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

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

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

STATE OF CALIFORNIA,
455 Golden Gate Avenue Suite
11000 San Francisco, CA 94102

STATE OF ILLINOIS,
100 West Randolph Street
Chicago, IL 60601

STATE OF NORTH CAROLINA,
114 West Edenton Street
Raleigh, NC 27603

STATE OF OHIO,
150 E. Gay Street, 22nd Floor
Columbus, OH 43215

COMMONWEALTH OF PENNSYLVANIA,
Strawberry Square
Harrisburg, PA 17120

and

COMMONWEALTH OF VIRGINIA,
202 North Ninth Street
Richmond, VA 23219

Plaintiffs,

v.

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

PHOENIXUS AG,
Hadlenstrasse 5

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

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.

Redacted Amended Complaint for Injunctive and Other Equitable Relief

Plaintiffs, the Federal Trade Commission ("FTC" or "the Commission"), by its designated attorneys, and the states of New York, California, Illinois, North Carolina, Ohio, Pennsylvania, and Virginia, by and through their Attorneys General, petition this Court, pursuant to Section 13(b) of the Federal Trade Commission Act, 15 U.S.C. § 53(b), Section 16 of the Clayton Act, 15 U.S.C § 26, Section 342 of the New York General Business Law, Section 63(12) of the New York Executive Law, Sections 16700 *et seq.* and 17200 *et seq.* of the California Business and Professions Code, Section 7 of the Illinois Antitrust Act, 740 ILCS 10/1 *et seq.*, North Carolina Unfair or Deceptive Practices Act, N.C. Gen. Stat. §75-1 *et seq*., Chapter 1331 and Section 109.81 of the Ohio Revised Code, Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P.S. § 201-1 *et seq.* and Common Law Doctrine against Restraints of Trade proceeding under 71 P.S. §732-204 (c), and the Virginia Antitrust Act, Virginia Code §

59.1-9.1 *et seq*.; for a permanent injunction and other equitable relief, including equitable monetary relief, against Defendants Vyera Pharmaceuticals, LLC ("Vyera"), Phoenixus AG ("Phoenixus"), Martin Shkreli, and Kevin Mulleady to undo and prevent their anticompetitive conduct and unfair methods of competition in or affecting commerce in violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, Section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a), and state law.

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] to over [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 purchasers 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. Defendants first locked up Fukuzyu Pharmaceutical Co., Ltd., the only supplier approved to manufacture pyrimethamine for the U.S. market. Under the exclusive supply agreement, Fukuzyu unequivocally agreed not to sell pyrimethamine for human use in the United States to anyone other than Defendants.

6. After locking up Fukuzyu, Defendants moved to sideline a new potential manufacturer, RL Fine Chem Pvt. Ltd. Upon learning that multiple generic companies had been working with RL Fine to develop their generic Daraprim products, Defendants executed another exclusive supply agreement. Defendants had no need for a second source of API, never purchased any API from RL Fine, and never even completed the regulatory work necessary to use RL Fine's API in Daraprim. Nonetheless, under this agreement, Phoenixus has paid RL Fine nearly [redacted] not to supply its potential competitors—while it has paid Fukuzyu only [redacted] for the API it actually uses in its Daraprim product.

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 were 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 Plaintiffs' 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 state. 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 to protect the state, its general economy, and its residents from Defendants' anticompetitive business practices. The Attorney General has authority under federal and state law to pursue an injunction and other equitable relief to prevent and remedy the harms caused by anticompetitive conduct. The state also has authority to seek civil penalties under state law to punish and deter those engaged in anticompetitive conduct.

C. Plaintiff State of California

18. Plaintiff State of California is a sovereign state. Xavier Becerra is the Attorney General of the State of California, the chief legal officer for the state, and brings this action on behalf of the people of the State of California to protect the state, its general economy, and its residents from Defendants' anticompetitive business practices. The Attorney General has authority under federal and state law to pursue an injunction and other equitable relief to prevent and remedy the harms caused by anticompetitive conduct. The state also has authority to seek civil penalties under state law to punish and deter those engaged in anticompetitive conduct.

D. Plaintiff State of Illinois

19. Plaintiff State of Illinois is a sovereign state. Kwame Raoul is the Attorney General of the State of Illinois, the chief legal officer for the state, and brings this action on behalf of the people of the State of Illinois to protect the state, its general economy, and its residents from Defendants' anticompetitive business practices. The Attorney General has authority under federal and state law to pursue an injunction and other equitable relief to prevent

and remedy the harms caused by anticompetitive conduct. The state also has authority to seek civil penalties under state law to punish and deter those engaged in anticompetitive conduct.

E. Plaintiff State of North Carolina

20. Plaintiff State of North Carolina is a sovereign state. Joshua H. Stein is the Attorney General of the State of North Carolina, the chief legal officer for the state, and brings this action on behalf of the people of the State of North Carolina to protect the state, its general economy, and its residents from Defendants' anticompetitive business practices. The Attorney General has authority under federal and state law to pursue an injunction and other equitable relief to prevent and remedy the harms caused by anticompetitive conduct. The state also has authority to seek civil penalties under state law to punish and deter those engaged in anticompetitive conduct.

F. Plaintiff State of Ohio

21. Plaintiff State of Ohio is a sovereign state. David Yost is the Attorney General of the State of Ohio, the chief legal officer for the state, and brings this action on behalf of the people of the State of Ohio to protect the state, its general economy, and its residents from Defendants' anticompetitive business practices. The Attorney General has authority under federal and state law to pursue an injunction and other equitable relief to prevent and remedy the harms caused by anticompetitive conduct. The state also has authority to seek civil penalties under state law to punish and deter those engaged in anticompetitive conduct.

G. Plaintiff Commonwealth of Pennsylvania

22. Plaintiff Commonwealth of Pennsylvania is a sovereign state. Josh Shapiro is the Attorney General of the Commonwealth of Pennsylvania, the chief legal officer for the state, and brings this action on behalf of the people of the Commonwealth of Pennsylvania to protect the state, its general economy, and its residents from Defendants' anticompetitive business practices.

The Attorney General has authority under federal and state law to pursue an injunction and other equitable relief to prevent and remedy the harms caused by anticompetitive conduct. The state also has authority to seek civil penalties under state law to punish and deter those engaged in anticompetitive conduct.

H. Plaintiff Commonwealth of Virginia

23. Plaintiff Commonwealth of Virginia is a sovereign state. Mark R. Herring is the Attorney General of the Commonwealth of Virginia, the chief legal officer for the state, and brings this action on behalf of the people of the Commonwealth of Virginia to protect the state, its general economy, and its residents from Defendants' anticompetitive business practices. The Attorney General has authority under federal and state law to pursue an injunction and other equitable relief to prevent and remedy the harms caused by anticompetitive conduct. The state also has authority to seek civil penalties under state law to punish and deter those engaged in anticompetitive conduct.

I. Corporate Defendants

24. 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.

25. 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. It designated its wholly-owned subsidiary, Vyera Pharmaceuticals, LLC, as the exclusive U.S. distributor for Daraprim. Phoenixus is responsible for the manufacture and warehousing of Daraprim and sells the product to Vyera for distribution in the United States.

Phoenixus is also involved in the distribution, pricing, and commercial and marketing activities of Daraprim.

26. 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.

27. Vyera is registered with the FDA as the owner of the Daraprim New Drug Application (No. 008578). Vyera purchases Daraprim from Phoenixus and then markets and distributes the product throughout the United States.

28. Defendants Phoenixus and Vyera have operated and continue to operate as a common enterprise while engaging in the unfair methods of competition alleged below. Defendants have engaged in this conduct as interrelated companies that share directors, officers, employees, business functions, and office locations. Phoenixus has only five direct employees and largely operates through Vyera, which has more than 50 employees. 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. Phoenixus's few Switzerland-based employees perform functions for Vyera. Phoenixus's board of directors controls Vyera, which has no board.

29. Vyera's sales of Daraprim account for over [redacted] of Phoenixus's revenues.

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

J. Individual Defendants

1. Martin Shkreli

31. 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.

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

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

34. 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.

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

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

37. 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.

38. 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.

39. 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."

40. 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.

41. In June 2017, Shkreli's close associates, including Mulleady and Akeel Mithani, were elected to Phoenixus's board of directors. Mulleady and Mithani were appointed as the only two members of the board's newly-formed "Executive Committee," which would "perform executive functions and [] take over the tasks of the Senior Management (CEO, CFO, CCO and CLO) on a temporary basis." Mulleady was appointed interim CEO notwithstanding the concerns of some board members that [redacted] Mulleady's appointment [redacted]

[redacted] Mulleady assumed the position of interim CEO of Vyera in September 2017 and CEO in November 2017.

42. 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. Since then, Mithani has been a member of the board's Executive Committee as well as executive director and senior vice president of business development of Vyera.

