20 CV 00706

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

JUDGE COTE

FEDERAL TRADE COMMISSION
600 Pennsylvania Ave., NW
Washington, DC 20580

STATE OF NEW YORK
28 Liberty Street
New York, NY 10005

Plaintiffs,

v.

VYERA PHARMACEUTICALS, LLC,
600 Third Ave., 10th Floor
New York, NY 10016

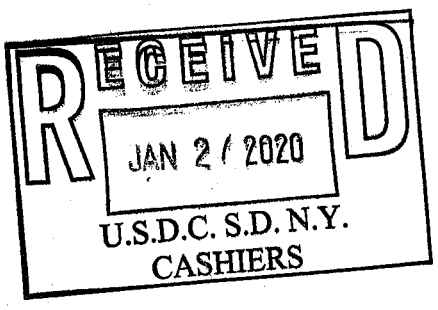
PHOENIXUS AG,
Hadlenstrasse 5
6340 Baar, Switzerland

MARTIN SHKRELI, individually, as an owner and former director of Phoenixus AG and a former executive of Vyera Pharmaceuticals, LLC,
FCI Allenwood Low
Federal Correctional Institution
P.O. Box 1000
White Deer, PA 17887

and

KEVIN MULLEADY, individually, as an owner and director of Phoenixus AG and a former executive of Vyera Pharmaceuticals, LLC,
330 East 38th St., Apt. 54K
New York, NY 10016

Defendants.



Complaint for Injunctive and Other Equitable Relief

Plaintiffs, the Federal Trade Commission ("FTC" or "the Commission"), by its designated attorneys, and the State of New York ("New York"), by and through its Attorney General, petition this Court, pursuant to Section 13(b) of the Federal Trade Commission Act, 15 U.S.C. § 53(b), Section 16 of the Clayton Act, 15 U.S.C § 26, Section 342 of the New York General Business law, and Section 63(12) of the New York Executive Law for a permanent injunction and other equitable relief, including equitable monetary relief, against Defendants Vyera Pharmaceuticals, LLC ("Vyera"), Phoenixus AG ("Phoenixus"), Martin Shkreli, and Kevin Mulleady to undo and prevent their anticompetitive conduct and unfair methods of competition in or affecting commerce in violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, Section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a), and state law.

I. Nature of the Case

1. This case challenges a comprehensive scheme by Vyera, its parent company Phoenixus, and two of the companies' owners and executives, Shkreli and Mulleady, to block lower-cost generic competition to Daraprim, an essential drug used to treat the potentially fatal parasitic infection toxoplasmosis. Their unlawful scheme to maintain a monopoly on Daraprim continues to this day.

2. Daraprim had been sold as an affordable, life-saving treatment for more than 60 years. In 2015, however, Defendants acquired the U.S. rights to Daraprim from the only existing supplier and immediately raised the price from $17.50 to $750 per tablet—an increase of more than 4,000%. This massive price hike delivered immediate benefits to Defendants, increasing Daraprim's annual revenues from [redacted].

3. Defendants knew, though, that this revenue boon could be short lived: Daraprim had no patent or regulatory protection and the massive price increase would attract competition

from lower-priced generic products. To preserve the Daraprim revenue stream, Vyera and Phoenixus—under the direction of Shkreli and Mulleady—executed an elaborate, multi-part scheme to block generic entry.

4. First, Defendants created a complex web of contractual restrictions that prohibit distributors and [redacted] from reselling Daraprim to generic companies or their agents. Defendants understood that restricting access to branded Daraprim could stifle generic competition. The U.S. Food & Drug Administration ("FDA") requires any generic applicant to conduct bioequivalence testing comparing its product to samples of the branded drug. Vyera's resale restrictions made it virtually impossible for generic companies to purchase sufficient quantities of Daraprim to conduct these FDA-required tests. Indeed, several generic companies tried for more than a year to secure enough branded Daraprim samples for testing, but were unable to do so. At least one other generic company simply abandoned its development plans.

5. Second, Defendants cut off competitors' access to pyrimethamine—the active pharmaceutical ingredient ("API") necessary to manufacture Daraprim. [redacted]

6. [redacted]

[redacted]

7. Third, Defendants signed "data-blocking" agreements with Vyera's distributors to prevent them from selling their Daraprim sales data to third-party data reporting companies, such as IQVIA. These reporting companies purchase, compile, and sell sales data on pharmaceutical products, which generic companies then buy. These data are critical for generic companies' assessment of whether a given development opportunity is worth pursuing. Defendants' data-blocking agreements prevented the reporting companies from obtaining accurate information about Daraprim sales. By obscuring these sales, Defendants sought to prevent generic companies from accurately assessing the market opportunity for a generic Daraprim product and thereby deter them from even pursuing development of a generic product.

8. The purpose and effect of Defendants' anticompetitive conduct has been to thwart potential generic competition and protect the Daraprim revenues resulting from Vyera's shocking price increase. Absent Defendants' anticompetitive conduct, Daraprim would have faced generic competition years ago. Instead, toxoplasmosis patients who need Daraprim to survive have been denied the opportunity to purchase a lower-cost generic version, forcing them and other purchasers to pay tens of millions of dollars a year more for this life-saving medication.

II. Jurisdiction and Venue

9. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1337(a), and 1345, as well as under the principles of supplemental jurisdiction codified in 28 U.S.C. § 1367(a). This Court's exercise of supplemental jurisdiction over Plaintiff New York's state law claims would avoid unnecessary duplication and multiplicity of actions, and should be exercised in the interests of judicial economy, convenience, and fairness.

10. This Court has personal jurisdiction over Vyera, Phoenixus, Shkreli, and Mulleady because each has the requisite constitutional contacts with the United States of America pursuant to 15 U.S.C. § 53(b). This Court also has personal jurisdiction over Vyera, Phoenixus, Shkreli, and Mulleady because each has the requisite constitutional contacts with the state of New York due to their domicile, extent of their business transactions within New York, contracts to supply goods and services in New York, soliciting business in New York, and/or committing illegal acts as alleged herein within the state of New York, pursuant to N.Y. CPLR §§301, 302.

11. Venue in this District is proper under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), 15 U.S.C. § 22, and 15 U.S.C. § 1391(b) and (c). Each Defendant resides, transacts business, committed an illegal act, or is found in this District.

12. Defendants' general business practices, and the unfair methods of competition alleged herein, are "in or affecting commerce" within the meaning of Section 5 of the FTC Act, 15 U.S.C. § 45.

13. Vyera and Phoenixus are, and at all times relevant herein have been, corporations as defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

14. Martin Shkreli and Kevin Mulleady are "persons" within the meaning of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45.

III. The Parties

A. Plaintiff Federal Trade Commission

15. Plaintiff Federal Trade Commission is an independent administrative agency of the United States government, established, organized, and existing pursuant to the FTC Act, 15 U.S.C. § 41 *et seq*., with its principal offices in Washington, DC, and a regional office in Manhattan in New York City, New York. The FTC is vested with authority and responsibility for

enforcing, *inter alia*, Section 5 of the FTC Act, 15 U.S.C. § 45, and is authorized under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), to initiate court proceedings to enjoin violations of any law the FTC enforces.

16. The FTC is authorized to bring this case in federal court because Defendants are violating or about to violate a provision of law enforced by the Federal Trade Commission, and this is a proper case for permanent injunctive relief within the meaning of Section 13(b) of the FTC Act, 15 U.S.C. § 53(b).

