The Debtors initiated payment of a portion of these retention bonuses ($124,850) prepetition, while the remaining amounts ($38,150) are due on or before August 31, 2023.

83. Additionally, prior to the Petition Date, the Debtors paid Averill Powers, the current Chief Executive Office of Vyera Pharmaceuticals LLC, a non-discretionary bonus of $270,000,

which the Debtors' deemed necessary, in their business judgment, to retain his employment as an essential employee with legacy knowledge of the Debtors' operations and businesses. As noted in the Employee Wage Motion, maintaining the Debtors' workforce is essential to the Debtors' ability to maintain their operations successfully and facilitate their efforts under the proposed Plan.

* * *

PART IV.

PLAN OVERVIEW[5]

84. As noted above, contemporaneously herewith, the Debtors have filed a proposed Plan, which the Debtors believe satisfies the requirements of section 1191 of the Bankruptcy Code.

85. The Plan is structured to support one or more sale transactions with respect to the assets of the certain of the Debtors and a parallel going-concern restructuring transaction with respect to Orpha Labs (referred to therein as the Reorganized Debtor). The cornerstone of this Plan lies in providing creditors with Liquidating Trust Certificates on the Effective Date (along with Pro Rata Distributions from Excess Liquidating Trust Cash, if available), entitling applicable creditors to Pro Rata Distributions in Cash from the Liquidating Trust out of the PRV Sale Proceeds, if any, in lieu of immediate Cash Distributions from the Liquidating Trust Assets. Cash Distributions from the Liquidating Trust Assets is likely to pay out general unsecured creditors a fraction of what is claimed. By contrast, assuming down-the-line success of the ORL Business, providing Liquidating Trust Certificates could make creditors whole, paying them 100 cents on the dollar. Further, to the extent any PRV Sale Proceeds are sufficient to satisfy creditors in full, any remainder will flow up to Phoenixus and from there to its shareholders.

86. The Plan is the product of robust discussions among the Board of Directors and the Debtors' advisors, considering, among other things, the universe of potential claims, various Bankruptcy Code requirements (and the nuances with respect to subchapter V), and the prospect of monetizing a PRV received from the FDA with respect to ORL-101.

87. The following chart illustrates the proposed mechanism for providing Distributions to Holders of Allowed Claims and Equity Interests:

[5] Capitalized terms used but not otherwise defined in this Section IV have the meanings ascribed to them in the Plan, filed contemporaneously herewith.

Effective Date	**Step 1**: Debtors transfer Liquidating Trust Assets to Liquidating Trust (including right to receive PRV Sale Proceeds) **Step 2**: Liquidating Trustee issues Liquidating Trust Certificates to Holders of Allowed Claims
PRV Sale	**Step 3**: Liquidating Trust, with guidance from Oversight Committee, monetizes a PRV issued by the FDA **Step 4**: Liquidating Trustee receives PRV Sale Proceeds
Post-PRV Sale	**Step 5**: Liquidating Trustee provides Cash Distributions out of PRV Sale Proceeds to holders of Liquidating Trust Certificates in full and final satisfactions of their respective Allowed Claims **Step 6**: Liquidating Trustee provides Cash Distributions to Debtor Phoenixus AG, as 100% Equity Interest holder of the Reorganized Debtor, from remainder of PRV Sale Proceeds and proceeds of any other Liquidating Trust Assets (including Retained Causes of Action) **Step 7**: Phoenixus distributes PRV Sale Proceeds it received from the Liquidating Trustee to Holders of Allowed Equity Interests

PART V.