43. By August 2017, Shkreli was once again formally evaluating business development options for Vyera and working on new tactics to impede generic competition for Daraprim. Phoenixus also initiated a share buy-back initiative, which several shareholders felt was "merely intended to increase Martin Shkreli's holding in the company and to facilitate his control over it."

44. Since his incarceration in September 2017, Shkreli has remained in regular contact with Mulleady and Mithani through phone calls, emails, in-person visits, WhatsApp messaging, 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.

45. 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]

46. Shkreli owns approximately [redacted] of Phoenixus shares and controls approximately [redacted] of shareholder votes.

2. Kevin Mulleady

47. Kevin Mulleady is the current chairman of the Phoenixus board of directors and former CEO of Vyera. At all times material to this Complaint (with the exception of a brief period from early 2016 until June 2017), 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.

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

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

50. 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.) Mulleady helped Shkreli start both Retrophin and Vyera.

51. At Vyera, Mulleady initially held the position of managing director and chief of staff to Martin Shkreli. He assisted with Vyera's search for a drug serving a small patient population to put into restricted distribution and helped to implement this model for Daraprim. In 2016, not long after Shkreli's arrest, Vyera terminated Mulleady's employment.

52. Mulleady returned in the summer of 2017 as a member of the Phoenixus board, a position he still holds, and CEO of Vyera, a position he held until March 2019. In these roles, Mulleady has directed Vyera's campaign to prevent generic competition to Daraprim, including

restricting its distribution and resale to potential generic competitors, paying an API supplier not to supply potential generic competitors, and entering agreements to pay two of Vyera's major distributors not to sell their Daraprim sales information to data-reporting companies.

53. Mulleady owns more than [redacted] of Phoenixus shares.

IV. Background

A. Federal Law Encourages Generic Competition

54. 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.

55. 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."

56. 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).

57. 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.

58. 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).

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

60. 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.

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

62. 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.

63. 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.

64. 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

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

66. 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.

67. 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.

68. 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

69. 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.

70. 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).

71. 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.

72. 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.

73. 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."

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

75. Daraprim (NDA No. 08578) is a branded version of pyrimethamine. It was first approved by the FDA in 1953. It long ago lost any patent protection or regulatory exclusivity.

76. 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.

77. 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.

78. From the time Vyera acquired Daraprim in 2015 until the FDA approved a generic version of Daraprim on February 28, 2020, Daraprim was the only FDA-approved pyrimethamine product (branded or generic).

D. Vyera's Acquisition of Daraprim

1. Prior ownership of Daraprim

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

80. 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.

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

82. In 2010, GSK sold its U.S. and Canadian Daraprim rights to CorePharma LLC, which then transferred the product to its sister company, Amedra Pharmaceuticals LLC.

83. Between 2010 and 2015, CorePharma and Amedra gradually increased the price of Daraprim to $13.50 per tablet. Additionally, Amedra developed a plan to remove Daraprim from normal distribution channels and put it into a restricted distribution system.

84. In March 2015, Impax Laboratories, Inc. acquired Daraprim as part of a $700 million acquisition of Amedra's parent company, Tower Holdings, Inc. At the time, Impax assessed Daraprim as a non-core asset with declining annual revenues of $5 million or less.

85. In June 2015, Impax increased the price of Daraprim by 30%, from $13.50 to $17.50 per tablet. Impax had considered a more "aggressive" price increase, but rejected the idea due to concern about a public backlash from the AIDS community. Impax also began to implement Amedra's restricted distribution system, signing contracts with two distributors.

2. Vyera's acquisition of Daraprim

86. From its inception in fall 2014, Vyera had been looking to acquire a sole-source drug with a small patient population that it could put into restricted distribution. As Vyera explored different drugs that fit this mold, it sought distribution partners that would "help [it] keep a tightly controlled supply chain, where [the] drug is only supplied to verified patients."

87. In April 2015, unaware of Impax's plan to place Daraprim into restricted distribution, Vyera contacted Impax with an unsolicited bid to acquire the U.S. Daraprim rights for [redacted]. At the time, Daraprim had annual U.S. net revenues of approximately [redacted] per year. Impax had assessed Daraprim's net present value at $17.1 million, assuming no generic entry.

88. On August 7, 2015, Vyera acquired the U.S. rights to Daraprim for the final negotiated price of $55 million—triple Impax's net-present-value assessment and more than 11 times Daraprim's annual net revenues.

89. 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%.

90. In advance of the price increase, Defendant Shkreli predicted that "nobody will notice and there will not be any consequence." He was very wrong. Vyera swiftly faced outcries from health care providers, patients, medical societies, the general public, and Congress.

91. In the words of Vyera's then chief scientist, "the only person that didn't speak against [the price hike] was the Pope . . . . [I]t was the poster child of everything that is considered wrong about the pharmaceutical industry."

92. 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

93. 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 purchasers from reselling Daraprim to potential generic competitors or their agents; entered exclusive agreements prohibiting API manufacturers from supplying pyrimethamine to potential generic competitors; 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

94. 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.

95. But Defendants understood that a restricted distribution system "can be a way to lower competition." 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."

96. 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.

97. 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."

98. When Vyera was seeking to acquire Daraprim, Defendant Mulleady made clear that setting up a similar restricted distribution system for Daraprim would be Vyera's "#1 priority" and "exceptionally time sensitive." He urged Vyera employees to "all work extra long hours to get this done."

99. Upon acquiring Daraprim, Vyera acted to implement Shkreli's blueprint. Vyera started with the restricted distribution system it inherited from Impax, expanding the number of distributors to improve distribution logistics. At the same time, however, Defendants tightened the resale restrictions by signing agreements with the distributors, hospitals, and pharmacies that purchased Daraprim barring resale of the drug to generic companies. 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

100. Vyera's generic-blocking agreements start with its distributors. Vyera imposes resale restrictions on all of its distributors to "block" generic companies from purchasing Daraprim, thereby "avoid[ing] generic competition." 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."

101. 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."

102. At the top of its distribution system, Vyera uses ICS (formerly Smith Medical Partners) as a third-party logistics provider. ICS receives Daraprim from Vyera's contract manufacturer, warehouses it, and ships it to Vyera's chosen distributors. ICS is compensated through a fixed monthly fee, as well as additional fees for each order it ships.

103. 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.

104. Below ICS, each of these four distributors is authorized to sell only to specific types of purchasers.

105. 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.

106. Initially, Vyera and ASD also agreed to "verbal business rules" that further limited sales to specific government and hospital customers. 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. Nor was ASD permitted to sell Daraprim to generic companies under the previous contractual iteration and verbal business rules. Consequently, ASD cannot sell Daraprim to generic companies without Vyera's approval.

107. Second, Vyera has an agreement with BioRidge Pharma to distribute Daraprim to certain identified specialty pharmacies—including those owned by Walgreens. Vyera compensates BioRidge by paying it [redacted].

108. Generic companies are not identified as acceptable purchasers under the BioRidge contract. Consequently, BioRidge cannot sell Daraprim to generic companies without Vyera's approval.

109. Third, Vyera has an agreement with [redacted] to distribute Daraprim only to "approved classes of trade," which are defined as "[h]ospitals, state AIDS Drug Assistance Programs (ADAPs), and their authorized purchasers." Purchase requests from any other "class of trade . . . require prior written approval by [Vyera]." Vyera compensates [redacted] by paying it [redacted].

110. Generic companies are not an approved class of trade under the [redacted] contract. Consequently, [redacted] cannot sell Daraprim to generic companies without Vyera's approval.

111. Fourth, Vyera has an agreement with Optime Care to distribute Daraprim only to "[a]uthorized customer types," which include hospitals, government customers, state AIDS Drug Assistance Programs, and patients with a prescription. Optime cannot sell Daraprim to a buyer that falls outside these authorized types without Vyera's approval. Under the agreement, Vyera compensates Optime by paying it [redacted], as well as [redacted].

112. Generic companies are not an authorized customer type under the Optime contract. Consequently, Optime cannot sell Daraprim to generic companies without Vyera's approval.

113. Taken together, Vyera's contractual restrictions prevent all of its distributors from selling Daraprim to generic companies seeking to conduct FDA-mandated bioequivalence studies unless Vyera approves the sale. And Vyera does not approve any sale of Daraprim to a generic company or a company it believes might sell to a generic company. Indeed, Vyera has denied each request from a distributor to sell Daraprim to a purchaser that might be a generic company or might sell Daraprim to a generic company, even though Vyera would make significant profits from any sales of Daraprim at list price.

2. Vyera's contractual restrictions prevent downstream purchasers from selling Daraprim to generic companies

114. In addition to locking up its distributors, Vyera was also concerned that downstream purchasers, such as hospitals or pharmacies, might sell Daraprim to a generic company. To prevent this, Vyera imposed direct and indirect restrictions on these purchasers.

115. First, Vyera required distributors to enter agreements with their own customers preventing the resale of Daraprim to generic companies.