B. Plaintiff State of New York

17. Plaintiff State of New York is a sovereign. Letitia James is the Attorney General of the State of New York, the chief legal officer for the state, and brings this action on behalf of the people of the State of New York in connection with the Attorney General's role to protect the State of New York and its residents from exploitative, anticompetitive business practices. The Attorney General is authorized to bring this suit to enjoin Defendants from their illegal, anticompetitive conduct and seeks appropriate relief on behalf of the state of New York and its residents harmed by Defendants' conduct.

C. Corporate Defendants

18. Phoenixus AG is a privately-held, for-profit Swiss corporation with its principal place of business located in Baar, Switzerland. Phoenixus was previously known as Turing Pharmaceuticals AG and Vyera Pharmaceuticals AG. Phoenixus transacts or has transacted business in this District.

19. Phoenixus is engaged in the manufacture and distribution of the pharmaceutical product Daraprim. Phoenixus acquired the rights to market and distribute Daraprim in the United States in August 2015. [redacted]

[redacted]

20. Vyera Pharmaceuticals, LLC, is a privately-held, for-profit limited liability corporation that is wholly owned by Phoenixus AG. Vyera is incorporated in Delaware with its principal place of business located in New York City, New York. Vyera was previously named Turing Pharmaceuticals, LLC. Vyera transacts business in this District and throughout the United States.

21. Vyera is registered with the FDA as the owner of the Daraprim New Drug Application (No. 008578). [redacted]

22. Defendants Phoenixus and Vyera have operated and continue to operate as a common enterprise while engaging in the unfair methods of competition alleged below. [redacted] The current CEO of Phoenixus, Averill Powers, is also Vyera's top executive and general counsel and works out of Vyera's New York office. [redacted]

23. [redacted]

24. Unless otherwise specified, this Complaint refers to Vyera and Phoenixus collectively as "Vyera" when discussing their joint conduct relating to Daraprim.

D. Individual Defendants

1. Martin Shkreli

25. Martin Shkreli is the founder of Phoenixus and Vyera, the largest shareholder and former chairman of the board of Phoenixus, and the former CEO of Vyera. At all times material to this Complaint, acting alone or in concert with others, Shkreli has formulated, directed, controlled, had the authority to control, or participated in the acts and practices set forth in this Complaint. Shkreli resided in this District until his federal incarceration for securities fraud in 2017. In connection with the conduct alleged herein, he transacts or has transacted business in this District and throughout the United States.

26. Prior to founding Vyera, from 2006 to 2011, Shkreli founded and ran three hedge funds, all of which failed.

27. In 2011, Shkreli abandoned hedge funds for pharmaceuticals. He founded the pharmaceutical company Retrophin, Inc., despite having no pharmaceutical business experience.

28. During his brief tenure at Retrophin, Shkreli acquired Thiola, a sole-source drug for a small but dependent patient population, placed it into a restricted distribution system, and significantly increased the price. He stated at the time that he intended to use distribution restrictions to prevent generic competition to Thiola.

29. Shkreli was ousted from Retrophin in 2014 by the board of directors for misconduct relating to improper grants and trades of company stock.

30. Upon leaving Retrophin, Shkreli started Vyera to look for similar products with which to replicate his Retrophin strategy.

31. As founder and CEO of Vyera, Shkreli directed the minute details of Vyera's business and strategy, including the decision to acquire Daraprim, securing a source for the drug's API, and implementing a restricted distribution system.

32. Shkreli remained CEO until his arrest in December 2015 for securities fraud stemming from conduct at his hedge funds and at Retrophin. He was subsequently convicted of several felonies, including securities fraud and conspiracy to commit securities fraud, and sentenced to seven years in federal prison. Shkreli remained free on bail until September 2017, when his bail was revoked for making threats against Hillary Clinton.

33. With the exception of a brief period in the first half of 2017, Shkreli has maintained his influence over Phoenixus and Vyera through associates as well as his position as Phoenixus's largest shareholder. Shkreli's longtime ally Ron Tilles served as interim CEO from Shkreli's departure in December 2015 until April 2017. Tilles co-founded Retrophin with Shkreli and was a founding board member of Phoenixus. As detailed in a report by the U.S. Senate Special Committee on Aging, Tilles was Shkreli's "handpicked successor"—"a broker by training whose main skillset was soliciting investors and who, by his own admission, did not know the most basic of pharmaceutical concepts."

34. In April 2017, Mr. Tilles was briefly replaced by Dr. Eliseo Salinas. When Dr. Salinas proved resistant to Shkreli's influence, however, Shkreli waged a successful proxy fight to oust Dr. Salinas and the Phoenixus board.

35. In June 2017, Shkreli's close associates, including Mulleady and Akeel Mithani, were elected to Phoenixus's board of directors. [redacted]

[redacted]

36. Mithani is Shkreli's protégé. Mithani obtained his undergraduate degree in 2014 and soon began communicating with Shkreli through Twitter. In 2015, Shkreli invited him to apply for a job at Vyera as a junior business development analyst, which Mithani did not get because (in his own words) he "sorely lacked the qualifications." In June 2017, however, Shkreli secured Mithani's election to the Phoenixus board. [redacted]

37. [redacted]

38. Since his incarceration in September 2017, Shkreli has remained in regular contact with Mulleady and Mithani through phone calls, emails, in-person visits, [redacted] and potentially other means. From June to December 2019 alone, Shkreli exchanged 240 emails with Mulleady and 391 emails with Mithani. In these communications, Shkreli continues to discuss strategies to prevent generic competition to Daraprim, as well as other matters of Vyera business strategy.

39. In March 2019, a Wall Street Journal article reported that Shkreli "remains the shadow power at Phoenixus AG" and that he was using a contraband cell phone to run Vyera

from prison. [redacted]

40. [redacted]

2. Kevin Mulleady

41. Kevin Mulleady is the current chairman of the Phoenixus board of directors and former CEO of Vyera. At all times material to this Complaint [redacted], acting alone or in concert with others, he has formulated, directed, controlled, had the authority to control, or participated in the acts and practices set forth in this Complaint. Mulleady resides in this District and, in connection with the matters alleged herein, he transacts or has transacted business in this District.

42. Before joining Vyera, Mulleady had little pharmaceutical experience.

43. Following his graduation from college in 2005, Mulleady held entry-level positions in wealth management and also worked as a real estate broker.

44. In 2011, Mulleady took a position finding investors for Shkreli's failing hedge funds. (He was an unindicted co-conspirator in the criminal securities fraud case against Shkreli.) [redacted]

45. [redacted]

46. [redacted]

[redacted]

47. [redacted]

IV. Background

A. Federal Law Encourages Generic Competition

48. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq*., as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act") and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 21 U.S.C. §§ 355(b)(2) and 355(j) and 35 U.S.C. § 271(e), establishes procedures designed to facilitate competition from lower-priced generic drugs.

49. A company seeking to market a new pharmaceutical product in the United States must file a New Drug Application ("NDA") with the FDA demonstrating the safety and efficacy of the new product. These NDA-based products generally are referred to as "brand-name drugs" or "branded drugs."

