Federal Trade Commission v. Martin Shkreli

BRYANT GODFREY & TINA PAPAGIANNOPOULOS*

WHY IT MADE THE LIST

The Federal Trade Commission (FTC) has been investigating and enforcing against potential anticompetitive conduct in the pharmaceutical industry for decades. The complexity of the regulatory framework under the Federal Food, Drug, and Cosmetic Act (FDCA), however, makes antitrust enforcement over certain practices in the pharmaceutical industry all the more challenging. The intense congressional debate over drug pricing over the past several years has started to focus on legislative solutions that would make it more difficult for pharmaceutical companies to manipulate or take advantage of the regulatory scheme in order to block or delay competition. This case provides some examples of the type of conduct that is at the heart of these concerns.

Within days of acquiring the rights to market a life-saving drug in the United States, "Pharma Bro" Martin Shkreli directed his company, Vyera Pharmaceuticals, LLC, to implement a drastic price hike that caught the nation's attention and prompted a congressional hearing on pharmaceutical pricing. FTC, along with several states, subsequently brought a civil action against Shkreli, Vyera, and others alleging a web of anticompetitive agreements that delayed generic competition by obscuring the profitability of the drug and by making it virtually impossible for generic entrants to complete the steps necessary to obtain regulatory approval from the Food and Drug Administration (FDA). As a witness in this case put it, the price hike was "the poster child of everything that is considered wrong about the pharmaceutical industry."[1]

The court agreed and banned Shkreli from ever working in the pharmaceutical industry again and held him jointly and severally liable with the other defendants for $64.4 million in consumer redress. Consumer redress was possible despite the Supreme Court's decision in *AMG Capital Management v. FTC*[2] because this remedy was available under state law. Pursuant to a consent order entered into shortly before the trial, Vyera and its parent company were also required to make Daraprim available to any potential generic competitor at the list price and to provide prior notification of any planned pharmaceutical transaction valued at $25 million or more.

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* Bryant Godfrey is a partner at Foley Hoag LLP, where he advises FDA-regulated companies throughout the product lifecycle, including development, approval, labeling, advertising/promotion, post-marketing obligations, enforcement investigations, and regulatory strategy and compliance. Mr. Godfrey previously held several Senior Counsel positions with FDA where he advised on a range of issues relating to medical products and tobacco products. Tina Papagiannopoulos is a senior associate at Foley Hoag LLP, where she provides policy advice and counsels FDA-regulated clients on applicable regulatory and compliance requirements under the Federal Food, Drug, and Cosmetic Act, Public Health Service Act, and Federal Trade Commission Act.

1 FTC v. Shkreli, No. 20cv00707, 2022 U.S. Dist. LEXIS 7715, at *29 (S.D.N.Y. Jan. 14, 2022).

2 AMG Cap. Mgmt., LLC v. Fed. Trade Comm'n, 141 S. Ct. 1341, 1352 (2021).

These orders send the message that pharmaceutical companies engaging in anticompetitive exclusionary conduct could face severe monetary remedies under state law. In light of the strong public policy favoring generic competition, brand companies could also become subject to a duty to deal on certain terms with generic companies. The message is also clear that pharmaceutical executives can be held personally liable for conduct that delays generic competition and may even face a permanent injunction under certain circumstances.

DISCUSSION

The Federal Trade Commission (FTC) and the Attorneys General for seven states[3] (collectively, "the Government") filed an antitrust action in the U.S. District Court for the Southern District of New York against Martin Shkreli; Vyera Pharmaceuticals, LLC; its parent company, Phoenixus AG (collectively "Vyera"); and Kevin Mulleady, the former Vyera CEO, due to conduct involving the sale and distribution of Daraprim. Shkreli was the founder of Phoenixus and Vyera, the largest shareholder and former chairman of the board of Phoenixus, and the former CEO of Vyera. Mulleady and the corporate defendants entered into a consent order settling the claims against them shortly before trial. The case against Shkreli proceeded to trial and is the subject of the court's Opinion.[4]

Daraprim has been approved by FDA for the treatment of toxoplasmosis, a parasitic infection that can cause severe disease and death, since1958. The infection principally impacts immunosuppressed and immunocompromised individuals (e.g., patients who are HIV positive or are recipients of organ transplants). The most common and acute presentation of the disease among immunosuppressed patients is toxoplasma encephalitis. Patients that are diagnosed with toxoplasma encephalitis could die within twelve to twenty-four hours and there is a risk of severe brain damage in those who survive.