116. For example, in September 2015, Vyera authorized ICS (then retained as a distributor as well as a third-party logistics provider) to sell Daraprim to a group of Puerto Rican pharmacies. As part of the authorization, Vyera required ICS to "provide some wording on the account prohibiting sale of daraprim to a third party." Vyera instructed that "[p]roduct should only be dispensed to patients in their facilities." This requirement prevented ICS's customers from selling Daraprim to generic companies.

117. Similarly, in May 2018, Vyera instructed Optime to include a "Product Use Attestation" in its agreements with hospitals. This attestation required hospitals to guarantee that Daraprim "will not be sold, resold, diverted or transferred to any other person or entity for any reason unless approved in writing by Vyera or its designee." This requirement prevented the hospitals from selling Daraprim to generic companies.

118. Second, Vyera also entered direct agreements with hospitals and pharmacies preventing them from reselling Daraprim to generic companies.

119. As part of its pricing agreements with thousands of hospitals, Vyera requires them to use Daraprim only for their "own use"—which is defined as the treatment of the hospital's patients. As a result, these hospitals are contractually prevented from selling Daraprim to anyone other than patients, including generic companies.

120. Vyera includes similar terms in its agreements with hospital group purchasing organizations ("GPOs"), which purchase products on behalf of large groups of member hospitals. For example, under Vyera's contract with the GPO Vizient, Vizient's member hospitals can purchase Daraprim only for "the use of the Member" and "not for resale to anyone other than the end use patient or customer." This restriction prevents GPO member hospitals from selling Daraprim to generic companies.

121. Vyera has also entered direct contracts with Walgreens, which sells Daraprim through its specialty pharmacies. The agreements specify that Walgreens can only provide Daraprim to its specialty pharmacies and to patients with a prescription. The contracts prevent Walgreens or its specialty pharmacies from selling Daraprim to generic companies without Vyera's approval.

122. Taken together, Vyera's restrictions on downstream purchasers prevent them from selling Daraprim to a generic company seeking to conduct FDA-mandated bioequivalence testing unless Vyera approves the sale. Vyera does not approve downstream purchasers to sell Daraprim to a generic company or a company that might sell to a generic company. Indeed, Vyera has never authorized such a sale, even though it would make significant profits any time Daraprim is sold at its list price.

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

123. In addition to its agreements with distributors and purchasers 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.

124. A bottle of Daraprim contains 100 tablets. Defendants knew that, 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.

125. Vyera thus limited the amount of Daraprim that any one approved entity could purchase. As a Vyera senior director informed at least one of Vyera's distributors, the goal of these quantity limits was to reduce the risk "that a generic company could access multiple bottles of [Daraprim], perhaps obtained through a hospital reselling it or distributing product to surrounding retail pharmacies." Thus, even if a generic company broke through Vyera's web of resale restrictions, it could not obtain enough Daraprim to conduct bioequivalence testing.

126. 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."

127. Similarly, Vyera's 2018 contract with Optime prevents Optime from selling more than three bottles to any purchaser without Vyera's express approval. Before it will approve such a sale, Vyera requires Optime to obtain "prescription level information" on the purchase, such as the prescriber and prescription quantity. Vyera then uses this information to make sure the requested Daraprim will not be diverted to a generic company.

128. And in February 2018, Vyera approved sales of Daraprim through a new pharmacy, Drug Mart, but limited Drug Mart to carrying only one bottle of Daraprim in inventory at a time.

129. 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."

130. Even with Vyera's complex web of resale restrictions and quantity limits, in 2017 Mulleady became concerned that there had been "leakage" to a generic competitor. In September 2017, Mulleady ordered a "full out audit of daraprim" so he could "know where every bottle of daraprim we sold went to." The next month, Mithani directed Vyera employees to establish a system with ASD—one of Vyera's main hospital distributors—for immediate notification of any orders. Mulleady and Mithani wanted to identify "outlier" purchases that might be intended for a generic company. ASD agreed to flag any such orders for Vyera. Mulleady and Mithani would then contact the buyer to "inquire as to what their purpose is."

131. In at least one instance, this aggressive monitoring allowed Vyera to quickly buy back Daraprim that might otherwise have been sold to a generic company. In April 2018, Vyera employees flagged an unusual purchase from ASD: a company called Centrastate Specialty Script—which shares common ownership with Reliant Specialty LLC—had purchased five bottles of Daraprim at one time, when it had previously never ordered more than two. Mithani was concerned that Centrastate had purchased Daraprim on behalf of a generic.

132. Mulleady determined that Vyera should buy back the five bottles from Centrastate. Using a middleman, Mulleady repurchased all five bottles for [redacted]—[redacted] the price Centrastate had paid.

133. As part of the repurchase contract, Centrastate agreed "not to purchase, directly or indirectly . . . any Daraprim, except directly through Vyera." Vyera subsequently directed ASD to block Centrastate from purchasing any further Daraprim.

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

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

135. Due to Vyera's agreements restricting resale, generic companies cannot purchase Daraprim at any point in Vyera's distribution chain. 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 monitoring 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.

136. 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.

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

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

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

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

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

142. 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.

143. 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. When Vyera initially explored the logistics of setting up a restricted distribution system, it rejected the idea of including additional patient services because they would "take forever" to set up. And the distribution restrictions have in fact made it harder for patients to obtain Daraprim, leading to adverse medical outcomes.

B. Defendants Enter Exclusive Agreements With API Manufacturers to Block Generic Companies' Access to Pyrimethamine API Supply

144. 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 locking up the two most viable manufacturers of pyrimethamine, the active pharmaceutical ingredient used in Daraprim.

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

146. 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.

147. 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. As Vyera's director of business development explained, contracting with a DMF holder for API supply diminishes a pharmaceutical company's "execution risk."

148. Understanding these market dynamics, Defendants acted to prevent generic competitors from obtaining pyrimethamine API from suppliers with an existing, FDA-approvable manufacturing process—especially those holding pyrimethamine DMFs. Defendants decided to sign exclusive contracts with any such manufacturers to force generic competitors to spend substantial time and money working with a new manufacturer to develop an FDA-approvable pyrimethamine manufacturing process.

1. Vyera locks up the only manufacturer with an FDA-approved manufacturing process for pyrimethamine API

149. 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 both Ipca and Fukuzyu seeking to enter into exclusive supply agreements for pyrimethamine API that would prevent generic companies from purchasing pyrimethamine from either company.

150. The next day, Ipca told Vyera it could not supply pyrimethamine and thus an "exclusivity deal is not possible." 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.

151. This left Fukuzyu as the only established manufacturer of pyrimethamine API for the U.S. market. Indeed, Fukuzyu sells pyrimethamine API worldwide and has supplied it for branded Daraprim in the United States for decades. Because Fukuzyu's pyrimethamine was already being used in an FDA-approved product, Vyera knew that the FDA had already approved Fukuzyu's manufacturing process and any company would be able to use Fukuzyu API immediately.

152. Vyera's initial attempts to reach an exclusivity agreement with Fukuzyu were rejected. But Vyera did not give up. In 2016, it retained a Japanese consultant to negotiate with Fukuzyu on its behalf and sent a formal letter seeking an in-person meeting. Beginning in fall 2016, Vyera and Fukuzyu began serious negotiations, and on or about November 22, 2016, they

reached an oral agreement for the exclusive supply of Fukuzyu API for human use in the United States. A Vyera executive broke the news of the agreement to colleagues by saying: "Fukuzyu has accepted our agreement to provide pyrimethamine exclusively for us for human drugs and will not sell to generic manufacturers. This is a big sigh of relief for us!"

153. In January 2017, Phoenixus signed a [redacted] with Fukuzyu. Following the [redacted] term, the agreement is [redacted]

154. As executed, the contract forbids Fukuzyu from selling pyrimethamine to anyone other than Vyera for human use in the United States. Vyera expected and intended that the exclusivity provision would prevent Fukuzyu from selling pyrimethamine API to generic companies.

155. Indeed, during the negotiations, Vyera told Fukuzyu that the "most critical issue[]" was obtaining an exclusivity provision that would prevent Fukuzyu from selling pyrimethamine to Vyera's generic competitors. Vyera explained 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." Vyera further stressed that entry of a generic Daraprim could prevent Vyera from working with Fukuzyu on future projects.

156. Fukuzyu has abided by the terms of its exclusive supply agreement and consistently consulted with Vyera to verify that proposed sales would not violate the exclusivity provision. Vyera regularly directs Fukuzyu not to sell API to any entity that could use the pyrimethamine in the United States for human use, such as for a generic version of Daraprim. Indeed, at least two potential generic competitors sought and were denied API from Fukuzyu due to the Vyera exclusive contract.