SUMMARY OF FIRST DAY PLEADINGS

88. Contemporaneously herewith, the Debtors have filed certain First Day Pleadings.[6] I have reviewed each of the First Day Pleadings (including the exhibits and schedules attached thereto) and, to the best of my knowledge, information and belief, the facts set forth therein are true and correct. Based on my personal knowledge, information supplied to me by and discussions with other members of Debtors' management, Debtors' counsel and professionals and representatives, my review of relevant documents, my opinion based upon my experience and the aforementioned review and discussions, and as set forth in more detail below, I believe the relief sought in the First Day Pleadings is: (a) vitally necessary for the Debtors to (i) effectuate a smooth transition into, and operate within, the Subchapter V Cases, (ii) avoid immediate and irreparable harm, and (iii) avoid interruption or disruption to their business and estates to the greatest extent practicable; (b) in the best interests of the Debtors' creditors, estates and other stakeholders; and (c) constitutes a critical element in maximizing value during the Subchapter V Cases.

i. *Motion of the Debtors for Entry of an Order Authorizing (I) the Joint Administration of the Debtors' Subchapter V Cases and (II) Granting Related Relief* (the "Joint Administration Motion")

89. By the Joint Administration Motion, the Debtors seek entry of an order directing the joint administration of these Subchapter V Cases for procedural purposes only.

90. I believe that joint administration will promote the economical and efficient administration of the Debtors' estates to the benefit of the Debtors, their creditors, the Office of the United States Trustee for Region 3 (the "U.S. Trustee"), and the Court. Specifically, joint administration of these Subchapter V Cases will permit the Debtors to avoid incurring substantial

[6] Unless otherwise defined herein, capitalized terms used herein shall have the meanings ascribed to them in the relevant First Day Pleading filed contemporaneously herewith.

time and expense preparing, replicating, filing, and serving duplicate notices, applications, and orders. I also believe that joint administration will relieve the Court of entering duplicative orders and maintaining duplicative files and dockets. Other parties-in-interest will similarly benefit from joint administration of the Subchapter V Cases as they will be spared the time, effort, and expense needed to review duplicative pleadings and papers.

91. Therefore, I believe that the relief requested in the Joint Administration Motion is in the best interests of the Debtors' estates, their creditors, and all parties-in-interest, and should be granted.

ii. *Application of the Debtors for Entry of an Order (I) Approving the Retention and Appointment of Epiq Corporate Restructuring, LLC as the Claims and Noticing Agent to the Debtors, Effective Nunc Pro Tunc to the Petition Date, and (II) Granting Related Relief* (the "Epiq Retention Application")

92. By the Epiq Retention Application, the Debtors seek entry of an order appointing Epiq Corporate Restructuring, LLC ("Epiq") as claims and noticing agent in the Debtors' Subchapter V Cases, effective as of the Petition Date.

93. Epiq has acted as the claims and noticing agent in numerous bankruptcy cases of comparable size, including cases currently pending in both the District of Delaware and in other districts. Additionally, in compliance with the Protocol for the Employment of Claims and Noticing Agents Under 28 U.S.C. § 156(c) of the United States Bankruptcy Court for the District of Delaware, the Debtors' obtained and reviewed engagement proposals from at least two (2) other Court-approved claims and noticing agents to ensure selection through a competitive process. I believe that Epiq's rates are competitive and reasonable given Epiq's quality of services and expertise. I have worked with Epiq before and have found them to be a highly competent and diligent provider of claims and noticing services.

94. As more fully detailed in the Epiq Retention Application, I understand that Epiq will engage in certain claims administration and noticing services as necessary, including, but not limited to, the distribution of notices and the maintenance, processing and docketing of proofs of claim filed in the Subchapter V Cases. I believe that by appointing Epiq as the claims and noticing agent in the Subchapter V Cases, the distribution of notices and the processing of claims will be expedited, and the Clerk will be relieved of the administrative burden of processing what may be an overwhelming number of claims. Accordingly, I believe that relief requested in the Epiq Retention Application is in the best interests of the Debtors and their estates and creditors and should be granted.

iii. *Motion of the Debtors for Entry of an Order (I) Authorizing the Debtors to Maintain and Continue Payment of Employee Compensation, Director Fees and Employee Benefits on a Postpetition Basis, (II) Authorizing and Directing Banks to Honor and Process Checks and Transfers Related to such Employee Obligations and (III) Granting Related Relief* (the "Employee Wage Motion")