Pyrimethamine, the active pharmaceutical ingredient (API) in Daraprim, remains the only drug approved by FDA for the treatment of toxoplasmosis and is a key component in a treatment regimen that is highly recommended by clinical practice guidelines for acute toxoplasmosis. Until the entry of a generic pyrimethamine product in 2020, Daraprim was the only FDA-approved pyrimethamine product available in the United States.

For more than sixty years, Daraprim had been sold as an affordable, life-saving treatment for toxoplasmosis. In 2015, however, Vyera Pharmaceuticals, LLC acquired the U.S. rights to Daraprim from the only existing supplier and raised the wholesale acquisition cost (WAC) of the drug from $17.50 to $750 per tablet—an increase of more than 4,000%—within days of the acquisition. (After subtracting discounts, chargebacks, and rebates from the WAC, the average net price of Daraprim ranged between $228 and $305 per tablet from 2016 to 2019.) This caught the attention of health care providers, patients, and Congress.

According to the Government, Vyera was able to maintain these prices by implementing a strategy that involved a web of anticompetitive restrictions that delayed generic entry for years. First, Vyera implemented a closed distribution scheme

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[3] New York, California, Illinois, North Carolina, Ohio, Pennsylvania, and Virginia.

[4] *Shkreli*, 2022 U.S. Dist. LEXIS 7715.

that prevented potential generic entrants from obtaining samples of the drug needed for bioequivalence testing. Vyera also restricted access to the API by entering into exclusivity agreements with the API suppliers that prevented them from supplying generic potential competitors. Vyera also entered into agreements with two distributors to prevent them from releasing Daraprim sales data that would have revealed the true size of the market opportunity for generic competition.

DELAY OF GENERIC ENTRY

Background on Generic Entry Requirements

Several generic companies sought to obtain marketing authorization from FDA for a generic version of Daraprim pursuant to the abbreviated new drug application (ANDA) pathway under Section 505(j) of the FDCA.[5] An ANDA application must provide information to show, among other things, that the active ingredient(s), as well as the route of administration, dosage form, strength, and conditions of use of the new drug are the same as those of the previously approved drug (the "reference listed drug" or "RLD") and that the new drug is bioequivalent to the reference listed drug.[6] "Bioequivalence" is defined in the regulations as "the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives become available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study."[7] In other words, the generic version must demonstrate that it delivers the same amount of active ingredients into a patient's bloodstream in the same amount of time as the reference listed drug. In order to demonstrate bioequivalence, a company needs to perform bioequivalence testing comparing the two products using "the most accurate, sensitive and reproducible approach available," which can include a variety of in vivo and/or in vitro methods.[8] A generic company needs to be able to access sufficient quantities of the brand product to complete bioequivalence testing and to fulfill other relevant testing requirements (such as tests necessary to establish appropriate dissolution specifications) and/or regulatory requirements (such as requirements to retain reserve samples).

An ANDA submission also must include a section on the chemistry, manufacturing, and controls (CMC) established for the generic product which provides information related to the manufacture of the API. This section of the ANDA must include details about all intermediate and final drug substance manufacturing facilities as well as all research and development manufacturing and testing sites that generated data to support the application.[9]

As the court explained, the defendants entered into agreements with other parties or otherwise engaged in activities that created obstacles for the generic companies to fulfill these essential ANDA requirements and therefore delayed the entry of generic competition.

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[5] 21 U.S.C. § 355(j).

[6] 21 U.S.C. § 355(j).

[7] 21 C.F.R. § 314.3.

[8] 21 C.F.R. § 320.24.

