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FEDERAL COURT IMPOSES PENALTIES ON FORMER CEO AND LARGE SHAREHOLDER OF PHARMACEUTICAL COMPANY FOR ALLEGED ANTITRUST VIOLATIONS

To Our Clients and Friends:

Antitrust Enforcement Actions Followed Highly Unusual Price Increases

Decision Illustrates Risks Faced by Shareholders That Exercise Direct Control Over Their Companies

On January 14, 2022, a federal court in New York issued its decision in *Federal Trade Commission v. Shkreli*, holding that Martin Shkreli, the former head of Vyera Pharmaceuticals, violated federal and state antitrust laws by allegedly interfering with the entry of generic competition for Vyera's drug Daraprim.[1] For his participation in the conduct, the District Court ordered Shkreli to disgorge $64.4 million in profits and banned him from participating in the pharmaceutical industry for life.[2] The court's decision followed a seven-day bench trial last month. The case was brought by the Federal Trade Commission, the New York Attorney General, and the attorneys general of six other states.

The case centered on Shkreli's conduct after Vyera, formerly known as Turing Pharmaceuticals, purchased the rights to Daraprim, a medication used to treat potentially fatal parasitic infections. In 2015, Vyera raised the price of Daraprim from $17.50 to $750 per pill. It also moved Daraprim from a retail distribution to a closed distribution system, and entered into agreements with the two primary manufacturers for Daraprim's active pharmaceutical ingredient that restricted access to that ingredient. The District Court held that, in doing so, Vyera made it difficult for generic manufacturers to obtain sufficient samples of the drug to conduct bioequivalence and other studies needed for FDA approval, thus delaying the entry of generic competition for at least eighteen months. The District Court found that this conduct violated federal and state antitrust laws, and that Shkreli himself was personally liable for such conduct due to the control he exercised over the company. Below, we provide several important takeaways from the court's decision.

Dramatic Price Hikes Untethered to Demand Can Lead To Intense Antitrust Scrutiny. The District Court cites testimony describing Shkreli's decision to dramatically increase the cost of Daraprim as the "poster child of everything that is considered wrong about the pharmaceutical industry."[3] Shkreli's over-the-top price increases clearly drew significant media and law enforcement attention to his company's business practices. The case shows that even though there is nothing unlawful about a company raising price, dramatic price increases unconnected with increased demand can draw extraordinary public attention and attract intense regulatory scrutiny. Here, that close scrutiny resulted in severe personal and professional penalties for Shkreli.

Closed Distribution Systems As An Anti-Generic Strategy. Daraprim had been in open retail distribution since the 1950s.[4] After purchasing the rights in 2015, Shkreli swiftly moved to create a highly

restrictive closed distribution system. To do so, Vyera imposed class of trade restrictions on its distribution contacts, limited the number of bottles that a single customer could purchase at a given time, bought back Daraprim inventory from wholesalers and distributors, and surveilled distributors sales reports "to prevent the diversion of Daraprim to generic drug companies for [bioequivalence] testing."[5] Vyera also allegedly blocked access to pyrimethamine, Daraprim's active pharmaceutical ingredient, by entering into exclusive supply agreements with two of its largest manufacturers. The District Court held that these practices dramatically heightened the barriers to generic market entry. The District Court's holding that this conduct was illegal, anticompetitive conduct, illustrates that closed distribution systems – while not ordinarily unlawful – can be the basis for an antitrust claim where they are allegedly used as a means to impede generic entry.

Risk of Liability For Large Shareholders. Shkreli founded Vyera (initially known as Turing), was the company's first CEO, and allegedly masterminded the scheme to exclude Daraprim's generic competitors from the market. Even after he stepped down as Vyera's CEO following his December 2015 arrest, the District Court found that Shkreli "remained in functional control of Vyera's management and its business strategy."[6] Even during his incarceration, the District Court stated that Shkreli continued to manage Vyera's leadership, direct corporate policy, and maintain the allegedly anticompetitive Daraprim scheme by wielding his authority as the company's largest shareholder. For this conduct, the District Court held Shkreli personally liable under the Sherman Act and joint and severally liable for the disgorgement remedy under New York State law. The Court's decision is a warning that shareholders who exert a high degree of control over companies' anticompetitive conduct can themselves be found directly liable. This case illustrates the risk that federal and state antitrust enforcers, and even private plaintiffs, will invoke similar reasoning in an attempt to impose liability on other types of shareholders (e.g., institutional shareholders).

Expansion of Remedies When FTC Cooperates With State AGs. By working with the Attorneys General of New York, California, Ohio, Pennsylvania, Illinois, North Carolina, and Virginia, the FTC was able to seek remedies unavailable under federal law. Chief among these was the remedy requiring Shkreli to disgorge $64.4 million in net profits – a remedy afforded by New York state law[7] but not currently available to the FTC since the Supreme Court's 2019 decision in *AMG Capital v. FTC*.[8] The District Court found the plaintiffs' federal and state injunctive authority also to be sufficient to order a lifetime ban on Shkreli from participating in the pharmaceutical industry. The case therefore highlights the risks posed when the FTC's enforcement power is paired with the additional remedies afforded to certain state attorneys general. Importantly, these remedies were available to the FTC and states without Mr. Shkreli having a right to a jury trial, because the FTC and state AGs did not pursue a traditional damages remedy.

The District Court's decision in *FTC v. Shkreli* is a reminder that pharmaceutical and other companies should seek legal advice when engaging in activities that have generated significant regulatory attention, such as price increases untethered to demand increases, and changing the distribution system used for a drug. In addition, as noted, the decision illustrates that institutional and other types of shareholders should seek legal advice when seeking to exert influence over a subsidiary or other company that is potentially subject to significant antitrust or other legal exposure.

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[1] *Federal Trade Commission, State of New York, State of California, State of Ohio, Commonwealth of Pennsylvania, State of Illinois, State of North Carolina, & Commonwealth of Virginia vs. Martin Shkreli*, No. 20CV00706 (DLC), 2022 WL 135026 (S.D.N.Y. Jan. 14, 2022).

[2] *Id.* at *1.

[3] *Id.* at *11, citing the testimony of Dr. Eliseo Salinas, Vyera's President of Research & Development from June 2015 to April 2017, and interim CEO from April to July 2017.

[4] *Id.* at *12.

[5] *Id.* at *14.

[6] *Id*. at *28.

[7] *Id.* at *46.

[8] *AMG Cap. Mgmt., LLC v. Fed. Trade Comm'n*, 141 S. Ct. 1341 (2021).