50. A company seeking to market a generic version of a branded drug may file an Abbreviated New Drug Application ("ANDA") with the FDA, referencing the branded drug's NDA. The generic applicant must demonstrate that its generic drug is therapeutically equivalent to the brand-name drug that it references, meaning that the generic drug is the same as the brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. If the FDA determines that the generic drug is therapeutically equivalent to the already-approved branded drug, it will assign the generic drug an "AB" rating and will allow the generic company to rely on the studies submitted in connection with the

already-approved branded drug's NDA to establish that the generic drug is safe and effective. 21 U.S.C. § 355(j)(2)(A)(iv).

51. To establish that the generic drug is therapeutically equivalent to the branded drug, the ANDA applicant must demonstrate bioequivalence, meaning that there is no significant difference in the rate and extent to which the active ingredient becomes available in the body. To make this showing, the applicant must acquire substantial quantities of the referenced branded drug and conduct bioequivalence testing comparing its generic version against that branded drug.

52. The ANDA applicant must conduct both in vivo and in vitro bioequivalence testing. In the in vivo testing, the same small group of human subjects (a minimum of 12, but often 20 to 30 people) sequentially takes the two products and the pharmacokinetic performance of the drug is measured through bloodwork. The in vitro dissolution testing compares the rate and extent to which the branded and generic drugs form a solution from their original dosage form (e.g., tablet or capsule).

53. The ANDA applicant must also reserve enough branded drug samples to perform each of the required tests five times.

54. Depending on the product, a generic manufacturer may need as many as 1,000 to 5,000 doses of the branded drug to conduct bioequivalence testing, all of which must be from the same manufacturing lot to assure uniform character and quality.

55. Normally, the ANDA applicant can obtain sufficient samples of the branded drug by purchasing them through normal distribution channels, such as drug wholesalers.

56. An ANDA applicant must also secure an acceptable, steady supply of the drug's API, which is the ingredient that provides the drug's pharmacological activity. Pharmaceutical companies typically purchase API from third-party suppliers. In order for an API to be used in a

pharmaceutical product, the FDA must approve the API product, the API manufacturing process, and the API manufacturer's quality controls, facility, and compliance with good manufacturing practices. An ANDA must therefore contain extensive information about the API and its manufacturer, including a complete description of the manufacturing process and process controls, the control of materials used in the manufacture of the drug substance, controls of critical steps and intermediates, process validation, and the manufacturing process development. In addition to reviewing this information in detail, the FDA will typically audit the API manufacturer and its facility.

57. If a generic cannot find an API supplier with an existing process that can meet the FDA's standards, it will typically need to work with a new supplier to develop a manufacturing process for the API, which can take months or years.

58. A supplier that has already developed a process to produce an API can separately submit a drug master file ("DMF") to the FDA containing this required information. In that case, an applicant using that supplier can reference the DMF in its ANDA rather than developing and submitting the information anew. The generic applicant's path to FDA approval is easier and faster if the FDA has already inspected the API supplier's facility and approved the manufacturing process. Even if the FDA still needs to inspect the API supplier, the DMF indicates that the manufacturer has an existing, FDA-approvable process to manufacture the API, which can shorten the ANDA development timeline.

B. Competition from Lower-Priced Generic Drugs Saves American Consumers Billions of Dollars Each Year

59. Generic drugs are uniquely close competitors to their branded counterparts and are a critical part of lowering prescription drug prices in the United States.

60. All 50 states and the District of Columbia have drug substitution laws that encourage and facilitate substitution of lower-cost AB-rated generic drugs for branded drugs. When a pharmacist fills a prescription written for a branded drug, these laws allow or require the pharmacist to dispense an AB-rated generic version of the drug instead of the more expensive branded drug, unless a physician directs or the patient requests otherwise. Conversely, these laws generally do not permit a pharmacist to substitute a non-AB-rated generic for a branded drug unless the physician specifically prescribes it by writing on the prescription the chemical name of the drug, rather than the brand name.

61. The Hatch-Waxman Act and state substitution laws have succeeded in facilitating generic competition and generating large savings for patients, healthcare plans, and federal and state governments. The first generic competitor's product is typically offered at a 20% to 30% discount to the branded product. Subsequent generic entry creates greater price competition, with discounts reaching 85% or more off the brand price. According to a 2010 Congressional Budget Office report, the retail price of a generic is 75% lower, on average, than the retail price of a brand-name drug. In 2018 alone, the Association of Accessible Medicines reported that use of generic versions of brand-name drugs saved the U.S. healthcare system $293 billion.

62. Because of these cost savings, many third-party payers of prescription drugs (e.g., health insurance plans and Medicaid programs) have adopted policies to encourage the substitution of AB-rated generic drugs for their branded counterparts. As a result of these policies and lower prices, many consumers routinely switch from a branded drug to an AB-rated generic drug upon its introduction. Consequently, AB-rated generic drugs typically capture over 80% of a branded drug's unit and dollar sales within six months of market entry.

C. Daraprim Is the Gold-Standard Treatment for Toxoplasmosis

63. Toxoplasmosis is a common parasitic infection typically transmitted through undercooked meat and infected cat feces. In most humans, toxoplasmosis is easily contained by their immune systems and causes no symptoms.

64. But in immunocompromised individuals—such as those with HIV/AIDS, cancer patients, or recipients of organ transplants—the infection can morph into a potentially fatal organ infection, most commonly in the brain, lungs, or heart. The parasite can also infect the eyes (ocular toxoplasmosis).

65. An expectant mother can also pass the *toxoplasma gondii* parasite in utero, causing congenital toxoplasmosis, which left untreated can lead to blindness, severe intellectual disabilities, and other neurological problems.

66. In the United States, the number of toxoplasmosis cases requiring treatment each year is small (less than 7,000 per year from 2003-2012) and declining as treatment of HIV/AIDS improves.

67. The gold-standard treatment for toxoplasmosis is pyrimethamine. All U.S. government health authority guidelines identify pyrimethamine as the preferred treatment for the infection. The Centers for Disease Control and Prevention advise that pyrimethamine is the "most effective drug against toxoplasmosis." The National Institute of Health calls pyrimethamine the "initial therapy of choice," and it advises other options only if pyrimethamine is "unavailable or there is a delay in obtaining it."

68. Pyrimethamine is on the World Health Organization's Model List of Essential Medicines, which identifies the minimum medicines needed for a basic healthcare system.

69. Daraprim (NDA No. 08578) is the only FDA-approved pyrimethamine product (branded or generic) on the market in the United States and the only drug approved by the FDA for the treatment of toxoplasmosis.

70. Daraprim was first approved by the FDA in 1953. It long ago lost any patent protection or regulatory exclusivity.

71. Daraprim is available only as a 25-milligram tablet. Generally, a toxoplasmosis infection is diagnosed in an acute hospital setting, and the patient typically remains hospitalized for two to three weeks. During this stage, the starting dosage for adults is 50 to 75 milligrams of Daraprim per day.

72. Following discharge, patients typically continue on about half that amount for four to five additional weeks, though some patients must remain on pyrimethamine for months or years to prevent recurrence.

D. Vyera's Acquisition of Daraprim

1. Prior ownership of Daraprim

73. GlaxoSmithKline plc and its predecessor entities owned the worldwide rights to Daraprim from its approval in 1953 until 2010.

74. By 2010, GSK charged around $1 per Daraprim tablet and had relatively low revenues of less than $1 million per year in the United States due to the low incidence of toxoplasmosis.