[9] U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY, ANDA SUBMISSIONS—CONTENT AND FORMAT (June 2019), https://www.fda.gov/media/128127/download.

Vyera Blocked Access to the Distribution of Daraprim Needed for Bioequivalence Testing

Before Vyera's rights to market Daraprim were even finalized, the company converted the distribution of the drug from a retail model (which had been used for decades) into a closed distribution system and imposed restrictions in its distribution contracts to limit the types of customers who could buy the drug to government customers, hospitals, specialty pharmacies, and other specialized entities. Essentially, a distributor could not sell Daraprim to a retail pharmacy or a generic drug company without Vyera's approval.[10] Vyera's agreements with hospitals required the hospitals to limit their use of Daraprim to their own use and not resell the drug.[11] Vyera also imposed limits on the number of Daraprim bottles that a single customer could purchase at a time without Vyera's approval.[12] As the court pointed out, these restrictions were not required by FDA; they were not necessary for safety purposes; and the product did not require any special shipping, handling, storage, or administration.[13]

FDA will, under certain circumstances, require prescription drugs and biologics to develop and implement a Risk Evaluation and Mitigation Strategy (REMS), which may include distribution restrictions as an element to assure safe use (ETASU) of the product. In determining whether a REMS is necessary to ensure that the benefits of the drug outweigh its risks, FDA applies a number of factors set forth in Section 505-1 of the FDCA, which include (among other factors) the seriousness of any known or potential adverse events that may be related to the drug, the seriousness of the disease or condition that is to be treated with the drug, and the expected benefit of the drug.[14]

Some generic companies have initiated antitrust lawsuits alleging that brand companies were using a REMS distribution restriction as a pretext for restricting access to samples of the branded drug needed to conduct bioequivalence testing. Brand companies, in turn, have argued that they were under no duty to deal with their potential competitors. FTC has taken the position that a monopolist's refusal to sell to its potential competitors may, under certain circumstances, violate Section 2 of the Sherman Act and that the regulatory framework designed to encourage the introduction of generics could not function as Congress intended if generics were unable to access samples of brand products to conduct bioequivalence testing.[15]

Congress stepped in with the CREATES Act, which was enacted in December 2019 as part of the Further Consolidated Appropriations Act of 2020.[16] The CREATES Act established a private right of action for a generic company against a brand company that refuses to provide sufficient quantities of the product on "commercially

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[10] FTC v. Shkreli, No. 20cv00707, 2022 U.S. Dist. LEXIS 7715, at *31–37 (S.D.N.Y. Jan. 14, 2022).

[11] *Id.* at *34.

[12] *Id.* at *34–37.

[13] *Id.* at *32.

[14] Section 505-1(a)(1) of the FDCA (21 U.S.C. § 355-1(a)(1)).

[15] *See, e.g.*, Mylan Pharms., Inc. v. Celgene Corp., Federal Trade Commission's Brief as Amicus Curia, Case No. 2:14-CV-2094-ES-MAH (D. N.J. June 17, 2014); Actelion Pharms. Ltd. v. Apotex Inc., Federal Trade Commission's Brief as Amicus Curiae, Case No. 1:12-cv-05743-NLH-AMD (D. N.J. March 11, 2013).

[16] Further Consolidated Appropriations Act, 2020, P.L. 116-94 § 610, 133 STAT 3130 (Dec. 20, 2019), 21 U.S.C. 355-2.

reasonable, market-based terms."[17] If the covered product is subject to a REMS with ETASU, the generic company must first obtain an authorization from FDA to obtain sufficient quantities of the product, referred to as a "Covered Product Authorization (CPA)," and request the samples from the brand company before bringing an action.[18] A generic company does not need to obtain a CPA before requesting samples of a product that is not subject to a REMS. In addition to obtaining access to the samples, a generic company that prevails in litigation under the CREATES Act may be entitled to attorneys' fees, litigation costs, and civil monetary penalties.