157. There is no legitimate business rationale for the exclusivity provision in the Fukuzyu supply contract. The exclusivity provision does not ensure Vyera's supply because Fukuzyu is not obligated to reserve any volume of pyrimethamine for Vyera and can sell any amount of pyrimethamine to companies outside the U.S. or for non-human use within the U.S. Nor does the exclusivity provision reflect a recoupment of any investment Vyera made in Fukuzyu. Instead, the purpose of the exclusivity provision is to prevent potential generic companies from obtaining pyrimethamine API from Fukuzyu.

158. The 2017 exclusive supply agreement with Fukuzyu remains in effect.

2. Defendants poach a second API manufacturer from generic competitors

159. After obtaining exclusivity from Fukuzyu, Vyera then signed a second exclusive agreement to lock up the next most viable manufacturer of pyrimethamine API.

160. In August 2017, Vyera became aware that another API supplier, RL Fine Chem, was preparing to file a DMF for pyrimethamine API in the United States and was working with two generic companies. RL Fine had a pyrimethamine manufacturing process in place, had filed a European DMF, and had experience manufacturing and selling pyrimethamine to European clients. RL Fine's European DMF indicated its facilities, quality standards, and manufacturing practices were likely sufficient to obtain FDA approval. After Fukuzyu, RL Fine was the next-best option for the supply of pyrimethamine API to any generic company seeking to develop a generic Daraprim product for sale in the U.S.

161. In August 2017, shortly after taking back control of Vyera through his successful proxy fight, Shkreli directed Mulleady and Mithani to pursue a supply agreement with RL Fine.

162. On August 21, 2017, Shkreli drafted an email to RL Fine inquiring about pyrimethamine API for the U.S. market and directed co-Executive Director Mithani to send it. RL Fine replied that it was "already working on pyrimethamine and would not be able to offer to

you." Undeterred, Mulleady and Shkreli (through Mithani) pushed for "a more robust relationship."

163. On November 2, 2017, Mulleady (then co-executive director with Mithani) offered RL Fine [redacted] as consideration for entering into an exclusive supply agreement with Vyera. By November 26, 2017, Vyera had agreed to pay RL Fine even more for an "exclusive agreement . . . for the distribution of any and all pyrimethamine based product." On December 27, 2017, Mulleady (then serving as Vyera CEO and Phoenixus board chairman) executed on behalf of Phoenixus two contracts with RL Fine: a product collaboration agreement and a distribution and supply agreement.

164. Under the product collaboration agreement, Vyera paid RL Fine [redacted], and the parties agreed to collaborate on the development of [redacted] products. Neither Vyera nor RL Fine, however, subsequently took any steps to develop any of these products.

165. Under the distribution and supply agreement, RL Fine designated Vyera as its exclusive distributor of pyrimethamine API worldwide. Vyera has no API distribution capabilities and no intention to become an API distributor. As RL Fine's pyrimethamine distributor, however, Vyera has the power to veto any pyrimethamine API sale outside of India. This allows Vyera to block any sale of pyrimethamine API from RL Fine to a potential generic competitor. Indeed, at Vyera's direction, RL Fine ceased supplying pyrimethamine API to the two generic companies with which it had been working. Since signing the agreement with Vyera, RL Fine has not supplied pyrimethamine to any company for use in the United States.

166. In return, Vyera agreed to pay RL Fine [redacted] and [redacted]. Under the distribution and supply agreement, Vyera has made monthly payments to RL Fine ranging from [redacted] to [redacted] from February 2018

through at least August 2019. Vyera agreed to make these payments whether or not it receives any API from RL Fine and irrespective of whether RL Fine's API is approved for use in Daraprim. To date, Vyera has paid RL Fine approximately [redacted] under the distribution and supply agreement and has not received any API from RL Fine.

167. The purpose of the RL Fine Agreement was to ensure that RL Fine could not supply any of Vyera's potential generic competitors.

168. There is no legitimate business rationale for the exclusivity agreement. Vyera did not need and was not seeking an additional source of pyrimethamine API. Fukuzyu is, and has been, a reliable supply partner. Throughout the term of its agreement with Vyera, Fukuzyu has never had a supply interruption or other event that prevented it from providing Vyera with pyrimethamine API. Indeed, Fukuzyu's minimum purchase batch size provides Vyera with more pyrimethamine than it can use. Vyera has purchased pyrimethamine API from Fukuzyu only twice—on August 1, 2017, and November 19, 2018—for approximately [redacted] each time. And Fukuzyu has the capacity to produce significantly greater quantities of pyrimethamine API, which it still regularly supplies to other manufacturers for human use outside the U.S. and for non-human use in the United States.

169. Even if Vyera had wanted an additional source of pyrimethamine API, it did not retain RL Fine for that purpose. For the entire term of the agreement, Vyera could not legally use RL Fine's pyrimethamine API in Daraprim because it never sought or obtained FDA approval to do so. Nor did RL Fine take any further steps to conform its process to FDA requirements.

170. Indeed, Vyera's approach to the RL Fine negotiations demonstrates that its goal was never to obtain usable pyrimethimane API from RL Fine. When negotiating its agreement with Fukuzyu, Vyera performed extensive diligence to ensure that Fukuzyu would be able to

comply with the FDA's current good manufacturing practices ("cGMPs") and other quality-oriented measures required by the FDA. Numerous Vyera technical personnel were involved in these efforts, and the Vyera executives responsible for Quality, Regulatory Affairs, and Chemistry, Manufacturing and Controls ("CMC") traveled to Japan to meet with their Fukuzyu counterparts.

171. The RL Fine negotiations, however, were conducted by Mulleady and Mithani alone and without any technical support. Neither Mulleady nor Mithani had any experience with or knowledge of API sourcing or FDA requirements, and neither had any relevant scientific background. No one at Vyera performed any diligence on RL Fine's ability to produce pyrimethamine API. Indeed, nobody from Vyera's CMC or Quality departments were involved in the negotiations with RL Fine in any capacity. As of September 2019, the Vyera chief scientific officer with ultimate responsibility for Daraprim manufacturing was not even aware Vyera had a contract with RL Fine.

172. On October 25, 2019, Vyera paid RL Fine [redacted] to terminate the agreement. By that date, the Federal Trade Commission had sent several discovery requests to Vyera and RL Fine and asked extensive questions about the RL Fine contracts during investigational hearings of Vyera employees.

173. Vyera's exclusive agreements with Fukuzyu and RL Fine have sidelined the two most viable suppliers of pyrimethamine API for potential generic Daraprim competitors. 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.

174. Typically, it takes months or years for a supplier to develop and test an API manufacturing process from scratch. For example, [redacted] spent several years and over [redacted] working with a supplier to develop an FDA-approvable manufacturing process for pyrimethamine API.

175. 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, Vyera's agreements 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

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

177. 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.

178. 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.

179. Vyera relied on sales data from IQVIA in determining whether to purchase Daraprim in 2015. Vyera continues to use IQVIA data to evaluate other drug opportunities.

180. 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.

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

182. Vyera feared that, after it raised the price of Daraprim, the increased sales would attract generic competitors. By preventing reporting companies from obtaining Daraprim sales data, Vyera understood that the publicly available data would be inaccurate, thereby obscuring the true size of the Daraprim market.

183. 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.

184. 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.

185. In 2017, Vyera agreed to pay [redacted] a "data blocking fee" of [redacted] in exchange for [redacted] agreement not to sell Daraprim sales data to IQVIA, Wolters Kluwer, or other third-party reporting companies.

186. Without reporting from significant distributors like ASD and [redacted], IQVIA's Daraprim data is "extremely incomplete and not very useful."

187. In April 2018, the FDA noticed that the IQVIA data for Daraprim suggested extremely low sales. The FDA contacted Vyera to ask if Daraprim was in shortage. When Vyera employees looked into the issue, they quickly determined that the low sales figures that had

concerned the FDA "likely related to the business decision [Vyera] made to block dispense/sales data reported by [its] distribution partners."

188. 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. Vyera engaged in this conduct "to prevent external visibility into [its] corporate performance." Vyera did not "want Gilead or any of the other major infectious disease companies coming in . . . and taking over [] what we created."

189. 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.

190. 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

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

192. Defendants' exclusionary conduct impeded ability to develop a generic version of Daraprim. Absent Vyera's conduct, likely would have entered the market years earlier with a generic version of Daraprim.

193. Founded in , is a pharmaceutical company with about employees located in . Since its inception, has successfully developed through ANDAs.

194. In 2013, decided to develop a generic version of Daraprim. Daraprim was attractive to because it was off patent and had no generic competition.

195. needed a minimum of six bottles of Daraprim for FDA-required bioequivalence testing. At that time, Amedra Pharmaceuticals owned Daraprim and the drug was available through traditional distribution channels.

196. In August 2013, bought nine 100-count bottles of Daraprim from a local pharmacy in New Jersey. It paid $10,350 for nine bottles, or $1,150 per bottle.