75. GSK still sells Daraprim in the United Kingdom, where it charges less than $1 per tablet.

76. In 2010, GSK sold its U.S. and Canadian Daraprim rights to CorePharma LLC,

[redacted]

77. Between 2010 and 2015, CorePharma and Amedra gradually increased the price of Daraprim to $13.50 per tablet. [redacted]

78. In March 2015, Impax Laboratories, Inc. acquired Daraprim as part of a $700 million acquisition of Amedra's parent company, Tower Holdings, Inc.. [redacted]

79. In June 2015, Impax increased the price of Daraprim by 30%, from $13.50 to $17.50 per tablet. [redacted]

2. Vyera's acquisition of Daraprim

80. [redacted]

81. [redacted]

82. On August 7, 2015, Vyera acquired the U.S. rights to Daraprim for the final negotiated price of $55 million— [redacted]

83. Vyera had a plan to turn Impax's $5 million-per-year drug into a $500 million-per-year drug. The plan started with a shocking price increase: the day after finalizing the deal in August 2015, Vyera raised the price from $17.50 to $750 per tablet, an increase of more than 4,000%.

84. [redacted] He was very wrong. Vyera swiftly faced outcries from health care providers, patients, medical societies, the general public, and Congress.

85. [redacted]

86. In September 2015, the HIV Medicine Association ("HIVMA") of the Infectious Diseases Society of America publicly urged Vyera "to immediately revise the pricing strategy for" Daraprim. HIVMA deemed the estimated annual cost of pyrimethamine treatment for toxoplasmosis ($336,000-$634,500 depending on the patient's weight) "unjustifiable for the medically vulnerable patient population in need of this medication and unsustainable for the health care system."

V. Defendants' Anticompetitive Agreements to Maintain Vyera's Daraprim Monopoly

87. Vyera knew that the dramatic price increase on its own would not secure long-term revenues because, with no patent or regulatory protection, Daraprim would be vulnerable to generic entry. Thus, to protect its Daraprim revenues, Vyera launched an elaborate scheme to prevent generic competition: it entered agreements prohibiting distributors and [redacted] from reselling Daraprim to potential generic competitors or their agents; [redacted] and entered data-blocking agreements to prevent distributors from selling their Daraprim sales

data, thus masking the true size of the Daraprim market to deter generic competitors. Defendants Shkreli and Mulleady implemented, oversaw, and participated in this scheme.

A. Defendants Implement Agreements Restricting Resale and Limiting Purchases to Block Generic Entry

88. Before 2015, Daraprim was distributed openly for more than 60 years without any restrictions. Generic companies were able to purchase Daraprim from a local pharmacy without entering into any written contract or obtaining any type of approval.

89. [redacted] One of Vyera's co-founders testified that "closed distribution can increase a product life cycle by preventing generics from potentially getting your referenced product," which they need for FDA-required bioequivalence testing. Vyera's former general counsel further testified that the use of a closed distribution system was "considered an integral part of the company's desire to block a generic entrant for at least three years."

90. Defendant Shkreli had experience using resale restrictions to block generic competition. In 2014, Shkreli's first pharmaceutical company, Retrophin, acquired the rights to Thiola, a drug used to treat the rare disease cystinuria. At Shkreli's direction, Retrophin raised the price of Thiola by 2,000% and put it into a restricted distribution system.

91. At that time, Shkreli told Retrophin investors that "[t]he closed distribution system . . . allows for us to control the release of our product. We do not sell Retrophin products to generic companies." As Shkreli explained, blocking generic access to drug samples in this way "takes the AB substitutable rating that generics rely on and neuters it."

92. [redacted]

[redacted]

93. Upon acquiring Daraprim, Vyera acted to implement Shkreli's blueprint. [redacted] The resulting web of contractual restrictions prevents generic companies from purchasing Daraprim at any point in the distribution chain, denying them the ability to conduct the bioequivalence testing necessary for FDA approval.

1. Vyera's contractual restrictions prevent distributors from selling Daraprim to generic companies

94. Vyera's generic-blocking agreements start with its distributors. [redacted] Each Vyera distributor can sell Daraprim only to specifically identified customers or customer types. Any other purchase request requires Vyera's direct approval. As Vyera's director of patient access explained, "[i]f someone else calls and asks for 50 bottles of Daraprim, they would have to come to me for approval."

95. None of Vyera's distributors is allowed to sell Daraprim to generic companies. Nor does Vyera approve such sales. If a distributor receives a purchase request from an entity that might be a generic company or might sell to one, Vyera will "block that purchase" to "avoid generic competition."

96. At the top of its distribution system, Vyera uses ICS (formerly Smith Medical Partners) as a third-party logistics provider. [redacted]

[redacted] ICS is compensated through a fixed monthly fee, as well as additional fees for each order it ships.

97. Under its agreement with Vyera, ICS can only ship Daraprim to four specifically approved distributors: ASD Healthcare, Cardinal Health, BioRidge Pharma, LLC, and Optime Care Inc. Generic companies are not approved purchasers, and ICS cannot sell Daraprim to them without Vyera's approval.

98. [redacted]

99. First, Vyera has an agreement with ASD Healthcare to distribute Daraprim to hospital and government purchasers. Vyera compensates ASD by paying it [redacted] of Daraprim's wholesale acquisition cost ("WAC," i.e. the list price) for each sale it makes.

100. [redacted] Vyera and ASD later amended their written contract to enumerate "authorized customers" and to specifically require that Vyera "approve any new authorized customers via email." Generic companies are not and have never been authorized customers under the ASD agreement. [redacted] Consequently, ASD cannot sell Daraprim to generic companies without Vyera's approval.

101. [redacted]

102. [redacted] Consequently, [redacted] cannot sell Daraprim to generic companies without Vyera's approval.

103. [redacted]

104. [redacted] Consequently, [redacted] cannot sell Daraprim to generic companies without Vyera's approval.

105. [redacted]

106. [redacted] Consequently, [redacted] cannot sell Daraprim to generic companies without Vyera's approval.

107. [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

108. [redacted]

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113. [redacted]

114. [redacted]

115. [redacted]

116. [redacted]

3. Vyera limits and monitors approved sales of Daraprim to prevent generic companies from obtaining it

117. In addition to its agreements with distributors and [redacted] not to sell Daraprim to generic companies, Defendants took further steps to ensure generic companies could not purchase the Daraprim they needed to conduct FDA-required bioequivalence testing.

118. A bottle of Daraprim contains 100 tablets. [redacted] in order to meet FDA requirements for bioequivalence testing, any potential generic competitor would need at minimum 500 to 1,000 tablets, or five to 10 bottles of Daraprim—and likely would need more.

119. Vyera thus limited the amount of Daraprim that any one approved entity could purchase. [redacted] Thus, even if a generic company broke through Vyera's web of resale restrictions, it could not obtain enough Daraprim to conduct bioequivalence testing.

120. For example, in August 2015, Vyera and ICS (then a Daraprim distributor) agreed that ICS would not sell more than five bottles to a single customer without Vyera's express approval. The purpose of the ICS restriction was to "ensure that the account is legit and not a generics manufacturer."