In this case, Vyera was not subject to a REMS, but it instituted the closed distribution system and other distribution restraints expressly in order to delay generic entry. For example, Vyera's Director of Patient Access admitted that the quantity limits were imposed to make it harder for generics to obtain enough Daraprim "in order to copy the drug and compete with it."[19] Moreover, the company actively monitored the distribution of the product, investigated larger orders, and intercepted the distribution of the drug in instances where it seemed likely that the units would end up in the hands of a generic company. Mulleady at one point met with a pharmacy owner in a parking lot to repurchase bottles that were destined for a distribution company that supplies reference listed products for bioequivalence and clinical trials at twice the price the pharmacy paid for the bottles.[20]

Vyera Blocked Access to the API

Vyera also frustrated generic development by blocking access to the two most important manufacturers of the pyrimethamine API, Fukuzyu Pharmaceutical Company and RL Fine, through exclusive supply agreements. Fukuzyu had a drug master file (DMF) registered in the United States and was the API manufacturer that was referenced in Daraprim's new drug application (NDA). A DMF allows the holder to authorize one or more applicants or sponsors of an NDA or ANDA to incorporate by reference proprietary information contained in the DMF without having to disclose that information to the applicants or sponsors.[21] FDA customarily reviews the technical contents of DMFs only in connection with the review of applications that reference them. RL Fine had a DMF registered in Europe, but it had not yet filed a DMF in the United States for pyrimethamine.[22]

In 2017, Vyera entered into an exclusive contract with Fukuzyu for the purchase of pyrimethamine in the United States. The contract did not ensure that Vyera would have a reliable supply of the API or even require Fukuzyu to fill a single Vyera order, but rather the contract acted to bar Fukuzyu from selling the API to another company for the use, sale, or distribution of the product in the United States.[23]

Vyera also executed two contracts with RL Fine in 2017. Vyera entered into a Distribution and Supply Agreement that "gave Vyera 'the exclusive right to sell, distribute, and market' RL Fine's pyrimethamine for five years and limited RL Fine

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[17] *Id.* at § 610(b)(2)(A).

[18] *Id.* at § 610(b)(2)(B).

[19] FTC v. Shkreli, No. 20cv00707, 2022 U.S. Dist. LEXIS 7715, at *35 (S.D.N.Y. Jan. 14, 2022).

[20] *Id.* at *38–39.

[21] 21 C.F.R. § 314.420.

[22] *Shkreli*, 2022 U.S. Dist. LEXIS 7715, at *46.

[23] *Id.* at *44–45.

to selling pyrimethamine for use outside India only 'with the consent' of Vyera."[24] The Supply Agreement included a royalty payment to RL Fine of 7.5% of net revenues on Verya's sales of Daraprim, with a guaranteed minimum payment of $3 million. Vyera's obligation to make royalty payments above the guaranteed amount would terminate upon the entry of a generic pyrimethamine product in the U.S. market.[25]

In addition, Vyera entered into a Product Collaboration Agreement with RL Fine, whereby Vyera paid RL Fine $1 million towards expenses for research and development and preparation of a DMF. Vyera had previously estimated that the cost for RL Fine to prepare a DMF for pyrimethamine was less than $100,000.[26] Neither of these agreements required RL Fine to file a DMF with FDA or conditioned the payment on any milestones necessary to file a DMF, and RL Fine did not take any steps toward filing a DMF with FDA for pyrimethamine.[27] Vyera likewise never tried to obtain FDA approval to use RL Fine's API in Daraprim as a backup supplier.[28] According to the court, "In sum, Vyera received nothing in return for the millions of dollars it paid to RL Fine except the foreclosure of generic competitors' access to RL Fine's pyrimethamine."[29] Indeed, once it signed the Supply Agreement, RL Fine stopped supplying pyrimethamine to two generic drug manufacturers.[30]

Vyera Blocked Access to Sales Data

The court's opinion describes in detail how the two types of vertical restraints described above "exploited features of the FDA approval process for generic drug products by unreasonably and unlawfully restricting the markets for RLD and API" and effectively delayed the entry of generic Daraprim.[31] The Government also proved at trial that data-blocking provisions in Vyera's contracts with its distributors prevented generic companies from receiving accurate information about Daraprim sales.[32] According to the complaint, the purpose of these provisions was 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."[33] The court, however, did not explore this element of the Government's claim in depth because it found that the lack of data did not actually impede the eventual entry of two generic companies.[34]

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[24] *Id.* at *49.