197. purchased this Daraprim with no difficulty. It approached only one pharmacy, did not negotiate, and did not enter any written agreement. It received the nine bottles one day after ordering them. Neither nor the pharmacy communicated with Amedra Pharmaceuticals or requested approval for the sale.

198. In 2013, secured Ipca as its supplier of pyrimethamine API. Ipca had a manufacturing process in place for pyrimethamine. After securing as a customer, Ipca submitted a DMF for pyrimethamine to the FDA.

199. Throughout late 2013 and early 2014, conducted bioequivalence testing comparing its generic product—made with pyrimethamine API from Ipca—to the branded

Daraprim it bought from the local pharmacy. In May 2014, [redacted] submitted the results of this testing to the FDA as part of its ANDA.

200. 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. These issues persisted, forcing [redacted] to find a new pyrimethamine API supplier.

201. [redacted] then contacted Fukuzyu. In 2016, Fukuzyu agreed to sell [redacted] pyrimethamine API, but required an initial purchase of 50 kilograms for approximately $300,000 or $400,000. Even though [redacted] wanted only four kilograms for its initial purchase and thought this minimum purchase size was unreasonable, it agreed to purchase 50 kilograms because the alternative of using a non-DMF supplier would have significantly delayed the approval of its generic Daraprim product.

202. About six months after agreeing to supply [redacted], however, Fukuzyu reneged on the deal, citing "economic reasons." Around this time, Fukuzyu had agreed to supply pyrimethamine to Vyera exclusively and not to any generic manufacturers for human use in the United States.

203. [redacted] had a "backup plan" for sourcing pyrimethamine API. In February 2016, [redacted] had identified [redacted] as another possible supplier of pyrimethamine API. [redacted] did not have a U.S. DMF for pyrimethamine API, but it had a European Union DMF and was supplying pyrimethamine in Europe and Asia. This indicated it likely had an FDA-approvable process for manufacturing pyrimethamine API.

204. In November 2016, [redacted] and [redacted] entered into a supply agreement for pyrimethamine API. [redacted] agreed to supply [redacted] with pyrimethamine API until December 31, 2021, for both product development and commercial production. The companies

also agreed that [redacted] would include in [redacted] all of the information needed for the FDA to approve [redacted] as its API supplier.

205. In April 2017, [redacted] submitted this [redacted] to the FDA.

206. On December 26, 2017, the FDA responded to this [redacted] and notified [redacted] that, to use [redacted] as its API supplier, [redacted] had to redo its bioequivalence testing using [redacted] pyrimethamine API. [redacted] had no remaining unexpired Daraprim and thus had to acquire at least six additional 100-count bottles of Daraprim.

207. This time, however, Vyera's agreements prohibiting resale to generic companies made it virtually impossible to obtain sufficient quantities of Daraprim. Over the course of the next year, [redacted] tried to obtain Daraprim samples from numerous sources.

208. On December 29, 2017, [redacted] approached the local pharmacy from which it had purchased Daraprim in 2013. The pharmacy responded that it no longer had access to Daraprim, as the product was no longer available from wholesalers.

209. On January 11, 2018, [redacted] tried to buy Daraprim through a pharmacist at a California hospital. That pharmacist could not obtain Daraprim from the hospital's usual wholesaler.

210. On January 18, 2018, [redacted] contacted a company called [redacted], which had access to a variety of drug sources. [redacted] checked over 20 wholesalers, as well as multiple hospitals and pharmacies. It also tried to have an animal clinic order Daraprim. But it was unable to procure Daraprim from any of these sources.

211. [redacted] also engaged numerous companies that specialize in obtaining branded drug samples for bioequivalence testing, including [redacted], [redacted],

[redacted], [redacted], and [redacted]. After significant efforts, three of these companies—[redacted], [redacted], and [redacted]—could not secure even one bottle of Daraprim. As [redacted] told [redacted], the "US item is impossible to get."

212. Two of these companies were able to obtain some Daraprim for [redacted], but only in limited quantities. In June 2018, [redacted] sold [redacted] bottle of Daraprim for $110,000. Over the next several months, [redacted] tried but failed to obtain more bottles. It told [redacted] that "the manufacturer is involved in every bottle transaction, which is very unusual." In November 2018, [redacted] sold [redacted] bottles of Daraprim for $125,000 per bottle. [redacted] was unable to obtain additional bottles.

213. After a year of effort, [redacted] was able to obtain only [redacted] of the six bottles it needed to conduct FDA-required bioequivalence testing. And because the [redacted] bottles were from a different lot than the [redacted] bottle, [redacted] could not combine them for bioequivalence testing under FDA regulations. [redacted]

214. [redacted]

215. [redacted]

216. On February 28, 2020, the FDA approved Cerovene's generic pyrimethamine.

217. On March 11, 2020, in response to Cerovene's approval, Phoenixus's subsidiary Oakrum Pharma, LLC announced that it would launch an "authorized generic" version of Daraprim. An authorized generic is chemically identical to the brand drug, but is sold as a generic product. Brand pharmaceutical companies often launch lower-priced authorized generic versions of their products when they expect generic entry. The authorized generic captures some of the sales that would otherwise have gone to a generic competitor, allowing the brand to retain some of the revenue it would otherwise lose.

218. On March 20, 2020, Dr. Reddy's Laboratories—Cerovene's commercial partner for the sale and distribution of generic pyrimethamine—announced that it had launched Cerovene's generic pyrimethamine in the United States after a "seven years' journey."

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

220. Even though Cerovene's generic Daraprim is currently being sold in the United States, [redacted] due to Vyera's exclusive API supply agreements. [redacted] after signing its exclusive supply agreement with Vyera. [redacted]—which are still subject to Vyera's tightly controlled resale restrictions—[redacted].

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

222. is a pharmaceutical company with about located in . To date, has developed generic products, of which are currently marketed.

223. In , decided to develop a generic version of Daraprim. Daraprim appealed to because it was off patent and had no generic competition.

224. needed at least six bottles of Daraprim to conduct FDA-required bioequivalence testing. At that time, Amedra Pharmaceuticals owned Daraprim and the drug was available through traditional distribution channels.

225. In , bought six 100-count bottles of Daraprim from a local pharmacy in . It paid $250 per bottle.

226. purchased this Daraprim with no difficulty. It did not sign any liability waivers or enter any indemnification agreements. Nor was informed of any risks associated with Daraprim. Neither nor the pharmacy communicated about this sale with Amedra Pharmaceuticals.

227. Like , initially retained Ipca—which had a U.S. DMF for pyrimethamine—as its API supplier. preferred a supplier with a DMF because using a supplier with an established manufacturing process would expedite the approval of its generic Daraprim product.

228. Like , however, was ultimately not able to use Ipca due to the FDA's January 2015 import ban. thus had to find a new pyrimethamine API supplier.

229. In [redacted], [redacted] contacted [redacted] after learning that it was supplying pyrimethamine in the European Union. After some discussions, the companies agreed that [redacted] would supply [redacted] with pyrimethamine API for its generic Daraprim product.

230. In [redacted], [redacted] and [redacted] formalized their partnership by entering a product collaboration agreement. Under this contract, [redacted] agreed to provide [redacted] with pyrimethamine API for both development and commercial use. The companies also agreed that [redacted] would provide a "[c]omplete set of Pyrimethamine DMF documents" for [redacted] "to include in the filing of [its] ANDA." And [redacted] agreed to "[a]ddress deficiencies by the USFDA related to the application in a timely manner."

231. In [redacted], [redacted] submitted its ANDA to the FDA. The ANDA included the results from bioequivalence testing that [redacted] had done using [redacted] pyrimethamine API and the Daraprim it purchased from the local pharmacy. It also included the information on [redacted] manufacturing process for pyrimethamine API.

232. The FDA issued a preliminary response in [redacted] requiring [redacted] to correct several deficiencies. [redacted] immediately sent [redacted] the deficiencies related to API. But by this time, [redacted] was negotiating its exclusive contract with Vyera for pyrimethamine API and told [redacted] that it was "no longer supporting" the company's ANDA.

233. Later that month, an [redacted] executive travelled to [redacted] to try to convince [redacted] to change its mind. As a potential compromise, he asked if [redacted] would supply the company with pyrimethamine API just for its initial launch of the product. [redacted] declined.

234. In [redacted], [redacted] received a complete response from the FDA on its ANDA. The FDA cited numerous deficiencies related to the API manufacturing process

developed by [redacted]. [redacted] once again asked [redacted] for help addressing these deficiencies. [redacted] again declined.

235. Faced with [redacted] complete refusal to engage, [redacted] was forced to switch pyrimethamine API suppliers for a second time. In or around [redacted], it settled on an API manufacturer called [redacted]. [redacted] planned to transfer [redacted] manufacturing process to [redacted] and to inform the FDA of this change in responding to the agency's complete response.

