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INTRO

The US Department of Justice's (DOJ) Antitrust Division (Division) has continued to actively investigate and pursue alleged criminal violations of antitrust laws and collusive activity in government procurement. US Attorney General Merrick Garland noted in a March 2022 speech at the ABA Institute on White Collar Crime that the Division ended last fiscal year "with 146 open grand jury investigations—the most in 30 years." As we near the end of the first quarter of 2022, the Division has a record number of criminal cases either in trial or awaiting trial.

In this installment of Cartel Corner, we examine and review recent and significant developments in antitrust criminal enforcement and profile what the Division has highlighted as its key priorities for enforcement. For 2022 and beyond, those priorities are—and likely will remain—identifying and aggressively pursuing alleged violations involving the labor markets, consumer products, government procurement and the generic pharmaceutical industry.

Attorney General Merrick B. Garland Remarks to the ABA Institute on White Collar Crime, Thursday, March 3, 2022, https://www.justice. gov/opa/speech/attorney-general-merrick-b-garland-delivers-remarks-aba-institute-white-collar-crime



LABOR MARKETS

Criminal investigations and prosecutions in the labor markets continue to be a top priority for the Division. Such enforcement has been gaining momentum since the Division and the Federal Trade Commission (FTC) issued their joint *Antitrust Guidance for Human Resources Professionals* in 2016 which warned that the DOJ—for the first time—intended to proceed criminally against "naked wage-fixing or no-poach agreements" between horizontal employers. That momentum lifted off in December 2020 and continued throughout 2021, with the Division bringing 12 criminal cases against nine individuals and three companies. Alleged wage-fixing and no-poach agreements have historically been prosecuted in the civil context, meaning fines for companies and individuals.

Several recent developments are worth highlighting. First, in November 2021, a federal court determined *for the first time ever* that an alleged wage-fixing conspiracy could constitute a *per se* criminal violation of the Sherman Act. In *U.S. v. Jindal*, the Division alleged that two former executives of a physical therapist staffing company fixed the wages paid to physical therapists in the Dallas-Ft. Worth area. In denying the defendant's motions to dismiss, a federal judge in the US District Court for the Eastern District of Texas determined that courts have not limited price-fixing conspiracies to the purchase and sale of goods but have also found them to cover the purchase and sale of services. The court continued, noting that buyers of services included employers in the labor market and that the alleged wage-fixing agreement was another form of price fixing.

Second, the DOJ's aggressive posture in these cases continued in January 2022 when it charged four home healthcare staffing company owners with allegedly fixing workers' wages and agreeing not to hire each other's workers in 2020.

Third, until recently, each of the criminal charges brought by the DOJ have involved healthcare companies. The ability of the DOJ to criminally prosecute alleged non-solicit agreements is being challenged, where motions to dismiss are pending. However, in December 2021, the Division expanded its reach into the aerospace industry, charging a former government contractor and five employees of its suppliers for alleged allocation agreements relating to the hiring of engineers (*U.S. v. Patel et al.*). The DOJ's indictment alleges that one of the defendants agreed with suppliers to allocate employees by restricting hiring and recruiting between the companies for almost a decade.

The increased focus and enforcement action relating to labor markets underscores the Biden administration's stated priorities. For example, in July 2021, President Biden issued an Executive Order "Promoting Competition in the American Economy" which provided wide-ranging guidance and instructions to the federal government to promote and increase competition. One specific, identified initiative involved strengthening of guidance to prevent employers from collaborating to suppress wages, reduce benefits or engage in other anticompetitive practices. With the recent flurry of criminal labor market charges; repeated statements by the Division to the effect that protecting competition in the labor markets continues to be a top priority; the Division's hosting of a joint workshop with the FTC in December 2021, titled "Making Competition Work: Promoting Competition in the Labor Markets"; and widespread support from the Biden administration, one can expect the Division's focus on criminal enforcement in the labor markets to be an increasing refrain.

TAKEAWAYS

The DOJ's novel and aggressive stance on expanding Sherman Act criminal violations to include the ways in which companies engage with their workers may not ultimately be sustained by trial or appellate courts. For now, however, the DOJ remains determined to investigate and prosecute alleged "wage-fixing and no-poach" issues.