95. By the Employee Wage Motion, the Debtors are seeking entry of an order (i) authorizing, but not directing, the Debtors to: (a) continue in the ordinary course of business the employee wages, salaries, and other compensation including compensation to temporary workers, directors fees and independent contractors; (b) honor prepetition obligations in respect of, and continue in the ordinary course of business, the Debtors' paid time off policies, and employee benefits programs and plans (all as described more fully below, the "Employee Benefits"); and (c) continue their Workers Compensation Programs and honor obligations related thereto (items (a) through (c), and any additional obligations to employees not expressly included herein, collectively, the "Employee Obligations"); (ii) authorizing and directing banks and other financial institutions to honor and pay all checks and transfers drawn on the Debtors' accounts related to the

foregoing obligations; and (iii) granting such other and further relief as the Court deems just and proper.

96. I believe the Debtors' Employees are particularly critical to maintaining going-concern value for the estates due to the technical nature of the Debtors' business; the Employees represent much of the core "know-how" that makes up the Debtors' assets. Thus, retaining the Employees is critical to the Debtors' ability to operate and maximize value in the Subchapter V Cases.

97. Fair and equitable treatment of these Employees is necessary to maintain the existing Employees' morale and goodwill, which is particularly important at this time. I believe that the relief requested in the Employee Wages Motion is in the best interests of the Debtors' estates, their creditors, and all parties-in-interest, and constitutes a critical element of achieving a successful and smooth transition to a Subchapter V process. Accordingly, this Court should grant the relief requested.

iv. *Motion of the Debtors for Entry of an Order (I) Authorizing the Debtors to Pay Certain Prepetition Claims of Foreign Vendors, (II) Authorizing and Directing Banks to Honor and Process Check and Electronic Transfer Requests Related Thereto, and (III) Granting Related Relief* (the "Foreign Vendor Motion")

98. By the Foreign Vendor Motion, the Debtors are seeking entry of an order (i) authorizing, but not directing, the Debtors to pay the prepetition claims of certain foreign vendors and service providers located outside the U.S. and (ii) authorizing and directing banks and other financial institutions to honor and process check and electronic transfer requests related to the foregoing. The Debtors do not believe any prepetition amounts are owed to the Foreign Vendors as of the Petition Date. Accordingly, in an abundance of caution, to the extent the Debtors receive invoices from the Foreign Vendors postpetition relating to prepetition periods, the Debtors are requesting authority, but not direction, to pay such claims under the Foreign Vendor Motion.

99. Foreign Vendors often have skeptical reactions to the United States bankruptcy process; many are unfamiliar with chapter 11 (and especially subchapter V) cases and the impact on a debtor's ongoing ability to operate and pay for goods in the ordinary course. I understand that nonpayment of prepetition claims may cause the Foreign Vendors to take certain precipitous actions, including, without limitation, delaying supply until more certainty develops, or even seeking to drag the Swiss Debtor into a Swiss insolvency proceeding. In light of these significant consequences (as set forth in greater detail in the Foreign Vendor Motion), payment of Foreign Vendor Claims on the terms set forth in the Foreign Vendor Motion is necessary to avoid unnecessary foreign litigation during these Subchapter V Cases. The amount of the Debtors' estimated Foreign Vendor Claims pales in comparison to the potential cost to the Debtors' estates if the Debtors were required to defend multiple foreign litigations during these Subchapter V Cases.

100. Further, upon discussions with Phoenixus' Swiss counsel, the relief requested in the Foreign Vendor Motion is necessary to harmonize Swiss corporate law with the proposed treatment of creditors through these Subchapter V Cases and the proposed Plan.