121. [redacted]

122. [redacted]

123. In August 2019, Shkreli had separate discussions with Mulleady and Mithani about limiting all sales of Daraprim to one bottle at a time in order to prevent a generic competitor from obtaining sufficient Daraprim samples to conduct bioequivalence testing. Shkreli urged Mulleady to "really carefully screen every doctor" and ensure that no one could "sell more than one bottle at a time" to prevent a generic company from "get[ting its] hands on anything." Shkreli instructed Mithani that Vyera should "do everything" it could to prevent a generic company from obtaining samples of Daraprim, because preventing generic competition would make Daraprim a "$600 million asset . . . in perpetuity."

124. [redacted]

125. [redacted]

[redacted]

126. [redacted]

127. [redacted]

4. Defendants' generic-blocking restrictions prevent generic competitors from purchasing Daraprim and have no legitimate rationale

128. Taken together, the purpose and effect of Vyera's resale restrictions, quantity limits [redacted] is to prevent potential generic competitors from obtaining sufficient samples of Daraprim to conduct FDA-mandated bioequivalence testing.

129. [redacted] Nor can generic companies purchase Daraprim directly from Vyera, which refuses to sell the product to generic companies or companies that might resell to generic companies. And Vyera's quantity limits and [redacted] ensure that, even if a generic company slips through the restrictions and purchases some Daraprim, it will not likely obtain enough to conduct bioequivalence testing.

130. Generic companies cannot circumvent Vyera's web of restrictions by obtaining a Daraprim prescription from a doctor. Doctors are allowed to write prescriptions for the treatment of a patient; a doctor cannot write a prescription for medication to be used in bioequivalence testing, which does not involve treatment of a patient. Moreover, even if a generic company could obtain a prescription and use that prescription to purchase Daraprim from a distributor or

purchaser, Vyera's quantity limits would prevent filling a single prescription for the minimum five bottles needed for bioequivalence testing. And even assuming the generic company were able to acquire Daraprim from a pharmacy with a prescription, it would have no way of ensuring that all the bottles came from the same manufacturing lot, as required by the FDA.

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

132. This purpose was publicly reported and widely known. In September 2015, the New York Times reported that "Daraprim's distribution is now tightly controlled, making it harder for generic companies to get the samples they need for the required testing" and that this could prevent generic competition. The Times further reported that Defendant Shkreli had previously used a similar strategy "as a way to thwart generics."

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

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

135. The restrictions preventing distributors [redacted] from selling Daraprim to generic companies do not have any legitimate business rationale.

136. The resale restrictions are not related to any safety concerns about Daraprim. Prior to 2015, Daraprim was sold in open distribution without incident for more than 60 years. Additionally, the FDA has never subjected Daraprim to any type of safety program. When drugs pose serious safety concerns, the FDA requires sellers to implement Risk Evaluation Mitigation Strategies (REMS) to minimize those risks. A REMS requirement can include warning labels, educational guides, and restrictions on distribution. The FDA has never required that Daraprim be subject to any form of REMS. Moreover, safety concerns are not, and have never been, the reason for the restricted distribution of Daraprim.

137. The resale restrictions are also not related to providing patient services as part of the distribution system. Blocking the sale of Daraprim to generic companies does not provide or support any services to Daraprim patients. Additionally, providing patient services is not and has never been the purpose of the restricted distribution system. [redacted] And the distribution restrictions have in fact made it harder for patients to obtain Daraprim, leading to adverse medical outcomes.

B. Defendants [redacted] to Block Generic Companies' Access to Pyrimethamine API Supply

138. In addition to denying potential generic competitors access to the Daraprim samples they need to conduct FDA-required testing, Vyera (under the supervision and direction of Defendants Shkreli and Mulleady) further impeded generic competition by [redacted] pyrimethamine, the active pharmaceutical ingredient used in Daraprim.

139. To develop and commercially market a generic version of Daraprim, a potential generic competitor would need to secure a reliable source of pyrimethamine API.

140. It is well known in the industry that it is significantly faster and less expensive to source API from a supplier that has a pre-existing manufacturing process that is either approved by the FDA or a good candidate for FDA approval. Different APIs require different equipment and methods to manufacture. It can take months or years, as well as an investment of hundreds of thousands of dollars or more, for a manufacturer without a pre-existing process to develop one. Moreover, the FDA must approve any API manufacturer's facilities, process, and product before the API can be used in a U.S. product. Retaining an API manufacturer with an unapproved process entails the risk that the FDA will not approve it or will require the manufacturer to invest additional time and expense correcting deficiencies. Thus, even if a manufacturer has a pre-existing process, it will not readily be able to supply API for a U.S. product if its process, facility, or manufacturing practices are not up to FDA standards.

141. One method commonly used in the industry to identify API manufacturers with an established, FDA-approvable manufacturing process is to search for DMFs. A DMF is a submission from an API manufacturer to the FDA providing detailed information about the manufacturer's facility and process for a given API. The filing of a DMF indicates that the manufacturer has already developed a manufacturing process for that API that it believes meets FDA standards, and thus that it could serve as a reliable source. [redacted]

142. [redacted]

[redacted]

143. In the summer of 2015, prior to acquiring Daraprim, Vyera contacted pyrimethamine suppliers from the FDA's DMF database. At that time, two API suppliers had filed DMFs with the FDA: Fukuzyu and Ipca Laboratories Ltd. On or about June 1, 2015, Vyera contacted [redacted] Fukuzyu seeking to enter into exclusive supply agreements for pyrimethamine API that would prevent generic companies from purchasing pyrimethamine [redacted]

144. [redacted] Several months earlier, in January 2015, the FDA had banned imports of most of Ipca's APIs, including pyrimethamine, due to manufacturing deficiencies. Vyera quickly understood that this import ban would generate the same effect as exclusivity. In a June 15, 2015 presentation to potential investors, Vyera touted how this import ban would cause "significant disruption" and delay to generic companies planning or desiring to use Ipca.

145. This left Fukuzyu as the only established manufacturer of pyrimethamine API for the U.S. market. [redacted]

146. Vyera's initial attempts to reach an exclusivity agreement with Fukuzyu were rejected. [redacted]

147. [redacted]

148. [redacted]

149. [redacted]

150. [redacted]

[redacted]

[redacted]

Indeed, at least two potential generic competitors sought and were denied [redacted]

[redacted]

151. [redacted]

[redacted]

152. [redacted]

[redacted]

153. [redacted]

[redacted]

154. [redacted]

[redacted]

155. [redacted]

156. [redacted]

157. [redacted]

158. [redacted]

159. [redacted]

[redacted]

160. [redacted]

161. [redacted]

162. [redacted]

163. [redacted]

[redacted]

164. [redacted]

165. [redacted]

166. [redacted]

167. [redacted] This has made it significantly more difficult for potential generic competitors to obtain pyrimethamine API. Although other manufacturers might eventually be able to supply pyrimethamine for the U.S. market, during the relevant time period these manufacturers did not have an established pyrimethamine manufacturing process, did not have facilities and processes in line with cGMP standards sufficient for FDA approval, or both.

168. Typically, it takes months or years for a supplier to develop and test an API manufacturing process from scratch. [redacted]

169. For those manufacturers with a non-compliant FDA process, it would take substantial time and investment to bring their facilities, quality controls, and manufacturing standards in line with cGMP requirements to be eligible for FDA approval. Therefore, [redacted] resulted in significant cost and delay for any potential generic applicant.

C. Vyera Enters Data-Blocking Agreements to Mask the True Size of the Pyrimethamine Market

170. Vyera also entered into data-blocking agreements with its primary distributors to mask the potential market opportunity for a generic Daraprim product.

