CPI's North America Column Presents:

Turing the Screws on Illegal "Comprehensive Schemes": The FTC and States' Bold Complaint Regarding Daraprim

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On January 27, 2020, the Federal Trade Commission ("FTC") and the State of New York ("NY AG") (collectively "Plaintiffs") filed a Complaint against Phoenixus AG and Vyera Pharmaceuticals, LLC (collectively "Turing"), Martin Shkreli, and Kevin Mulleady. On April 14, 2020, Plaintiffs filed an amended Complaint, adding the states of California, Illinois, North Carolina, Ohio, and the commonwealths of Pennsylvania and Virginia.[2] Plaintiffs allege an anticompetitive scheme to prevent generic versions of pyrimethamine (brand name Daraprim®) from launching. Specifically, Plaintiffs allege that Defendants are preventing generic manufacturers from launching by: (1) restricting sales of reference listed drug samples to generic manufacturers by instituting a restricted distribution program with distributors, (2) restricting sales of pyrimethamine API to generic manufacturers, and (3) agreeing with distributors to withhold sales data to prevent generic manufacturers from having a sense of Daraprim's financial viability.

As background, pyrimethamine was approved in 1953 and is still the recommended first line treatment for toxoplasmosis, a condition that requires treatment primarily in immunocompromised patients, notably among patients with HIV/AIDS. Before Turing acquired this product, Daraprim cost approximately $1 per tablet in 2010 and $13.50 per tablet in 2015. The Complaint states that Impax, the previous owner of the rights to Daraprim, considered a larger price increase for Daraprim but "rejected the idea due to concern about a public backlash from the AIDS community." In August 2015, Impax sold the rights to Daraprim to Turing. Upon acquiring Daraprim, Turing increased prices to $750 per tablet. This price increase resulted in an immediate and vociferous public backlash against Shkreli and Turing.

The Complaint

Plaintiffs allege an illegal, three-part scheme by the Defendants to monopolize the market for Daraprim.

Turing Allegedly Restricts Distribution to Prevent Generic Manufacturers from Acquiring Samples

First, Turing allegedly "created a complex web of contractual restrictions" with distributors, preventing them from selling the Daraprim samples to generic manufacturers or their agents. These samples would be necessary for any generic to conduct the FDA-required bioequivalence testing for a generic product launch. Turing allegedly limits each distributor's sales to pre-approved customers and requires Turing's direct approval for any other sales. Specifically, Turing allegedly uses a third-party logistics provider, ICS, to distribute Daraprim. ICS is allegedly only permitted to provide Daraprim to four approved distributors and cannot sell to generic companies. These four distributors are also only permitted to sell Daraprim to specific customers and not to generic companies. For example, ASD Healthcare, one of the four approved distributors, is allegedly only permitted to distribute Daraprim to hospitals or government purchasers. Additionally, the Complaint alleges that Turing requires distributors to enter

agreements with their customers not to resell Daraprim. Turing entered into similar contracts directly with hospitals and pharmacies.

Although somewhat reminiscent of a Risk Evaluation and Mitigation Strategy ("REMS") program, which the FDA may require for certain products with safety concerns, the Complaint expressly distinguishes Turing's conduct, explaining that "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."

Turing Allegedly Prevents Generic Manufacturers from Acquiring Daraprim API

Second, Turing allegedly prevented generic manufacturers from dealing with the only FDA-approved manufacturer of pyrimethamine API and agreed with another manufacturer to, effectively, not sell pyrimethamine in the United States. At the time of Turing's acquisition of Daraprim, there were only two FDA-approved API suppliers. However, one of the suppliers was subjected to an import ban several months before Turing's acquisition. This left the other manufacturer, Fukuzyu, as the sole remaining authorized API supplier. In 2017, Fukuzyu allegedly agreed with Turing not to sell pyrimethamine to anyone other than Turing for human use in the United States. At least two generic manufacturers were allegedly rebuffed by Fukuzyu.