With the DOJ's resolute approach changing the landscape of antitrust labor market cases, companies would be prudent to ensure that their compliance programs are up to date and include specific and appropriate guidance on these issues. When considering typical antitrust cartel investigations, the focus has traditionally been on alleged conspiracies relating to pricing, sales, and/or bidding of certain products or in certain geographic areas. The DOJ's changing attitude toward labor market antitrust issues is a notable shift and may be directed at entirely different segments of a corporate business, including human resources and hiring, in any industry. To address the DOJ's assertive approach, employers involved in hiring and compensation-related decisions would be well served to receive training addressing these potential antitrust issues.

CONSUMER PRODUCTS

Consumer products have recently been a hotbed of DOJ investigations for antitrust violations. The DOJ has several long-running investigations into a wide range of industries, including broiler chickens, commercial flooring and, most recently, DVDs and Blu-Rays in e-commerce. The latest developments in these investigations reflect the DOJ's continued, and increasingly heightened, focus on prosecuting companies and high-ranking executives engaged in alleged anticompetitive conduct that directly affects American consumers.

BROILER CHICKENS

The DOJ's first trial in its ongoing investigation into the \$95 billion broiler chicken industry resulted in a hung jury. The lengthy trial began in October 2021, in Denver, against 10 current and former executives from major broiler chicken producers (and came on the heels of a guilty plea obtained by the DOJ earlier in 2021 in a price-fixing case against Pilgrim's Pride Corp (Pilgrim's Pride), which resulted in a \$107 million criminal fine). The DOJ alleged that the defendants engaged in an overarching price-fixing and bid-rigging scheme for approximately a decade. But after seven weeks of trial, including four days of deliberation, the jurors remained deadlocked, resulting in the judge declaring a mistrial. The result highlights the challenge facing the DOJ in meeting its burden of proof on an alleged conspiracy based largely on documents and without cooperating witnesses.

After the mistrial, the defendants asked the court for a judgment of acquittal. The judge denied that request, and a retrial in the case began in late February 2022. Additionally, the DOJ has other cases in the pipeline in the same long-running investigation, including against broiler-chicken producers Claxton Poultry Farms and Koch Foods, Inc., as well as criminal charges against four additional former Pilgrim's Pride executives. Trials for those additional corporate and individual defendants are set for October 31, 2022, and July 18, 2022, respectively.

In a related civil action, a federal judge in Illinois gave final approval for a \$181 million settlement between six poultry producers and end-user consumers who claimed the companies conspired to fix broiler-chicken prices. The deal was reached between the consumer plaintiffs and Peco Foods, Fieldale Farms, George's, Tyson Foods, Pilgrim's Pride and Mar-Jac Poultry. Consumers are still pursuing claims against 12 additional poultry companies.

Going forward, the DOJ indicated it will prioritize and pursue more matters that impact competition in agriculture. In fact, the DOJ and the Department of Agriculture (USDA) recently issued a joint statement on their shared commitment to effectively enforcing federal competition laws that protect farmers, ranchers, and other agricultural producers and growers from unfair and anticompetitive practices. As part of their effort to step up enforcement in the agriculture sector, the agencies launched farmerfairness.gov, a new online tool that allows farmers and ranchers to anonymously report potentially unfair and anticompetitive practices in the livestock and poultry sectors. If, after a preliminary review, a complaint raises sufficient concern under antitrust laws, it will be selected for further investigation, and may lead to the opening of a formal investigation.

One area to watch is the cattle civil antitrust litigation. While the DOJ is still in the investigation stage, direct purchaser plaintiffs filed a civil lawsuit against the Big Four meatpacking companies, accusing them of conspiring to drive up the price of beef to make bigger profits by suppressing slaughter volumes and constraining the supply of meat. On February 1, 2022, the proposed class of direct buyers reached a \$52.5 million deal with one of the Big Four defendants JBS USA (JBS), which provided both monetary relief to the class, and JBS's "extensive cooperation" in the buyers' ongoing litigation against the three remaining non-settling defendants. The settlement is currently before the US District Court for the District of Minnesota awaiting preliminary approval. It will be interesting to see what next steps the DOJ will take considering the civil litigation, particularly the evidence that will be provided by JBS's cooperation.