171. One of the first steps for a generic company considering whether to develop a competing generic product is to analyze the branded product's sales data to determine the size of the market opportunity. Based on the market size and sales data, the company can determine the potential profits it can expect from developing the product.

172. To make this assessment, generic companies rely on commercially available sales information. These data are sold by companies such as IQVIA and Wolters Kluwer. These companies purchase sales data from drug distributors and pharmacies, aggregate the data, and sell it to pharmaceutical industry participants.

173. [redacted]

174. Vyera is a privately-held company and does not publicly report Daraprim sales figures. Thus, the only way for a potential generic competitor to assess the size of the Daraprim market is to purchase commercial sales data from a third-party data reporting company.

175. After acquiring Daraprim, Vyera sought to prevent its distributors from selling Daraprim sales information to IQVIA or other data reporting companies.

176. [redacted]

177. Under Vyera's agreements with its distributors, Vyera paid them a "data blocking fee" in exchange for their agreement not to sell data to IQVIA or other similar companies.

178. In 2017, Vyera agreed to pay ASD a "data restriction" fee of [redacted] per month in exchange for ASD's agreement not to sell Daraprim sales data to IQVIA, Wolters Kluwer, or other third-party data reporting companies.

179. [redacted]

180. [redacted]

181. [redacted]

182. The purpose and effect of Vyera's data-blocking restrictions was to obscure the size of the Daraprim market to make it less attractive to generic competitors. [redacted]

183. Vyera's conduct had the desired anticompetitive effect. As result of Vyera's data-blocking restrictions, at least one generic company decided not to initiate a project to develop a generic version of Daraprim.

184. The data-blocking restrictions imposed on two of Vyera's most important distributors have no legitimate rationale. While Vyera has no obligation to publicly report its own Daraprim sales data, the wholesalers' Daraprim sales data is not Vyera's to control. Prior to the more lucrative offer from Defendants, ASD and [redacted] were regularly selling their Daraprim sales data to IQVIA and others. The sole purpose of the data-blocking agreements is to mask the size of the Daraprim market.

VI. Defendants' Anticompetitive Conduct Successfully Delayed and Excluded Numerous Potential Generic Competitors

185. Defendants' anticompetitive course of conduct worked. As the result of Vyera's agreements restricting the resale of Daraprim, [redacted], and data-blocking agreements, at least four potential generic competitors have been delayed or excluded from the market: [redacted], and [redacted]

[redacted]

186. Defendants' exclusionary conduct impeded [redacted] ability to develop a generic version of Daraprim. Absent Vyera's conduct, [redacted] likely would be on the market today with a generic version of Daraprim.

187. [redacted]

188. [redacted]

189. [redacted] At that time, Amedra Pharmaceuticals owned Daraprim and the drug was available through traditional distribution channels.

190. [redacted]

191. [redacted]

[redacted]

192. [redacted]

193. [redacted]

194. In January 2015, however, the FDA banned Ipca from importing API into the United States until it remedied certain issues with its manufacturing facility in India. [redacted]

195. [redacted]

196. [redacted]

197. [redacted] This indicated it likely had an FDA-approvable process for manufacturing pyrimethamine API.

198. [redacted]

199. [redacted]

200. [redacted]

201. This time, however, Vyera's agreements prohibiting resale to generic companies made it virtually impossible to obtain sufficient quantities of Daraprim. [redacted]

202. [redacted]

203. [redacted]

204. [redacted]

205. [redacted]

206. [redacted]

207. [redacted]

[redacted]

208. [redacted]

209. [redacted]

210. Absent Defendants' anticompetitive conduct, [redacted] likely would have launched its product in 2018 or earlier.

211. [redacted] which are still subject to Vyera's tightly controlled resale restrictions.

[redacted]

212. Defendants' exclusionary conduct also impeded [redacted] ability to develop a generic version of Daraprim. Absent Defendants' conduct, [redacted] likely would be on the market today with a generic version of Daraprim.

213. [redacted]

214. [redacted]

215. [redacted] At that time, Amedra Pharmaceuticals owned Daraprim and the drug was available through traditional distribution channels.

216. [redacted]

217. [redacted]

218. [redacted]

219. [redacted]

220. [redacted]

221. [redacted]

222. [redacted]

223. [redacted]

224. [redacted]

225. [redacted]

[redacted]

226. [redacted]

227. [redacted]

228. [redacted]

229. Absent Defendants' anticompetitive conduct, [redacted] likely would have launched its product in 2019 or earlier.

[redacted]

230. Defendants' exclusionary conduct also impeded [redacted] ability to develop a generic version of Daraprim. Absent Defendants' conduct, [redacted] likely would be on the market today with a generic version of Daraprim.

231. [redacted]

[redacted]

232. [redacted]

233. [redacted]

234. [redacted]

235. [redacted]

236. [redacted]

237. [redacted]

238. [redacted]

239. [redacted]

240. [redacted]

241. [redacted]

242. [redacted]

243. [redacted]

[redacted]

244. [redacted]

245. [redacted]

246. [redacted]

247. [redacted]

[redacted]

248. [redacted]

249. [redacted]

250. [redacted]

251. [redacted]

252. Absent Defendants' anticompetitive conduct, [redacted] likely would have launched its product in 2018 or earlier.

[redacted]

253. Defendants' exclusionary conduct caused [redacted] to stop pursuing a generic version of Daraprim. [redacted] is one of the largest generic pharmaceutical companies in the world.

254. [redacted]

255. [redacted]

256. [redacted]

257. [redacted]

5. Other generic companies

258. Vyera's exclusionary conduct has also likely impeded the ability of at least one other generic company to obtain Daraprim samples. Although the name of this generic company is not yet known, it tried to procure samples through [redacted]

259. [redacted]

260. [redacted]

261. [redacted]

262. [redacted]

263. [redacted]

VII. Defendants' Foreclosure of Generic Entry Caused Consumers to Pay Higher Prices

264. Defendants' anticompetitive course of conduct delayed generic Daraprim entry. Absent Defendants' conduct, at least one generic version of Daraprim would have entered the market in 2018 or earlier, and multiple generic versions would likely be on the market today.

265. Vyera's agreements prohibiting the resale of Daraprim impeded potential generic competitors, including [redacted], [redacted], and [redacted], from procuring sufficient Daraprim samples to meet FDA testing requirements. Absent these restrictions, potential generic competitors readily could have purchased sufficient quantities of Daraprim through ordinary distribution channels.

266. Vyera's [redacted]—impeded potential generic competitors, including [redacted], [redacted], and [redacted], from securing a reliable source of pyrimethamine API, an indispensable ingredient of generic Daraprim. [redacted]

[redacted]

267. Vyera's data-blocking agreements denied potential generic competitors accurate and reliable information to properly assess the generic market opportunity, thereby deterring potential generic competitors from pursuing a generic Daraprim product. Absent these agreements, which distorted Daraprim's reported sales revenues, [redacted] and other pharmaceutical companies [redacted] due to Vyera's 4,000% price increase, and thus offered a lucrative competitive opportunity.

268. By impeding generic competition, Defendants' anticompetitive conduct denied consumers and other purchasers of Daraprim access to AB-rated generic versions of Daraprim that would offer the same therapeutic benefit as branded Daraprim, but at a fraction of the price.