236. [redacted], however, had never manufactured pyrimethamine before. As a result, before [redacted] could respond to the FDA, [redacted] had to replicate [redacted] manufacturing process and redo three months of stability testing that [redacted] had previously done. It also had to determine how to respond to the API-related deficiencies cited by the FDA relating to the manufacturing process developed by [redacted].

237. [redacted]

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

[redacted]

239. 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.

240. [redacted]

[redacted]

241. [redacted] decided to pursue an ANDA for generic Daraprim in early 2016 after seeing the publicity about Vyera's price increase.

242. In February 2016, [redacted] contacted Fukuzyu, then the only active pyrimethamine API supplier with an approved U.S. DMF, about buying pyrimethamine. Fukyzyu never responded.

243. In June 2016, [redacted] partnered with an [redacted] manufacturer called [redacted]. [redacted] agreed to make pyrimethamine for [redacted], but did not have a manufacturing process in place for pyrimethamine API. [redacted] began working with [redacted] to develop a pyrimethamine manufacturing process that [redacted] would file as a DMF.

244. Meanwhile, [redacted] still pursued Fukuzyu because using its API would have been faster and less expensive. In September 2017, [redacted] engaged an intermediary to contact Fukuzyu on its behalf but keep its identity anonymous. Later that month, the intermediary began discussing pyrimethamine API with Fukuzyu.

245. In October 2017, Fukuzyu told the intermediary that it had an exclusive agreement with Vyera for the supply of pyrimethamine API for use in human products in the United States. At Vyera's direction, Fukuzyu told the intermediary that it would sell pyrimethamine only if the intermediary attested that the API would "not be used to make pyrimethamine drug product, for human use, that will find its way back to the US for commercial purposes."

246. Because this restriction would prevent [redacted] from using Fukuzyu's pyrimethamine API for its generic Daraprim product in the U.S., [redacted] ended the intermediary's discussions with Fukuzyu in January 2018.

247. This left [redacted] as [redacted] best remaining API option. Since 2016, [redacted] had been working to develop an FDA-approvable manufacturing process for pyrimethamine API. In [redacted] [redacted]—three years after partnering with [redacted]—[redacted] submitted a DMF for pyrimethamine API.

248. In addition to the difficulty securing a supply of pyrimethamine API, [redacted] also struggled to secure Daraprim samples to conduct bioequivalence testing.

249. In late 2016, [redacted] sought to buy Daraprim samples through Pharmaceutical Buyer's Inc., a company that specializes in obtaining branded samples. [redacted] has often purchased samples of other branded products through Pharmaceutical Buyers Inc., but the company was unable to acquire any Daraprim for [redacted].

250. In January 2017, [redacted] contract manufacturer engaged AdiraMedica, LLC—a company that specializes in obtaining branded samples—to buy Daraprim for [redacted]. AdiraMedica first contacted ASD Healthcare, which responded that "Daraprim is available to hospitals and government facilities only at this time."

251. In early 2017, [redacted] itself tried to buy Daraprim from a local hospital. But the hospital told [redacted] it had an agreement with its supplier barring it from selling Daraprim to third parties. At that time, Vyera had its agreements in place with hospitals and hospital GPOs prohibiting the resale of Daraprim to anyone other than patients.

252. In March 2017, AdiraMedica contacted Vyera directly. Vyera asked for the identity of AdiraMedica's customer and claimed that it "may be interested in negotiating an indemnification agreement from the ultimate purchaser." Over five weeks later, Vyera sent

AdiraMedica a purchase agreement containing a provision requiring the buyer to indemnify Vyera for **all** legal claims related in any way to Daraprim—regardless of whether the claim stemmed from the buyer's purchase or use of the product. Vyera further insisted that if the product was for a generic company, that company had to disclose its identity and sign the agreement.

253. In August 2017, at [redacted] request, AdiraMedica asked Vyera to delete the highly unusual and overbroad indemnity provision. Vyera never responded to AdiraMedica on the proposed deletion of this provision. As a result, AdiraMedica could not buy any Daraprim from Vyera for [redacted].

254. In January 2018, after a year of efforts, [redacted] was able to buy two 100-count bottles of Daraprim for $115,250 per bottle from Reliant Specialty LLC. Several months later, Reliant Specialty told [redacted] that Vyera had barred it from selling Daraprim. Reliant Specialty also told [redacted] that Defendant Mulleady, on behalf of Vyera, had bought back its remaining Daraprim inventory.

255. Soon thereafter, [redacted] was approached by Vyera. In an April 2018 call, Mulleady proposed that [redacted] drop its effort to develop a competing generic product and instead partner with Vyera on a Daraprim ANDA. At a meeting later that month, Mulleady and Akeel Mithani presented [redacted] with a financial model showing that [redacted] would be better off partnering with Vyera than competing with its own generic product.

256. On May 4, 2018, Mulleady again met with [redacted] and further discouraged it from competing with Vyera. Mulleady told [redacted] that he had prevented Reliant Specialty from selling Daraprim. He also bragged that Vyera had entered into an exclusive API agreement with RL

Fine that eliminated two potential generic competitors. He then told [redacted] that he knew [redacted] was its API supplier.

257. Discussions between [redacted] and Vyera ceased in June 2018. [redacted] then pushed forward with its own ANDA.

258. [redacted]

259. [redacted]

260. [redacted]

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

D. Mylan, N.V.

262. Defendants' exclusionary conduct caused Mylan to stop pursuing a generic version of Daraprim. Mylan is one of the largest generic pharmaceutical companies in the world.

263. In late 2015, Mylan began considering developing a generic version of Daraprim. To assess the sales of Daraprim, Mylan analyzed the IQVIA data on the drug. Mylan knew that this data for Daraprim was underreported, but it could not determine a more accurate sales number because Vyera had no public financial filings.

264. From October 2015 to April 2018, Mylan inquired about purchasing Daraprim from seven suppliers: [redacted]

265. Multiple suppliers told Mylan they could not access Daraprim. They provided varying reasons. In 2016, [redacted] told Mylan that Daraprim was in restricted distribution and that it was "[f]or inpatient hospitals only." [redacted] similarly told Mylan that Daraprim was "only available to inpatient hospital pharmacies."

266. In [redacted] Mylan abandoned its pursuit of a generic Daraprim product. It decided that obtaining Daraprim samples was too difficult and expensive. It also cited its inability to get a "real sense" of Daraprim's sales because the product was "no longer reported in [IQVIA]" as a reason for abandoning the project.

E. Other generic companies

267. 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 Ambegen Pharmaceutical and Services Pvt. Ltd., an Indian company that sources branded drugs for bioequivalence testing.

268. On April 3, 2019, Ambegen contacted ASD Healthcare about buying Daraprim for a "pre-clinical study." ASD Healthcare forwarded the request to Vyera, which told the distributor to "**NOT** fulfill this order/request" and to have Ambegen contact it directly. Ambegen then spoke to Vyera's deputy general counsel, who denied its request to purchase Daraprim.

269. The next day, Ambegen contacted [redacted], another company specializing in obtaining branded drugs, about buying Daraprim.

270. [redacted] initially contacted numerous suppliers, including Myoderm and Low Cost RX LLC. As Myoderm explained, Daraprim is "restricted with the manufacturer and our suppliers do not have access due to manufacturer restrictions." Low Cost RX similarly emphasized: "This is a very strict and limited drug."

271. In May 2019, [redacted] contacted ASD Healthcare about purchasing Daraprim. ASD Healthcare told [redacted] that the manufacturer must first approve the request and sent [redacted] a request form to complete. [redacted] completed the form, which ASD Healthcare forwarded to Vyera.

272. On June 22, 2019, Vyera told ASD Healthcare to "**NOT** fulfill this order/request" and to have [redacted] contact it directly. Over the next couple of months, [redacted] communicated with Vyera's deputy general counsel, who would not approve the sale and instead kept asking for increasingly more information about [redacted] customer. [redacted] thereafter abandoned its efforts to buy Daraprim from Vyera.

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

273. 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.

274. Vyera's agreements prohibiting the resale of Daraprim impeded potential generic competitors, including [redacted], [redacted], and Mylan, 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.

275. Vyera's exclusive supply agreements with Fukuzyu and RL Fine—the two most viable suppliers of pyrimethamine API—impeded potential generic competitors, including [redacted], [redacted], and [redacted], from securing a reliable source of pyrimethamine API, an indispensable ingredient of generic Daraprim. Absent these exclusive agreements, potential generic competitors could have sourced pyrimethamine API from Fukuzyu or RL Fine instead of

a manufacturer that needed to devote the time and expense of developing an FDA-approvable process for manufacturing pyrimethamine API.

276. 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, Mylan and other pharmaceutical companies would have known that Daraprim revenues had grown substantially due to Vyera's 4,000% price increase, and thus offered a lucrative competitive opportunity.

277. 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.

278. 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.