101. I believe that the relief requested in the Foreign Vendor Motion is in the best interests of the Debtors' estates, their creditors, and all parties-in-interest, and constitutes a critical element of achieving a successful and smooth transition to a subchapter v process. Accordingly, this Court should grant the relief requested.

v. *Motion of the Debtors for Entry of an Order (I) Authorizing the Debtors to Honor Obligations to Customers and Related Third Parties and to Otherwise Continue Customer Programs; (II) Granting Relief from the Automatic Stay to Permit Setoff in Connection with Customer Programs; (III) Authorizing Financial Institutions to Honor and Process Related Checks and Transfers; and (IV) Granting Related Relief* (the "Customer Programs Motion")

102. By the Customer Programs Motion, the Debtors are seeking entry of an order (i) authorizing, but not directing, the Debtors to maintain and administer their customer-related programs as described in the Customer Programs Motion (collectively, the "Customer Programs"), and honor prepetition obligations to customers related thereto, and to otherwise continue, renew replace, modify, implement, revise, or terminate the Customer Programs in the ordinary course of business and consistent with past practice, (ii) granting relief from the automatic stay to permit ordinary course setoff in connection with the Customer Programs, (iii) authorizing and directing banks and other financial institutions to honor and process check and electronic transfer requests related to the foregoing, and (iv) granting related relief.

103. The Debtors have ongoing distribution relationships with (i) Specialty Pharmacies, which buy the Products from the Debtors and dispense them directly to patients with eligible insurance; (ii) Specialty Distributors, which distribute Products to hospitals and other eligible entities, and (iii) General Distributors (collectively, the "Customers").

104. The Customer Programs enable the Debtors to maximize Customer loyalty by, among other things, providing certain incentives, discounts, and other accommodations. Maintaining the goodwill of their customers is critical to the Debtors' ongoing operations and the maximization of estate value, all with an eye toward consummating a consensual Plan.

105. Additionally, I understand that the Setoff Procedures contemplated in the Customers Programs Motion are standard in the pharmaceutical industry in which the Debtors operate, are vital to the Debtors' cash flow system and ability to make vendor payments thereunder, and allow the Debtors to forecast out cash flow and demand. Absent authorization to implement the Setoff Procedures in the ordinary course of business, the Debtors' operations would be

interrupted irreparably and would likely be unable to make vendor payments in the ordinary course of business, to the detriment of all parties in interest.

106. The relief requested in the Customer Programs Motion is in the best interests of the Debtors' estates, their creditors, and all parties-in-interest, and constitutes a critical element of achieving a successful and smooth transition to a subchapter v process. Accordingly, this Court should grant the relief requested.

vi. *Motion of the Debtors for Entry of an Order (I) Authorizing the Continued Use of the Debtors' Cash Management System, (II) Authorizing Continued Intercompany Transfers Among Debtors, and (III) Granting Related Relief* (the "Cash Management Motion")

107. By the Cash Management Motion, the Debtors are seeking entry of an order, (i) authorizing, but not directing, the Debtors to continue to use their current cash management system, existing bank accounts, and business forms, including authorizing the Debtors to open and close bank accounts in the ordinary course of business and authorizing all banks participating in the cash management system to honor certain transfers and charge bank fees and certain other amounts; (ii) authorizing continued Intercompany Transfers in the ordinary course of business; and (iii) granting related relief.

108. Any disruptions in the Cash Management System, including the requirement to close their current Bank Accounts and open up new debtor-in-possession accounts, could lead to delays in satisfying the Debtors' obligations to employees, vendors, and suppliers, which could erode value for the Debtors' estates. This is especially true in light of the Debtors' recent efforts to open up Bank Accounts listed on the Authorized Depository List promulgated by the U.S. Trustee. Therefore, it is imperative that they be authorized to continue the Cash Management System consistent with the Debtors' historical practice, subject to the limitations proposed in the Cash Management Motion.

109. I believe that the relief requested in the Cash Management Motion is in the best interests of the Debtors' estates, their creditors, and all parties-in-interest, and constitutes a critical element of achieving a successful and smooth transition to a subchapter V process. Accordingly, this Court should grant the relief requested.

vii. *Motion of the Debtors for Entry of an Order (I) Authorizing the Debtors to File Under Seal Portions of the Debtors' Consolidated Creditor Matrix and List of Equity Security Holders Containing Certain Personally Identifiable Information* (the "Motion to Seal")

110. By the Motion to Seal, the Debtors are seeking entry of an order authorizing, among other things, the Debtors to file a redacted version of the Debtors' consolidated creditor matrix and list of equity security holders for Debtor Phoenixus AG. The relief requested has become standard in this District and I am informed falls squarely in line with the protective provisions of the Bankruptcy Code.