269. The first generic competitor's product is typically offered at a 20% to 30% discount to the branded product. Subsequent generic entry creates greater price competition with discounts potentially reaching 85% or more off the brand price. Defendants' anticompetitive conduct has delayed the introduction of this price competition to the detriment of consumers and other purchasers of Daraprim.

270. Most consumers would have purchased the lower-priced AB-rated substitutes for Daraprim rather than the higher-priced branded product. [redacted]

271. Defendants' anticompetitive conduct, however, has forced consumers to continue paying Vyera's monopoly price for Daraprim. As a result of Defendants' conduct, there is no lower-cost generic alternative to Daraprim on the market today.

272. Defendants' anticompetitive conduct has caused, and is continuing to cause, significant economic harm. Consumers and other purchasers of Daraprim likely would have saved tens of millions of dollars by purchasing generic versions of Daraprim.

273. The economic harm from Defendants' conduct is ongoing as generic entry has not yet occurred.

274. Defendants' anticompetitive conduct, and the corresponding reduction in the availability of Daraprim, has also resulted in harm to patients from delays in treatment, prolonged hospital stays, and poor medical outcomes. And in at least one case, Defendants' anticompetitive conduct may have contributed to a patient's death.

275. Toxoplasmosis is a rare condition. Many hospitals treat few or no toxoplasmosis patients each year. Nonetheless, for decades, hospitals regularly stocked Daraprim because it was affordable and because patients with acute toxoplasmosis need to begin taking it immediately. Vyera's massive price increase—maintained through Defendants' anticompetitive scheme—has changed this approach. Daraprim is no longer affordable. Hospitals are now reluctant to incur the substantial cost of keeping Daraprim stocked in their inpatient pharmacies when it may never be used to treat a patient. This can lead to delays in treatment when patients present at the hospital with acute toxoplasmosis. Defendants' anticompetitive conduct has denied these hospitals the option of stocking lower-cost generic versions of Daraprim.

276. Similarly, the extremely high price of Daraprim creates challenges in discharging patients from the hospital. Physicians often delay hospital discharge of their toxoplasmosis patients until they are confident the patient will be able to obtain Daraprim after discharge. Because of the high price and limited availability of Daraprim, however, many rehabilitation facilities will no longer accept patients who need it. These patients instead remain in the hospital

for weeks longer than necessary, resulting in unnecessary costs, medical complications, and, in at least one case, even death.

277. In February 2018, a toxoplasmosis patient was ready to be discharged after several weeks in the hospital. But the hospital was unable to procure Daraprim on an outpatient basis for the patient. The patient continued to be hospitalized and eventually contracted a severe hospital infection that proved fatal.

278. In another example, a toxoplasmosis patient could not be transferred to a rehabilitation facility because the facility refused to take on the risk that it might be obligated to pay Daraprim's high price. Forced to remain in the hospital, the patient developed medical complications from the prolonged stay, including multi-drug resistant infections.

279. Absent Defendants' anticompetitive conduct, hospitals and rehabilitation facilities would have access to lower-cost generic versions of Daraprim.

280. Additionally, Defendants' anticompetitive conduct has the collateral effect of making it more difficult for some patients to obtain Daraprim from hospitals or pharmacies.

281. For example, in November 2018, one patient with lifelong congenital toxoplasmosis sought to obtain Daraprim for necessary prophylactic outpatient treatment. Neither she nor a local hospital was able to obtain Daraprim immediately, and pharmacies in the area lacked supply. The patient was forced to contact Vyera directly and had Daraprim drop-shipped directly to her residence, where it arrived over two weeks after she first needed it.

282. The reduced availability of Daraprim attributable to Vyera's conduct is ongoing, as generic entry has not yet occurred.

283. Absent relief, Defendants' anticompetitive conduct is likely to recur and cause additional harm to consumers. Defendants have continued to engage in their anticompetitive conduct despite congressional hearings and Plaintiffs' investigations.

284. Vyera acquired Daraprim for the express purpose of raising its price and protecting that higher price with an anticompetitive scheme. Vyera is and has been actively looking for other drugs with a similar profile to Daraprim that it could acquire and execute a similar strategy to prevent generic competition. Absent relief, Vyera is likely to carry out a similar anticompetitive scheme with another drug.

285. Defendant Shkreli directed Vyera to acquire Daraprim for the express purpose of raising its price and protecting that higher price with an anticompetitive scheme. Shkreli previously started another pharmaceutical company, Retrophin, for the purpose of purchasing a different drug, raising the price, and enacting distribution restrictions to impede generic competition. Shkreli is and has been actively looking for other drugs with which to replicate this strategy, either through Vyera or a new company. Absent relief, Shkreli is likely to purchase another drug and carry out a similar anticompetitive scheme.

286. Defendant Mulleady directed, participated in, and carried out the anticompetitive scheme to protect Vyera's Daraprim price increase. [redacted] Absent relief, Mulleady is likely to direct or participate in a similar anticompetitive scheme with another product.

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

287. Vyera has exercised and continues to exercise monopoly power in the United States with respect to Daraprim.

288. Vyera's monopoly power can be observed directly. In 2015, Vyera raised the price of Daraprim by more than 4,000%. [redacted] After raising the price 4,000%, [redacted]

289. [redacted]

290. Vyera's monopoly power with respect to Daraprim has persisted for an appreciable period. Since 2015, Vyera has not lowered its list price and [redacted]

291. Vyera's monopoly power can also be observed indirectly based on its 100% share of the relevant market for pyrimethamine products approved by the FDA for sale in the United States. Vyera has maintained this 100% market share since it purchased Daraprim in 2015.

292. The relevant product market is FDA-approved pyrimethamine products.

293. Despite Vyera's 4,000% price increase for Daraprim, most doctors continue to prescribe Daraprim instead of switching patients to non-pyrimethamine products or non-FDA-approved pyrimethamine products.

294. Non-pyrimethamine pharmaceutical products are not reasonably interchangeable with pyrimethamine products.

295. Pyrimethamine is the "gold standard" treatment for toxoplasmosis. Guidelines from U.S. government health authorities identify pyrimethamine as "the most effective drug against toxoplasmosis" and advise other options only when pyrimethamine is "unavailable or

there is a delay in obtaining it.” [redacted]

296. Non-FDA-approved pyrimethamine products, such as compounded pyrimethamine, also are not reasonably interchangeable with FDA-approved pyrimethamine products.

297. Most doctors have serious safety concerns about compounded products because they are not FDA approved. Additionally, federal law imposes significant restrictions on how compounded pharmaceuticals are sold, and they are thus not available for all patients.

298. To the extent that Vyera’s 4,000% price increase caused any doctors to prescribe a non-pyrimethamine product or a non-FDA approved pyrimethamine product, the change was due to the extreme nature of the price hike and the increased difficulty of obtaining Daraprim, not because such products are reasonably interchangeable with Daraprim. Indeed, if these products were reasonably interchangeable with Daraprim, a sufficient number of doctors would have switched to them to make the price increase unprofitable because they are orders of magnitude cheaper than Daraprim.

299. Unlike non-pyrimethamine products and non-FDA-approved pyrimethamine products, generic Daraprim would be reasonably interchangeable with Daraprim. [redacted] Thus, unlike non-pyrimethamine or non-FDA approved pyrimethamine products, generic Daraprim would constrain the price of branded Daraprim and is thus in the same relevant product market.