Separately, Turing learned that another API supplier, RL Fine Chem, was preparing to sell pyrimethamine API in the United States, as it had for years in Europe. The Complaint alleges that Turing entered into an exclusive supply agreement with RL Fine Chem to prevent it from supplying API to generic manufacturers. The parties also allegedly entered into a product collaboration agreement that neither party "subsequently took any steps to develop." RL Fine also allegedly agreed to stop supplying pyrimethamine to two generic companies. Turing has continued to pay RL Fine for exclusive rights even though Turing could not actually use RL Fine's API to produce Daraprim under its FDA approval. Since entering this agreement, RL Fine has not sold pyrimethamine in the United States.

The Complaint also alleged that other manufacturers were not able to reliably create pyrimethamine to provide alternative channels for generic manufacturers to acquire API. Instead, a separate manufacturer would have to develop a new production system from scratch, which would take substantial time and investment.

Turing Allegedly Restricts Distribution of Sales Data

Finally, Turing and distributors allegedly agreed to withhold data from companies like IQVIA (formerly known as IMS) to block generic manufacturers' access to sales data. Turing allegedly paid a "data restriction fee" in exchange for not releasing this information. In 2018, the FDA asked Turing why IQVIA sales data seemed low. Turing employees allegedly determined that the low sales figures "likely related to the business decision [Turing] made to block dispense/sales data reported by [its] distribution partners." The Complaint alleges that at least one generic company did not develop generic Daraprim due to the lack of reliable data.

Anticompetitive Effects

The Complaint alleges that an unidentified generic manufacturer ("Company A") attempted to develop a generic pyrimethamine product in 2013. To conduct its bioequivalence testing, Company A successfully purchased Daraprim samples from a pharmacy in New Jersey. In early 2016, Company A allegedly contacted Fukuzyu to manufacture pyrimethamine API for its generic Daraprim product. Initially, Company A agreed to purchase over ten times more API than it needed to meet Fukuzyu's minimum purchase size. About six months after agreeing to supply Company A, Fukuzyu allegedly reneged on the deal. It was around the same time that Fukuzyu allegedly entered into an agreement with Turing restricting Fukuzyu from selling pyrimethamine to generic manufacturers. Company A tried to find a back-up supplier but was allegedly unable to do so, despite contacting over twenty wholesalers as well as hospitals and pharmacies.

A second unidentified generic manufacturer ("Company B") purchased six bottles of Daraprim from a local pharmacy when Daraprim was still available through traditional channels. The Complaint alleges that "[Company B] did not sign any liability waivers or enter any indemnification agreements." Company B later submitted an abbreviated new drug application ("ANDA"). The ANDA was eventually rejected when an unnamed API manufacturer said it would no longer support the ANDA, and that Company B would have to procure new a API source, and that Company B would have to redo its bioequivalence testing. Company B then attempted to have a new API manufacturer produce pyrimethamine, further delaying its launch.

A third unidentified generic manufacturer ("Company C") attempted to purchase API from Fukuzyu, both by itself and via an intermediary. Similarly, Company C did not succeed. Allegedly, at Turing'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.'" Company C also tried to purchase Daraprim from wholesalers specializing in drug samples, but failed. The Complaint alleges that Turing required onerous indemnification terms from one wholesaler and prevented another from making a sale by initiating an inventory buy-back instead.

A fourth generic manufacturer ("Company D") also attempted to develop generic Daraprim but could not find accurate sales information due to the lack of IQVIA data. Additionally, multiple suppliers allegedly told Company D they could not provide samples, stating that their inventories were "for inpatient hospitals only." Company D ultimately abandoned this project because of its "inability to get a real sense of Daraprim's sales because the product was no longer reported in [IQVIA]."

Similarly, a fifth generic manufacturer ("Company E") tried to purchase pyrimethamine from several wholesalers but was unable to procure supplies after Turing allegedly twice told ASD Healthcare to "NOT fulfill this order/request." Other suppliers, including Myoderm and Low Cost RX, also indicated they could not provide samples.

Finally, Cerovene launched generic Daraprim on February 28, 2020. Dr. Reddy's (which distributes Cerovene's product) announced "it had launched Cerovene's generic pyrimethamine in the United States after a 'seven years' journey,'" implying Turing's conduct resulted in a multi-year delay before this product launched.