111. The relief requested also will serve to minimize risks to employees and individual shareholders and will not prejudice any party in interest. I believe that the relief requested in the Motion to Seal is in the best interests of the Debtors' estates, their creditors, and all parties-in-interest, and, accordingly, should be granted.

[*Signature Page Follows*]

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the contents of the foregoing Declaration are true and correct to the best of my information and belief.

Dated: May 10, 2023

Respectfully submitted,

Debtor Phoenixus AG
Debtor Vyera Pharmaceuticals, LLC
Debtor Oakrum Pharma, LLC
Debtor SevenScore Pharmaceuticals, LLC
Debtor Orpha Labs AG
Debtor Dermelix Biotherapeutics, LLC

/s/ Lawrence R. Perkins
By: Lawrence R. Perkins
Its: Chief Restructuring Officer

EXHIBIT A

SDNY Opinion

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION, STATE OF NEW YORK, STATE OF CALIFORNIA, STATE OF OHIO, COMMONWEALTH OF PENNSYLVANIA, STATE OF ILLINOIS, STATE OF NORTH CAROLINA, and COMMONWEALTH OF VIRGINIA, Plaintiffs, -v- MARTIN SHKRELI, Defendant.	20cv00706 (DLC) OPINION AND ORDER

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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

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

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 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

[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. 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.

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 (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. See Fed. Trade Comm'n v. Vyera Pharms., LLC, No. 20CV00706 (DLC), 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.

[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.

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 evidence relating to Retrophin, Inc. ("Retrophin"), a pharmaceutical company that Shkreli and Mulleady founded in 2011, was denied. Id., 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

[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.

admissibility of such testimony. Id., 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 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 WL 5300019 (S.D.N.Y. Nov. 15, 2021), and excluded testimony from Defendants' expert Justin McLean, id., 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 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

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

Consulting Group, a pharmaceutical consulting company, was largely granted. Id., 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 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

[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.

early 2019, and current Executive Vice President of 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,

[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.

McDougal, Mukhopadhyay, Patel, Shah, and Valiveti.[10] Affidavits constituting the 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

[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.

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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]

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

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.

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 (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 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

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

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 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

[13] Statement from FDA Commissioner Scott Gottlieb, M.D., on New Agency Efforts to Shine Light on Situations Where Drug Makers May Be Pursuing Gaming Tactics to Delay Generic Competition, 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.

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 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

[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.

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 co-founded 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."

[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

[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.

and inferior alternative 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

[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.

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 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

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

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 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.

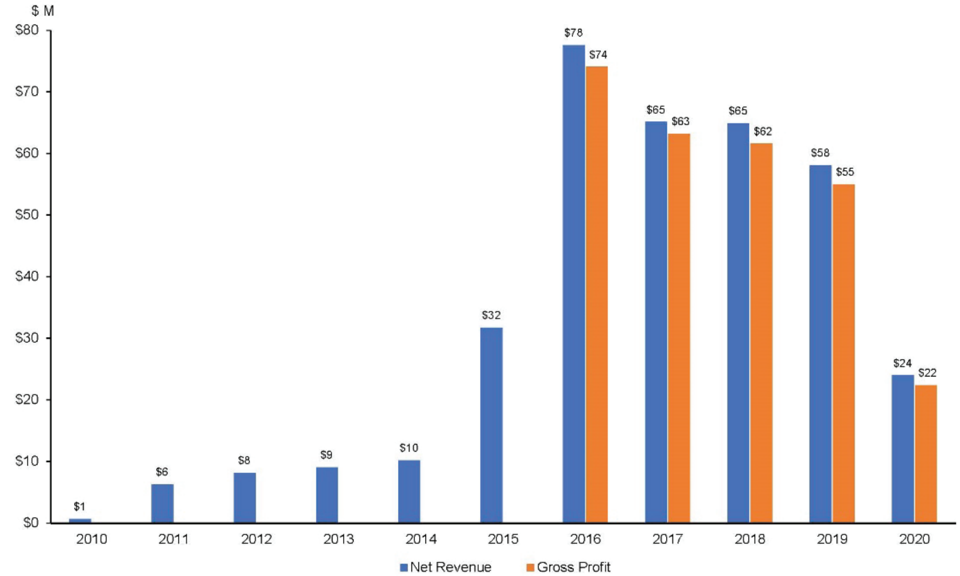
B. Daraprim's 2015 Price Hike and Vyera's Revenues