[25] *Id.* at *49–51.

[26] *Id.* at *46–49.

[27] *Id.* at *50.

[28] *Id.*

[29] *Id.*

[30] *Id.* at *49.

[31] *Id.* at *98–99.

[32] *Id.* at *98 n. 35.

[33] Redacted Amended Complaint for Injunctive and Other Equitable Relief, FTC v. Shkreli, No. 20cv00707 (S.D.N.Y. Apr. 16, 2020), ECF No. 91, at ¶7.

[34] *Shkreli*, 2022 U.S. Dist. LEXIS 7715 at *98 n.35.

VIOLATION OF ANTITRUST LAWS

The court found Shkreli liable for Vyera's unreasonable restraint of trade and monopolization of the FDA-approved pyrimethamine market in violation of Sections 1 and 2 of the Sherman Act and that his conduct also violated the competition laws of each of the plaintiff states.[35]

The restrictive distribution contracts for Daraprim and exclusive supply agreements for the API constituted unreasonable restraints of trade in violation of Section 1, which prohibits "every contract, combination . . . , or conspiracy, in restraint of trade or commerce among the several States."[36] Most vertical restraints of trade are analyzed under the rule of reason, which requires an analysis of any procompetitive benefits of the restraint and the competitive characteristics of the relevant market. Exclusive dealing arrangements can implicate Section 1 when they exclude competitors or new entrants from a necessary input or when they allow a supplier to deprive other suppliers of a market for their goods.[37] For exclusive dealing to violate Section 1, the agreement must exclude "a significant fraction of buyers or sellers from the market."[38] The court found Shkreli's proffered justifications for these distribution and supply agreements pretextual.

The court also found that through these agreements, Shkreli and Vyera unlawfully and willfully maintained a monopoly in the relevant market through anticompetitive conduct in violation of Section 2 of the Sherman Act, which makes it unlawful to "monopolize, or attempt to monopolize . . . any part of the trade or commerce among the several States."[39] A claim under Section 2 requires a plaintiff to establish "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident."[40] The court had no trouble concluding that Vyera had a monopoly in the market for FDA-approved pyrimethamine market, as evidenced by the company's ability to raise the price to an astronomical level, and that it maintained that monopoly power through the absence of competition and not because it possessed a superior product or business acumen.[41]

Shkreli was found to be personally liable for Vyera's conduct due to the control he exercised over the company. The court characterized Shkreli as the "prime mover in this anticompetitive scheme," which the court explained was Shkreli's "brainchild" that he drove "each step of the way."[42] The opinion describes several instances where Shkreli specifically directed the activities at issue in the case, even in the midst of serving a prison sentence for an unrelated violation of the Securities and Exchange

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[35] *Id.* at *98.

[36] 15 U.S.C. § 1.

[37] *Shkreli*, 2022 U.S. Dist. LEXIS 7715 at *89, citing Geneva Pharms. Tech. Corp. v. Barr Lab'ys Inc., 386 F.3d 485, 508 (2d Cir. 2004).

[38] *Id.*

[39] 15 U.S.C. § 2.

[40] *Shkreli*, 2022 U.S. Dist. LEXIS 7715 at *90, citing United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Takeda Pharm. Co. Ltd., 11 F.4th 118, 137 (2d Cir. 2021) (quoting United States v. Grinnell Corp., 384 U.S. 563, 570–71, 86 S. Ct. 1698, 16 L. Ed. 2d 778 (1966)).

[41] *Id.* at *99–108.

[42] *Id.* at *133.