The Complaint states that the alleged foreclosure of generic competitors resulted in Daraprim prices remaining supracompetitive since at least 2018, when the first generic would have otherwise entered. This has allegedly resulted in hospitals purchasing less Daraprim, causing at least one patient to die from complications arising from a prolonged hospital stay.

Ex Post Facto Defense

According to media reports, Defendants argued that the FDA's recent approval of a generic Daraprim ANDA undermines the complaint's allegations of input foreclosure. Furthermore, Defendants contend that exclusive API supply agreements are common, and that the antitrust laws do not prohibit a manufacturer from restricting its customers' sharing and publication of sales data. These arguments are expected to be developed in the motion to dismiss, which is currently scheduled to be submitted on May 22, 2020.

However, at this preliminary stage, we observe that it appears insufficient to argue that there was no absolute foreclosure given that delayed generic entry caused by delays in obtaining brand drug samples can still constitute anticompetitive effect. As for the exclusive API supply agreements, Defendants will need to address the specific facts alleged in the complaint, such as the allegation that Turing continued to pay at least one API supplier for exclusivity despite its inability to actually use the supplier's API under its FDA approval. Finally, Defendants may have to address the "monopoly broth" theory (i.e., consideration of the effects of all components of the alleged scheme together), a theory which has been generally accepted by the courts.

Relief Sought

Plaintiffs allege that Defendants' conduct violated Section 1 of the Sherman Act, Section 2 of the Sherman Act, Section 5(a) of the FTC Act's prohibition on unfair methods of competition, state antitrust and unfair competition laws, and New York Executive Law § 63(12). Plaintiffs seek to enjoin the conduct, enjoin Shkreli and Mulleady from owning or working for a pharmaceutical company, and seek "such other equitable relief, including equitable monetary relief, as the Court finds necessary to redress and prevent recurrence of Defendants' violations." Additionally, the states are seeking civil penalties and forfeitures under their respective laws.

FTC Concurrences

Commissioners Slaughter and Chopra concurred with the complaint but also called for a standalone count alleging violation of the prohibition on unfair acts or practices under Section 5 of the FTC Act. Commissioner Slaughter in particular opined that Defendants' "conduct — dramatically increasing the price while also taking actions to prevent competition — undoubtedly

satisfies the elements of our long-standing law that prohibits unfair acts or practices," but also clarified that her position "is not simply about condemning price increases alone."

Significance

This Complaint marks a significant development in antitrust enforcement.

First, this Complaint signals government enforcement interest at the federal and state levels regarding anticompetitive measures throughout the development and supply chain in the pharmaceutical space and willingness to investigate and ultimately challenge these practices. The FTC's investigation of the facts, from API supply to IQVIA reporting demonstrates government interest in pursuing broad conduct like that of Turing's here, and the deployment of a "monopoly broth" allegation could portend future enforcement premised on such misconduct. This Complaint marks the FTC's first ever action based upon a restricted distribution system in the small molecule space.

Second, the Complaint highlights the FTC's and states' evolving roles and expanding cooperation in the healthcare space and the pharmaceutical industry especially. This coordination may be a result of the wider scope of remedies that are available under state law rather than under the FTC Act, as some states, including New York, provide for monetary penalties.

Third, the FTC has rarely named individual defendants in a competition case where the allegation is a not a typical *per se* violation such as price fixing or group boycott. Instead, the FTC more frequently brings actions against individuals in consumer protection cases. In addition to naming individuals as defendants here, this is also one of the first cases where the relief sought includes a lifetime ban on working in the industry.

Finally, the claims appear to indicate that the FTC is unlikely to use Section 2 to fight price increases absent some wrongful conduct to allow or maintain the elevated prices. This is consistent with Commissioner Slaughter's remark on this issue in her concurring statement.

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[2] The Amended Complaint can be accessed at the FTC's website: https://www.ftc.gov/system/files/documents/cases/161_0001_vyera_amended_complaint.pdf.