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.

GX7012
Daraprim Net Revenue and Gross Profit
2010–2020



Source: GX3555 (IQVIA National Sales Perspectives), GX1618 (Vyera_01560868), GX1619 (Vyera_01560869)
Note: [1] Available sales data for 2010 through Q2 2015 takes account of chargebacks but not rebates; thus, for 2010 through 2015, reported net revenue is an upper bound. [2] Gross Profit = Net Revenue - Cost of Goods Sold.

GX7012-001

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

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

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 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

[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.

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, 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, 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]

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

[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.

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.

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 <u>Abbott Laboratories Inc. v. Portland Retail</u>

Druggists, 425 U.S. 1 (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 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

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

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

> [Fukuzyu] shall provide the API Bulk Drug Substance, pyrimethamine exclusively to [Phoenixus] for the use,

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

> 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 acknowledge the order in writing

[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.

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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 other financial

[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 WL 2201382 (S.D.N.Y. June 1, 2021).

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.

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

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]

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.

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

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 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

[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.

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 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

[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.

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 2017 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 or 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]

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

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 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

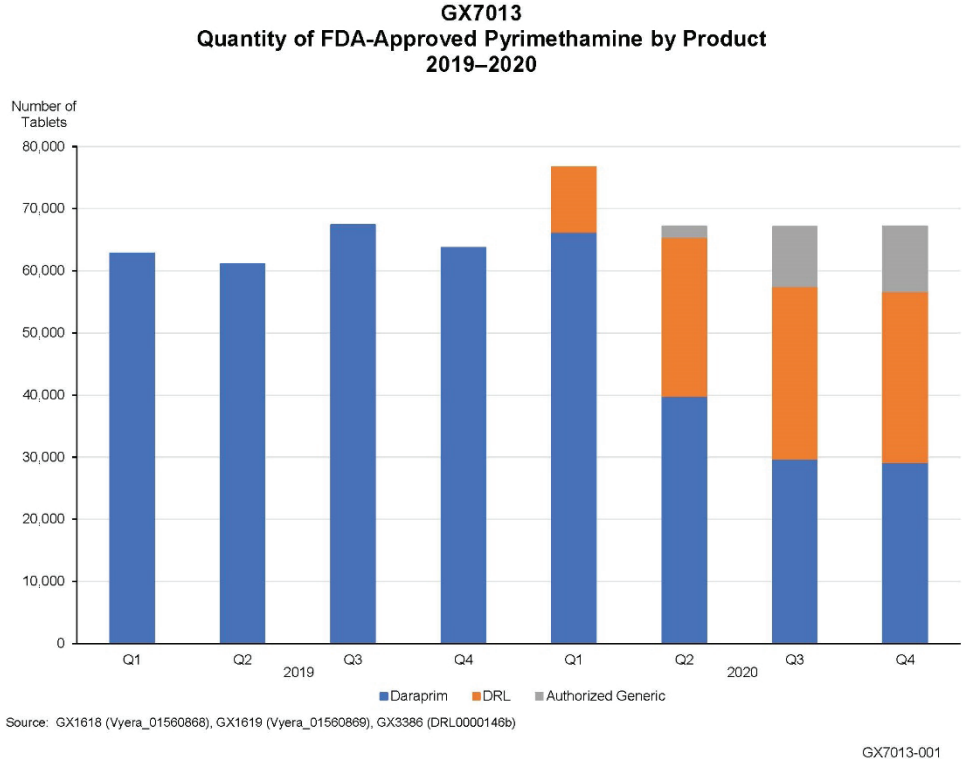
In early 2020, Vyera braced for the imminent approval of Cerovene's ANDA and subsequent launch of Dr. Reddy's FDA-approved generic pyrimethamine product. In an internal forecast prepared in March 2020, Vyera projected that the net price for a Daraprim tablet would immediately drop from $278 to $126 after 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