COMMERCIAL FLOORING

Another long-running bid-rigging investigation in the commercial flooring industry resulted in additional indictments last year, as well. To date, the DOJ has indicted three companies and six individuals, including Mr. David's Flooring International LLC (Mr. David's), a Chicago-based commercial flooring contractor that pleaded guilty in August 2021. Like the first two companies that the DOJ charged, Mr. David's was charged for conspiring with other companies—for at least eight years, from 2009 to 2017—to rig bids for commercial flooring by agreeing which company would win the bid and which would submit a complementary, intentionally losing bid. The DOJ also charged Mr. David's with money laundering for allegedly concealing kickback payments the company made, in exchange for unauthorized discounts, to an account executive for a large flooring manufacturer.

As part of its guilty plea, Mr. David's agreed to pay at least a \$1.2 million criminal fine for its role in the conspiracies. This follows guilty pleas that the DOJ obtained from PCI FlorTech, Inc., in 2019 and Vortex Commercial Flooring in 2020, which resulted in a \$150,000 criminal fine and \$1.4 million in fines and restitution, respectively.

DVDS AND BLU-RAYS

With the expansion of e-commerce, the DOJ has also been active in prosecuting price-fixing conspiracies for consumer goods in online marketplaces. In 2021, the DOJ charged four individuals, one in June and three in November, with conspiring to fix prices of DVDs and Blu-Ray discs sold through an online marketplace. According to the charges, between November 2017 and October 2019 the defendants agreed to raise and maintain the prices of DVDs and Blu-Ray discs sold in the marketplace's storefronts, the business addresses of which were located in five different states. The affected sales to customers throughout the United States by the four defendants ranged between \$360,000 to \$1,100,000. Each of the defendants have pleaded guilty. While the affected sales pale in comparison to large-scale matters like broiler chickens, the DOJ has shown equal willingness to aggressively pursue alleged collusive conduct in smaller and emerging sectors, particularly in online marketplaces.

TAKEAWAYS

Given the long-running nature of the investigations involving broiler chickens and commercial flooring, the change in the US presidential administration seems to have only increased the DOJ's scrutiny into industries affecting consumer goods. Looking ahead, consumer products will likely remain one of the DOJ's top priorities. Indeed, while the Biden administration recognizes the strain the pandemic has put on supply chain issues, resulting in higher prices in consumer goods, the White House has also placed the blame on "another culprit": "dominant corporations in uncompetitive markets taking advantage of their market power to raise prices."

The DOJ recently announced an initiative to deter, detect and prosecute those who would exploit supply chain disruptions to engage in collusive conduct. As part of that initiative, the DOJ is prioritizing any existing investigations where competitors may be exploiting supply chain disruptions for illicit profit and is undertaking measures to proactively investigate collusion in industries particularly affected by supply disruptions. The DOJ is also working with authorities in other countries to detect and combat global supply chain collusion.

Those who work in the consumer goods space can expect additional scrutiny and enforcement from the DOJ in the months and years to come, especially in industries that have experienced higher consumer price increases. It is therefore important to have robust compliance programs, including appropriate employee training, in place to address and provide guidance on these issues.

PROCUREMENT

The DOJ's Procurement Collusion Strike Force (PCSF)—an interagency partnership established in November 2019 to combat antitrust crimes and related fraud involving government procurement and funding—remained a top priority for the Division in 2021. Since its inception in 2019, the PCSF has significantly expanded in scope. The strike force now has offices in 22 federal districts staffed with DOJ trial attorneys, assistant US attorneys and agents from seven national law enforcement partner agencies. The PCSF has trained more than 17,000 special agents, attorneys, prosecutors, investigators, analysts, auditors, data scientists and procurement officials. In addition, in the spring of 2021 the PCSF announced the creation of PCSF Global. The goal of PCSF Global is to build connections with enforcement counterparts around the world and to investigate and prosecute collusion in procurement relating to US government funds spent overseas. The PCSF currently has almost three dozen investigations open domestically and internationally.

Below are a few key highlights from 2021:

PCSF'S RECENT WORK

On October 13, 2021, PCSF Director Daniel Glad delivered a speech recapping the strike force's recent work and highlighting enforcement priorities, including "set-aside fraud" and collusion targeting infrastructure spending. Set-aside fraud refers to collusion and fraud affecting government programs that are designed to provide opportunities for disadvantaged communities and individuals to participate more fully in public procurement. Glad highlighted the PCSF's recent investigation into set-aside fraud involving construction contracts in San Antonio. The director also commented that infrastructure will continue to be a focus for the PCSF as federal spending for infrastructure increases. Glad added that while the Sherman Act is the PCSF's "lodestar," the strike force's focus includes prosecuting other crimes that also corrupt the competitive process for obtaining government contracts and funding.

