

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

BCBSM, INC., d/b/a BLUE CROSS and
BLUE SHIELD OF MINNESOTA, on
behalf of itself and those similarly situated,

Plaintiff,

v.

VYERA PHARMACEUTICALS, LLC,
PHOENIXUS AG, MARTIN SHKRELI,
and KEVIN MULLEADY,

Defendants.

Case No. 1:21-cv-1884

Class Action Complaint

Jury Trial Demanded

Plaintiff BCBSM, Inc., d/b/a Blue Cross and Blue Shield of Minnesota, (“Blue Cross of Minnesota”), files this action, individually on behalf of itself and as a class action on behalf of all others similarly situated, against Defendants Vyera Pharmaceuticals, LLC, Phoenixus AG, Martin Shkreli (individually, as an owner and former director of Phoenixus AG, and a former executive of Vyera Pharmaceuticals, LLC), and Kevin Mulleady (individually, as an owner and director of Phoenixus AG, and a former executive of Vyera Pharmaceuticals, LLC), for damages, injunctive relief, and any and all other available forms of relief. Plaintiff demands a trial by jury on all issues so triable and complains and alleges as follows:

I. Nature of the Case

1. This lawsuit challenges Defendants’ scheme to monopolize the U.S. market for Daraprim—an essential, life-saving drug used in the treatment of toxoplasmosis—through an array of anticompetitive conduct that successfully thwarted generic competition for years and continues to cause supracompetitive prices to this day.

2. Toxoplasmosis is a parasitic infection that can be fatal for people with compromised immune systems, particularly those with HIV/AIDS and cancer patients.

3. Daraprim is the gold-standard treatment for toxoplasmosis. It was first brought to market in the United States in 1953 by a predecessor of GlaxoSmithKline (“GSK”) and, for many decades, was affordable. However, in 2015, under the direction of Shkreli and Mulleady, Vyera and Phoenixus acquired the U.S. rights to Daraprim from the only existing supplier and raised the price from \$17.50 to \$750 per tablet—an increase of approximately 4,185 percent.

4. Because Daraprim lacked patent and regulatory protections, Defendants understood that such an astronomical price increase would cause competitors to develop generic versions of Daraprim and sell them at lower prices. To prevent this, and to make their planned price increase

commercially viable, Defendants executed a scheme to thwart generic competition and force Daraprim purchasers to pay grossly inflated prices—all while concealing and misleading the public about their anticompetitive conduct.

5. Defendants’ scheme, which began before the price increase itself, spanned multiple fronts. First, Defendants prevented competitors from obtaining the Daraprim samples they needed to launch a generic product. Before a generic drug can be sold in the United States, the U.S. Food & Drug Administration (“FDA”) requires manufacturers to perform testing to establish that the proposed generic drug is “bioequivalent” to the branded drug.

6. Publicly, Defendants claimed they welcomed generic competition, calling it a “great thing.” But in private, Defendants blocked competitors from performing generic testing through contractual restrictions that forbade distributors and other purchasers from selling Daraprim to generic companies. These resale restrictions, the purpose and scope of which Defendants repeatedly misrepresented, prevented would-be generic entrants from obtaining the Daraprim samples they needed to perform FDA-required bioequivalence testing.

7. Defendants also ensured that their competitors would lack the necessary ingredients to manufacture generic Daraprim. Generic companies typically do not synthesize the active pharmaceutical ingredients (“API”) used in their products, but rather purchase the API from specialty manufacturers. Defendants therefore worked to corner the market for pyrimethamine, the API needed to manufacture Daraprim, to cut-off generic companies’ access.

8. Defendants first entered into a lucrative exclusive supply agreement with Fukuzyu Pharmaceutical Co., Ltd. (“Fukuzyu”), then the only supplier approved by the FDA to manufacture pyrimethamine in the U.S. Later, when Defendants learned that RL Fine Chem. Pvt. Ltd. (“RL Fine”), another specialty supplier, was working with generic companies to develop

pyrimethamine, Defendants negotiated an exclusive supply agreement with RL Fine, despite already having locked-in Fukuzyu.

9. Third, Defendants denied generic suppliers access to the sales data that was critical to determining whether developing generic Daraprim would be commercially viable. Generic companies acquire such data from third-party data-reporting companies that collect and aggregate sales information from the marketplace. Defendants imposed “data-blocking” agreements that prevented their distributors from selling Daraprim sales information to the data-reporting companies, thereby preventing Defendants’ would-be competitors from accurately assessing, and thus pursuing, the market opportunity for generic Daraprim.

10. Defendants sought to conceal their scheme through deception and fraud. They publicly denied their efforts to exclude generic competition, misrepresented the scope and purpose of their sale and distribution restrictions on Daraprim, and claimed what little was known about their scheme was necessary to serve patients’ interests. None of their claims were truthful.

11. The purpose and effect of Defendants’ scheme has been to unlawfully monopolize the U.S. market for Daraprim by excluding lower-priced generic competition, with the goal of extracting monopoly profits at the expense of Daraprim customers.

12. Absent Defendants’ anticompetitive and deceptive conduct, multiple generic competitors would have entered the Daraprim market sooner and at lower prices, rendering Defendants’ price hike unsustainable—such that they would not have pursued it in the first place.

13. By instead planning to thwart generic entry from the start, Defendants determined they could impose monopoly prices and reap significant profits at the expense of Plaintiff and Class members, who were forced to pay inflated prices in violation of the federal antitrust laws, various state antitrust and consumer protection laws, and the common law of unjust enrichment.

II. Jurisdiction and Venue

14. This Court has jurisdiction over the subject matter of this action pursuant to Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15, 26, Sections 1 and 2 of the Sherman Antitrust Act, 15 U.S.C. §§ 1 and 2, and 28 U.S.C. §§ 1331 and 1337. This Court has subject matter jurisdiction over the state law claims pursuant to 28 U.S.C. §§ 1332(d) and 1367, because this is a class action in which the matter or controversy exceeds \$5,000,000, exclusive of interest and costs, and in which some members of the proposed Classes are citizens of a state different from some Defendants. This Court's exercise of supplemental jurisdiction over Plaintiff's state law claims would avoid unnecessary duplication and multiplicity of actions, and should be exercised in the interests of judicial economy, convenience, and fairness.

15. Venue is proper in this District pursuant to Section 12 of the Clayton Act, 15 U.S.C. § 22, and 28 U.S.C. §§ 1391 (b), (c), and (d), because a substantial part of the events giving rise to Plaintiff's claims occurred in this District, a substantial portion of the affected interstate trade and commerce discussed below has been carried out in this District, and one or more Defendants reside, are licensed to do business in, are doing business in, had agents in, or are found or transact business in this District.

16. This Court has personal jurisdiction over Defendants 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. C.P.L.R. §§301, 302.

17. The Federal Trade Commission ("FTC") along with the Attorneys General of California, Illinois, North Carolina, New York, Ohio, Pennsylvania, and Virginia have initiated an

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