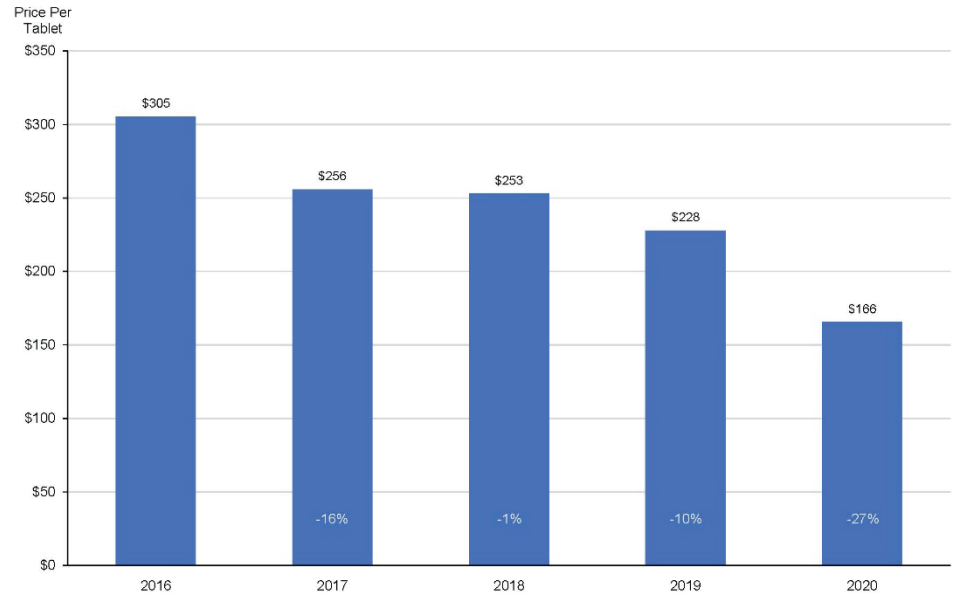


[33] A generic of a brand name drug may be launched under the brand's preexisting FDA approval. It is known as an authorized generic.

Dr. Reddy's generic pyrimethamine (identified as "DRL") between the first quarter of 2019 and the last quarter of 2020.

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.

GX7004
Average Net Price of FDA-Approved Pyrimethamine
2016–2020



Source: GX1618 (Vyera_01560868), GX1619 (Vyera_01560869), GX3386 (DRL0000146b)
Note: Percentage change from previous year is reported inside the bars.

GX7004-001

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 himself to Mark Zuckerberg and

[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.

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 (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 (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 (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 (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 (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 procompetitive 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 (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 (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 (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 (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., 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., 870 N.Y.S.2d 315, 316 (1st Dep't 2009); see also Vyera, 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., 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., 407 N.E.2d 507, 509 (Ohio 1980). "Ohio has long followed federal law in interpreting the Valentine Act." Johnson v. Microsoft Corp., 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, 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

[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.

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 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

> [c]ompounded drugs can pose serious health risks to patients. Compounded drugs are not FDA-approved.

[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.

> 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 (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 (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 (1945); see also Lorain Journal Co. v. United States, 342 U.S. 143, 145 n.2 (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 (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 (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., 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 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.

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

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 wellbeing 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. 1936, 1943 (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

[39] The FTC is precluded from seeking disgorgement. Vyera, 2021 WL 4392481, at *2.

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 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

DENISE COTE
United States District Judge