300. The lack of an adequate substitute to Daraprim is also confirmed by the fact that the [redacted] largest pharmacy benefit managers ("PBMs")—which act as third-party administrators for a health plan's pharmaceutical benefits—have all continued to include Daraprim on their formularies. PBMs have independent pharmacy and therapeutics committees that determine whether a given drug must be included on a formulary to provide adequate medical coverage. These independent committees for [redacted] PBMs determined that their formularies had to include Daraprim despite the price increase and notwithstanding the availability of non-pyrimethamine and compounded pyrimethamine products.

301. As then-CEO Ron Tilles explained in January 2016, [redacted]

302. A relevant market consisting of FDA-approved pyrimethamine products can also be observed through application of the "SSNIP" test. The SSNIP test is a well-recognized and widely used economic method to define a relevant product market. The objective of this test is to identify the narrowest set of products for which a hypothetical monopolist could profitably impose a small but significant and non-transitory increase in price. If enough purchasers would accept a SSNIP—rather than switch to another product—such that the price increase would be profitable, then the product set constitutes an antitrust market.

303. In the past 10 years, the price of Daraprim has increased substantially at least twice: approximately 675% in 2011 and approximately 4,000% in August 2015. Each of these price increases is significantly larger than a SSNIP. In each case, Daraprim retained the majority

of its sales and yielded significantly increased profits. Thus, a monopolist owning the only FDA-approved pyrimethamine product has a proven ability to impose a price increase greater than a SSNIP while retaining enough sales to make the price increase profitable. [redacted]

304. The relevant geographic market is the United States. Pharmaceutical products are sold and regulated on a nationwide basis. Additionally, because the U.S. market is limited to FDA-approved products, it can only include products sold inside the United States.

305. Substantial barriers to entry exist in the market for FDA-approved pyrimethamine products. Potential new sellers of pyrimethamine products need to obtain FDA approval, which can take up to several years. Additionally, Vyera has erected additional barriers to entry by (1) blocking generic companies from purchasing sufficient Daraprim for FDA-required bioequivalence testing and (2) blocking generic companies from accessing pyrimethamine API suppliers necessary to make Daraprim.

COUNT I

Monopoly Maintenance Against All Defendants

306. Plaintiffs re-allege and incorporate by reference the allegations in paragraphs 1 through 305 above.

307. At all relevant times, Vyera and Phoenixus have had monopoly power in the United States with respect to FDA-approved pyrimethamine products.

308. Vyera, Phoenixus, Shkreli, and Mulleady have willfully maintained this monopoly power through their course of anticompetitive conduct.

309. There is no valid procompetitive justification for Defendants' exclusionary conduct in the market for FDA-approved pyrimethamine products.

310. Defendants' anticompetitive acts constitute unlawful monopoly maintenance in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, and an unfair method of competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

COUNT II

Agreements in Restraint of Trade (Restrictions and Limitations on Resale of Daraprim) Against All Defendants

311. Plaintiffs re-allege and incorporate by reference the allegations in paragraphs 1 through 305 above.

312. Defendants' agreements with distributors, [redacted] barring them from reselling Daraprim to potential generic competitors, which were conceived, negotiated, signed, and/or enforced by the individual Defendants, are unreasonable restraints of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, and unfair methods of competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

COUNT III

Agreements in Restraint of Trade [redacted] Against All Defendants

313. Plaintiffs re-allege and incorporate by reference the allegations in paragraphs 1 through 305 above.

314. [redacted], which were conceived, negotiated, signed, and/or enforced by the individual Defendants, are unreasonable restraints of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, and unfair methods of competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

COUNT IV

Anticompetitive Contracts, Agreements and/or Arrangements in Violation of New York's Donnelly Act Against All Defendants

315. Plaintiff State of New York re-alleges and incorporates by reference the allegations in paragraphs 1 through 305 above.

316. Defendants' agreements with distributors, [redacted] barring them from reselling Daraprim to potential generic competitors, which were conceived, negotiated, signed, and/or enforced by the individual Defendants, constitute anticompetitive contracts, agreements, and arrangements in violation of New York's Donnelly Act, New York General Business Law § 340 *et seq*.

317. [redacted], which were conceived, negotiated, signed, and/or enforced by the individual Defendants, constitute agreements in restraint of trade in violation of New York's Donnelly Act, New York General Business Law § 340 *et seq*.

318. Defendants' course of conduct as detailed above was done with the purpose of maintaining a monopoly in FDA-approved pyrimethamine and thus violates New York's Donnelly Act, New York General Business Law § 340 *et seq*.

COUNT V

Illegality in Violation of New York Executive Law § 63(12) Against All Defendants

319. Plaintiff State of New York re-alleges and incorporates by reference the allegations in paragraphs 1 through 305 above.

320. Defendants' conduct violates § 63(12) of New York's Executive Law, in that Defendants engaged in repeated and/or persistent illegal acts—violations of Sections 1 and 2 of

the Sherman Act and sections 340 *et seq* of the Donnelly Act—in the carrying on, conducting, or transaction of business within the meaning and intent of Executive Law § 63(12).

Prayer for Relief

WHEREFORE, Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), empowers this Court to issue a permanent injunction against violations of the FTC Act; Section 16 of the Clayton Act, 15 U.S.C. § 26, authorizes this Court to issue a permanent injunction for violations of the Sherman Act; New York General Business Law § 342 authorizes this Court to issue a permanent injunction for violations of New York's Donnelly Act; and New York Executive Law § 63(12) authorizes this Court to issue a permanent injunction for violation of the aforementioned state and federal antitrust laws; therefore the FTC and State of New York respectfully request that this Court, as authorized by statute and its own equitable powers, enter final judgment against Defendants, declaring, ordering, and adjudging:

1. That Defendants' course of conduct violates Section 2 of the Sherman Act, 15 U.S.C. § 2;
2. That Defendants' agreements in restraint of trade violate Section 1 of the Sherman Act, 15 U.S.C. § 1;
3. That Defendants' course of conduct violates Section 5(a) of the FTC Act, 15 U.S.C. § 45(a);
4. That Defendants' agreements in restraint of trade violate Section 5(a) of the FTC Act, 15 U.S.C. § 45(a);
5. That Defendants' course of conduct violates New York's Donnelly Act, N.Y. GBL § 340 *et seq*.;
6. That Defendants' course of conduct violates New York's Executive Law, N.Y. § 63(12);

7. That Defendants are permanently enjoined from continuing their course of conduct;

8. That Defendants are permanently enjoined from engaging in similar and related conduct in the future;

9. That Shkreli and Mulleady are permanently enjoined from owning in part or whole or working for a company engaged in the pharmaceutical industry;

10. That the Court grant such other equitable relief, including equitable monetary relief, as the Court finds necessary to redress and prevent recurrence of Defendants' violations of Section 1 of the Sherman Act, Section 2 of the Sherman Act, and Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), as alleged herein;

11. That the Court grant such other equitable relief, including equitable monetary relief, as the Court finds necessary to redress and prevent recurrence of Defendants' violations of New York's Donnelly Act and New York Executive Law § 63(12); and

12. That all Defendants pay Plaintiff State of New York civil penalties for their violations of the asserted state and/or federal antitrust laws, as authorized by law, N.Y. GBL § 341.

Dated: January 27, 2020

Respectfully submitted,

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