279. Most consumers would have purchased the lower-priced AB-rated substitutes for Daraprim rather than the higher-priced branded product. A 2018 Vyera contemporaneous forecast assumed that approximately [redacted] of Daraprim unit sales would switch to an AB-rated generic version of Daraprim within three months of generic entry.

280. Defendants' anticompetitive conduct, however, forced consumers to continue paying Vyera's monopoly price for Daraprim by depriving them of access to a lower-cost generic alternative.

281. 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.

282. The economic harm from Defendants' conduct is ongoing. Absent Defendants' anticompetitive scheme, there would likely be multiple generic versions of Daraprim available today, leading to more intense price competition and lower prices for consumers.

283. 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.

284. 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—changed hospitals' approach. Due to the price increase, hospitals became 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 denied these hospitals the option of stocking lower-cost generic versions of Daraprim.

285. 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.

286. 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.

287. 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.

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

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

290. 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.

291. 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.

292. 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.

293. 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.

294. Defendant Mulleady directed, participated in, and carried out the anticompetitive scheme to protect Vyera's Daraprim price increase. Mulleady is and has been actively looking for other drugs with which Vyera or a new company could replicate the Daraprim anticompetitive scheme. 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

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

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

the price 4,000%, Vyera's annual Daraprim revenues were approximately [redacted]—an increase of more than [redacted].

297. Vyera sells and has sold Daraprim at prices far above its cost of production, making it highly profitable. Even accounting for other direct expenses Vyera allocates to selling and marketing Daraprim, Vyera's profit margins on Daraprim's net sales are substantial.

298. Vyera's monopoly power with respect to Daraprim persisted for an appreciable period. Since 2015, Vyera maintained its high price and continued to reap significantly higher profits.

299. 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 maintained this 100% market share from the time it purchased Daraprim in 2015 at least until generic entry occurred in March 2020.

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

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

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

303. 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." Many doctors are "at a loss to think of an appropriate alternative to pyrimethamine."

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

305. 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.

306. 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.

307. Unlike non-pyrimethamine products and non-FDA-approved pyrimethamine products, generic Daraprim would be reasonably interchangeable with Daraprim. Vyera estimates that more than [redacted] of patients would immediately switch to generic Daraprim and that [redacted]. Vyera expects a generic Daraprim product to cause this [redacted] shift even though it will likely be much more expensive than existing non-pyrimethamine products and non-FDA-approved pyrimethamine products. 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.

308. The lack of an adequate substitute to Daraprim is also confirmed by the fact that the four 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 the four largest PBMs determined that their formularies had to include Daraprim despite the price increase and notwithstanding the availability of non-pyrimethamine and compounded pyrimethamine products.

309. As a Vyera executive explained in January 2016, Vyera has "not had any rejections from commercial payers for Daraprim . . . because payers recognize the potential life-saving value of the medication, it is the only FDA approved therapy for toxo[plasmosis] (there are no on label alternatives), and the budget impact is low given the relatively low volume of patients."

310. 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.

311. 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. Indeed, the only possible constraint Impax identified for its June 2015 Daraprim price increase was potential backlash from the HIV/AIDS community.

312. 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.

313. 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

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

315. From 2015 until at least March 2020, Vyera and Phoenixus had monopoly power in the United States with respect to FDA-approved pyrimethamine products.

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

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

318. 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

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

320. Defendants' agreements with distributors, hospitals, and other downstream purchasers 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 (API Supply Exclusivity Agreements) Against All Defendants

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

322. Defendants' exclusive pyrimethamine API contracts with Fukuzyu and RL Fine, 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
A. Anticompetitive Contracts, Agreements and/or Arrangements in Violation of New York's Donnelly Act Against All Defendants

323. Plaintiff State of New York re-alleges and incorporates by reference the allegations in paragraphs 1 through 313 above.

324. Defendants' agreements with distributors, hospitals, and other downstream purchasers 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*.

325. Defendants' exclusive pyrimethamine API contracts with Fukuzyu and RL Fine, 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*.

326. 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*.

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

327. Plaintiff State of New York re-alleges and incorporates by reference the allegations in paragraphs 1 through 313 above.

328. 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).

COUNT V

A. Anticompetitive Contracts, Agreements and/or Arrangements in Violation of California's Cartwright Act Against All Defendants

329. Plaintiff State of California re-alleges and incorporates by reference the allegations in paragraphs 1 through 313 above.

330. Defendants' agreements with distributors, hospitals, and other downstream purchasers 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 California's Cartwright Act, California Business and Professions Code § 16700 *et seq*.

331. Defendants' exclusive pyrimethamine API contracts with Fukuzyu and RL Fine, which were conceived, negotiated, signed, and/or enforced by the individual Defendants, constitute agreements in restraint of trade in violation of California's Cartwright Act, California Business and Professions Code § 16700 *et seq*.

B. Anticompetitive Contracts, Agreements and/or Arrangements in Violation of California's Unfair Competition Act Against All Defendants

332. Plaintiff State of California re-alleges and incorporates by reference the allegations in paragraphs 1 through 313 above.

333. Defendants' agreements with distributors, hospitals, and other downstream purchasers 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 California's Unfair Competition Act, California Business and Professions Code § 17200 *et seq*. Defendants have engaged, and continue to engage, in acts or practices that are unlawful, unfair, or fraudulent, and

which constitute unfair competition within the meaning of § 17200 of the Business and Professions Code.

334. These acts or practices include, but are not limited to, Defendants' exclusive pyrimethamine API contracts with Fukuzyu and RL Fine, which were conceived, negotiated, signed, and/or enforced by the individual Defendants, which constitute agreements in restraint of trade in violation of California's Cartwright Act, California Business and Professions Code § 16700 *et seq*.

COUNT VI
Anticompetitive Contracts, Combinations and/or Conspiracies in Violation of the Illinois Antitrust Act Against All Defendants

335. Plaintiff State of Illinois re-alleges and incorporates by reference the allegations in paragraphs 1 through 313 above.

336. Defendants' contracts and agreements restricting resale of Daraprim, to block access to pyrimethamine API, and to mask the true size of the pyrimethamine market as conceived, negotiated, signed, and/or enforced by the individual Defendants, constitute unlawful contracts, combinations or conspiracies with one or more other persons for the purpose, or with the effect, of unreasonably restraining trade in violation of the Illinois Antitrust Act, 740 ILCS 10/3(2).

337. Defendants' course of conduct as detailed above was done with the purpose of maintaining monopoly power over a substantial part of trade or commerce of Illinois in the market for FDA-approved pyrimethamine and Daraprim, for the purpose of excluding competition or controlling, fixing, or maintaining prices for these drugs, in violation of the Illinois Antitrust Act, 740 ILCS 10/3(3).

COUNT VII
Unfair Methods of Competition and/or Unfair Acts or Practices in Violation of the North Carolina Unfair or Deceptive Practices Act Against All Defendants

338. Plaintiff State of North Carolina re-alleges and incorporates by reference the allegations in paragraphs 1 through 313 above.

339. Defendants' agreements with distributors, hospitals, and other downstream purchasers barring them from reselling Daraprim to potential generic competitors, as well as the data-blocking agreements with its primary distributors, which were conceived, negotiated, signed, and/or enforced by the individual defendants, constitute unfair methods of competition and/or unfair acts or practices within their meaning under the North Carolina Unfair or Deceptive Practices Act, N.C. Gen. Stat. § 75-1 *et seq*.

340. Defendants' exclusive pyrimethamine API contracts with Fukuzyu and RL Fine, which were conceived, negotiated, signed, and/or enforced by the individual defendants, constitute agreements in restraint of trade in violation of the North Carolina Unfair or Deceptive Practices Act, N.C. Gen. Stat. § 75-1 *et seq.*

341. Defendants' course of conduct as detailed above was done with the purpose of maintaining a monopoly in FDA-approved pyrimethamine and thus violates the North Carolina Unfair or Deceptive Practices Act, N.C. Gen. Stat. § 75-1 *et seq.*

342. The aforesaid methods, acts, or practices constitute unfair methods of competition and/or unfair acts or practices within their meaning under the North Carolina Unfair or Deceptive Practices Act, N.C. Gen. Stat. § 75-1 *et seq.*, and are injurious to North Carolina consumers and the general economy of the State of North Carolina.

343. Plaintiff State of North Carolina is entitled to relief pursuant to the Unfair or Deceptive Acts or Practices Act, N.C. Gen. Stat. § 75-1 *et seq*.

COUNT VIII
Violations of Ohio's Valentine Act Against All Defendants

344. Plaintiff State of Ohio re-alleges and incorporates by reference the allegations in paragraphs 1 through 313 above.

345. Defendants' activities detailed above, including the vertical arrangements, constitute a Trust under Ohio Rev. Code § 1331.01 and are thus illegal under Ohio's Valentine Act, codified in Ohio Rev. Code Chapter 1331.