Act. Shkreli was also described as being the mastermind of the scheme, having launched Vyera with a plan to "acquire sole-source drugs that were the gold standard treatment option for life-threatening diseases with a small patient population and inferior alternative treatments, with the intent to raise their prices, block generic competition, and reap extraordinary profits."[43] According to the court, Shkreli "road-tested" the strategy of acquiring sole source orphan drugs, creating a closed distribution system, and raising the drugs' prices at his previous firm, Retrophin, and later touted this experience to Vyera investors.[44]

REMEDIES

The consent order requires Vyera and Phoenixus to pay up to $40 million total in equitable monetary relief and to make Daraprim available to any potential generic competitor at list price. The companies must also provide FTC with prior notification of any planned pharmaceutical transaction valued at $25 million or more.[45] The consent order also subjects Mulleady to a suspended judgment of $250,000 in equitable monetary relief and prohibits him from engaging in certain activities on behalf of a pharmaceutical company for seven years. Mulleady, Vyera, and Phoenixus also are prohibited for ten years from entering into any contract that, with certain exceptions, restricts the ability of 1) any purchaser to provide a drug product to a generic company for the purpose of developing a generic version of that product; 2) any manufacturer or distributor of an API to sell or provide that API to a pharmaceutical company; or 3) any distributor, wholesaler, pharmacy, or group purchasing organization to provide sales or distribution data to a data aggregator.

Personal Liability for Shkreli

The court order against Shkreli bans him for life from the pharmaceutical industry. While the court acknowledged that banning an individual from an entire industry is a serious remedy, the court found that "Shkreli's egregious, deliberate, repetitive, long-running, and ultimately dangerous illegal conduct warrants imposition of an injunction of this scope."[46] The court pointed to Shkreli's pattern of conduct at Retrophin and Vyera and his utter lack of remorse, characterizing the Daraprim scheme as "particularly heartless and coercive," since the drug must be administered within hours to patients with acute toxoplasma encephalitis.[47]

The order against Shkreli also awards disgorgement to the states in the amount of $64.6 million, which it calculated by determining the excess profits based upon the hypothetical dates on which two generic drug companies would have entered the market but for Vyera's anticompetitive conduct. The court estimated that the defendants' actions caused one of the generic companies a thirty-month delay and the other company a twenty-four-month delay. Because Shkreli was the person principally responsible for the conduct, the court found him jointly and severally liable for the full

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[43] *Id.* at *23.

[44] *Id.* at *20–25.

[45] Joint Motion for Entry of Stipulated Order for Permanent Injunction, FTC v. Shkreli, No. 20cv00707 (S.D.N.Y. Dec. 7, 2021), ECF No. 753.

[46] *Shkreli*, 2022 U.S. Dist. LEXIS 7715 at *124–25.

[47] *Id.* at *125–26.

amount of the disgorgement, to be offset by any amounts paid by the settling defendants.[48]

IMPACT

The case illustrates that restrictive pharmaceutical distribution systems, particularly in the absence of any safety risk, can be considered anticompetitive if they are intended to delay the entry of generic products. The strong public policy favoring generic competition may create a duty to deal in this industry that is far more compelling than the general presumption in antitrust doctrine that a company has no duty to deal with its competitors. Even when the distribution system is restricted as a REMS element due to a legitimate safety risk, FTC has argued, and Congress has made clear, that a reference listed drug product must still make its drug available to a prospective generic entrant on commercially reasonable terms for the purpose of conducting the necessary testing to support an ANDA.

This case also provides a prime example of FTC's ability to coordinate with state enforcers to maximize the relief available to consumers. The cooperation among the federal and state enforcers allowed the agencies to obtain disgorgement relief despite the Supreme Court's ruling in the *AMG Capital Management* case. As a result, disgorgement is still on the table as a potential remedy when there is a joint enforcement action involving certain states.

Finally, this case should serve as a reminder that pharmaceutical executives can and will be held personally liable for their company's actions, particularly when they direct or control the anticompetitive conduct at issue in the case. To be sure, Shkreli's brazen conduct and the egregiousness of the price hike sealed his fate. While few would dare to act as shamelessly as Shkreli did, the prospect of personal liability should deter executives from directing companies under their control to engage in exclusionary conduct, especially if such conduct would result in supracompetitive pricing of a critical therapy.

[48] *Id.* at *128–35.