COUNT IX
A. Pennsylvania's Unfair Trade Practices and Consumer Protection Law

346. Plaintiff Commonwealth of Pennsylvania re-alleges and incorporates by reference the allegations in paragraphs 1 through 313 above.

347. In distributing, marketing and selling of the pharmaceutical product Daraprim to consumers through drug wholesalers and distributors, pharmacy chains, and other downstream purchasers of Daraprim and in otherwise engaging in the conduct more fully described herein with respect to Daraprim, the Defendants are engaging in trade or commerce that has directly or indirectly harmed the Commonwealth of Pennsylvania and Pennsylvania consumers within the meaning of 73 P. S. § 201-2(3) of the Pennsylvania Unfair Trade Practices and Consumer Protection Law ("PUTPCPL").

348. Defendants' conduct as set forth in the preceding counts has been unfair or unconscionable because it offends public policy as established by statutes, the common law, or otherwise, and is immoral, unethical, oppressive, unscrupulous, or substantially injurious to the Commonwealth of Pennsylvania and Pennsylvania consumers.

349. The Defendants' impairment of choice and the competitive process has had the following effects: (1) competition in the market for FDA-approved pyrimethamine products has

been restrained, suppressed, and eliminated throughout Pennsylvania; (2) Daraprim prices have been raised, maintained, and stabilized at artificially-high levels throughout Pennsylvania; (3) Commonwealth of Pennsylvania and Pennsylvania consumers have been deprived of free and open markets; and (4) Commonwealth of Pennsylvania and Pennsylvania consumers have paid supra-competitive, artificially inflated prices for Daraprim.

350. The aforesaid methods, acts, or practices constitute unfair methods of competition and/or unfair acts or practices within their meaning under Sections 2 and 3 of the PUTPCPL, including, but not limited to, "Engaging in any other fraudulent or deceptive conduct which creates a likelihood of confusion or of misunderstanding" in violation of 73 P.S. § 201-2(4)(xxi).

351. The above described conduct created the likelihood of confusion and misunderstanding and exploited unfair advantage of the Commonwealth of Pennsylvania and Pennsylvania consumers seeking to exercise a meaningful choice in a market expected to be free of impairment to the competitive process and thus constitutes constructive fraud through one or more of the following breaches of legal or equitable duties:

a. Violating federal antitrust laws as set forth in Counts I through III;

b. Violating Pennsylvania antitrust common law through restricting the resale of Daraprim;

c. Violating Pennsylvania antitrust common law through restricting access to a supply of the pyrimethamine API;

d. Violating Pennsylvania antitrust common law through willfully maintaining its monopoly power over FDA-approved pyrimethamine products; and/or

e. Engaging in any conduct which causes substantial injury to consumers.

352. The above described conduct substantially injured Pennsylvania consumers and the Commonwealth of Pennsylvania.

353. The above described conduct has been willful within the meaning of 73 P.S. § 201-8 and is unlawful under the PUTPCPL.

B. Common Law Doctrine against Restraint of Trade

354. Plaintiff Commonwealth of Pennsylvania re-alleges and incorporates by reference the allegations in paragraphs 1 through 313 above.

355. The agreements to restrict the resale of Daraprim and the supply of the pyrimethamine API as set forth in the preceding counts constitute an unreasonable restraint of trade in violation of Pennsylvania antitrust common law.

356. The Defendants' contracts in restraint of trade have had the following effects: (1) competition in the market for FDA-approved pyrimethamine products has been restrained, suppressed, and eliminated throughout Pennsylvania; (2) Daraprim prices have been raised, maintained, and stabilized at artificially-high levels throughout Pennsylvania; (3) Commonwealth of Pennsylvania and Pennsylvania consumers have been deprived of free and open markets; and (4) Commonwealth of Pennsylvania and Pennsylvania consumers have paid supra-competitive, artificially inflated prices for Daraprim.

COUNT X
A. Anticompetitive Agreements in Violation of the Virginia Antitrust Act Against All Defendants

357. Plaintiff State of Virginia re-alleges and incorporates by reference the allegations in paragraphs 1 through 313 above.

358. Defendants' agreements with distributors, hospitals, and other downstream purchasers barring them from reselling Daraprim to potential generic competitors, which were

conceived, negotiated, signed, and/or enforced by the individual Defendants constitute contracts, combinations, or conspiracies in restraint of trade or commerce in violation of the Virginia Antitrust Act, Virginia Code § 59.1-9.5.

359. Defendants' exclusive pyrimethamine API contracts with Fukuzyu and RL Fine, which were conceived, negotiated, signed, and/or enforced by the individual Defendants, constitute contracts, combinations, or conspiracies in restraint of trade or commerce in violation of the Virginia Antitrust Act, Virginia Code § 59.1-9.5.

B. Monopoly Maintenance in Violation of the Virginia Antitrust Act

360. Plaintiff State of Virginia re-alleges and incorporates by reference the allegations in paragraphs 1 through 313 above.

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

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

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

364. Defendants' anticompetitive acts constitute unlawful monopoly maintenance in violation of the Virginia Antitrust Act, Virginia Code § 59.1-9.6.

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; New York Executive Law § 63(12) authorizes this Court to issue a permanent injunction for violation of the aforementioned state and federal antitrust laws; CA Bus & Prof Code § 16754.5 authorizes this Court to issue a permanent injunction in violation of California's Cartwright Act, CA Bus & Prof Code § 16700 *et seq*.; CA Bus & Prof Code § 17203 authorizes this Court to issue a permanent injuction for violations of and California's Unfair Competition Act, Ca Bus & Prof Code § 17200 *et seq.*; the Illinois Antitrust Act, Sections 7(1) and 7(2) authorizes this Court to issue a permanent injunction for violation of the aforementioned state and federal antitrust laws; N.C. Gen. Stat. §75-14 authorizes this Court to issue a permanent injunction for violations of the North Carolina Unfair or Deceptive Practices Act; Ohio Revised Code Chapter 1331 and §109.81(A) authorizes this Court to issue a permanent injunction for violations of Ohio's Valentine Act and the aforementioned federal antitrust laws; 73 P.S. §201-4 authorizes this Court to issue a permanent injunction for violations of Pennsylvania Unfair Trade Practices and Consumer Protection Law; Pennsylvania Common Law Doctrine against Restraints of Trade provides equitable relief including a permanent injunction; the Virginia Antitrust Act § 59.1-9.15(a) authorizes this Court to issue a permanent injunction for violations of the Virginia Antitrust Act, therefore the FTC and the states of New York, California, Illinois, Ohio, North Carolina, Pennsylvania, and Virginia 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' course of conduct violates California's Cartwright Act, CA Bus & Prof Code § 16700 *et seq*., and California's Unfair Competition Act, CA Bus & Prof Code § 17200;

8. That Defendants' course of conduct violates Illinois Antitrust Act, 740 ILCS 10/1 *et seq*.;

9. That Defendants' course of conduct violates the North Carolina Unfair or Deceptive Practices Act, N.C. Gen. Stat. § 75-1 *et seq*.;

10. That Defendants' course of conduct violates Ohio's Valentine Act; Ohio Revised Code Chapter 1331;

11. The Defendants' course of conduct violates the Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P. S. §§ 201-3, 201-2(4)(xxi) and 201-4, as well as Pennsylvania's Common Law Doctrine against Restraints of Trade;

12. The Defendants' course of conduct violates Virginia Antitrust Act, Virginia Code § 59.1-9.1 *et seq*.;

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

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

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

16. 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;

17. 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, New York Executive Law § 63(12); California's Cartwright Act, Ca Bus & Prof Code §16700 *et seq*.; California's Unfair Competition Act, CA Bus & Prof Code §17200; Illinois Antitrust Act, 740 ILCS 10/1 et seq.; North Carolina Unfair or Deceptive Practices Act, N.C. Gen. Stat. §75-1 et seq; Ohio's Valentine Act, Ohio Rev. Code Chapter 1331; Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P.S. §§ 201-4.1; Pennsylvania Common Law Doctrine against Restraints of Trade; Virginia Antitrust Act, Virginia Code § 59.1-9.1 et seq.;

18. That the Court grant Plaintiff states of New York, California, Illinois, North Carolina, Pennsylvania, Ohio, and Virginia an award of reasonable attorneys fees and costs;

19. That the Court order Defendants to pay Plaintiff states of New York, California, Illinois, North Carolina, Ohio, Pennsylvania, and Virginia civil penalties/forfeitures for their violations of the asserted state and/or federal antitrust laws, as authorized by law, N.Y. GBL § 341; CA Bus & Prof Code §17206; 740 ILCS 10/7(1), 740 ILCS 10/7(2) and 740 ILCS 10/7(4); N.C. Ge. Stat. §75-15.2; Ohio Rev. Code § 109.81 and Ohio Rev. Code §§

1331; Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P.S. §§ 201-8(b); and Virginia Code § 59.1-9.11.

Dated: April 14, 2020

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