BELGIAN SECURITY SERVICES

On June 25, 2021, a Belgian security services company, G4S Secure Solutions NV (G4S), pled guilty for its role in a conspiracy to rig bids, allocate customers and fix prices for contracts with the US Department of Defense and with the NATO Communications and Information Agency (NCI Agency) to provide security services for military bases and installations in Belgium. The NCI Agency is funded in part by the United States. This was the first international resolution obtained by the PCSF, as well as the PCSF's first charged matter.

The DOJ alleged that G4S participated in a conspiracy with two competitors to coordinate price increases, submit artificially determined, non-competitive bids and refrain from bidding for certain contracts from spring 2019 through summer 2020. The DOJ further alleged that the conspirators colluded during in-person meetings and via phone, text messages, encrypted messaging applications and email. G4S agreed to pay a \$15 million criminal fine. In October 2021, two former employees of G4S also pled guilty to charges relating to the same conspiracy. Both individuals are Belgian nationals residing in Belgium.

The investigation demonstrates that the PCSF is focused on conspiracies that victimize the US government, whether the conspiracies or government activities are based in the United States or abroad. The PCSF remains committed to actively investigating and prosecuting companies and individuals based outside of the United States, such as the defendants here, who distort the competitive process for US government contracts.

NORTH CAROLINA ENGINEERING

In June 2021, a North Carolina engineering firm pled guilty to conspiring to rig bids and defraud the North Carolina Department of Transportation (NCDOT). Contech Engineered Solutions LLC and Brent Brewbaker, one of its former executives, had been indicted in October 2020. They were charged with six counts of bid rigging, conspiracy to commit fraud, mail fraud and wire fraud. The conspiracies, reaching back to at least 2009, involved water drainage systems projects. Contech agreed to pay a criminal fine of \$7 million and approximately \$1.5 million in restitution to the NCDOT. On February 1, 2022, Brewbaker was convicted by a jury of all six charged counts.

Contech argued that the conspiracy was not a *per se* violation because Contech and Pomona Pipe Products, its co-conspirator, competed vertically: Contech as the supplier, Pomona Pipe as the reseller. The district court disagreed, holding that Contech and Pomona held themselves out to NCDOT as competitors and, as such, this was bid-rigging subject to the *per se* analysis.

This matter is precisely the type of case the PCSF was designed to investigate. The PCSF trains law enforcement officers, procurement officials and others across the country "to better deter and detect antitrust crimes affecting government procurement, grant, and program funding." With more government funding earmarked for infrastructure and an increased budget for the Antitrust Division, the PCSF is likely to increase its footprint at all levels of government.

MINNESOTA CONCRETE

In September 2021, Minnesota concrete contractor Clarence Olson pled guilty to a bid-rigging charge. Olson and his co-conspirators conspired to rig bids on concrete repair and construction contracts submitted to at least four municipalities in Minnesota, including local governments and school districts in the Minneapolis-St. Paul area. The conspiracy began as early as September 2012 and continued through at least June 2017. Minnesota law required that municipalities obtain two or more quotations from independent bidders before awarding contracts above a certain threshold. According to the plea agreement, at a competitor's request Olson submitted bid quotes with prices higher than that of the competitor to ensure that Olson would lose the bid.

RISKS BEYOND PRISON AND FINES

Charges of bid rigging and procurement fraud can have collateral consequences beyond criminal liability. Companies and individuals are subject to state and federal suspension and debarment procedures. A suspension temporarily prevents a company from government contracting and typically lasts until the investigation or subsequent legal proceedings have terminated. If a company pleads guilty or is convicted, it may be debarred—a permanent ban from doing business with a government for a specified time period. The duration of the

debarment typically correlates to the severity of the offense. Under federal law, a contractor may be debarred without a conviction if the evidence shows a knowing failure to disclose credible evidence of a criminal violation of federal antitrust law (48 CFR § 9.406-2(b)(vi)(A)).

Moreover, charges filed against affiliated individuals may impute the company when that individual was acting as an agent of the company. Although suspensions and debarments may last for shorter periods of time, the reputational damage may last far longer. If made public, the debarment could also impact a company's or individual's ability to do business in the private sector. Suspension and debarment are collateral consequences that the DOJ may consider in the process of investigating and prosecuting a criminal antitrust violation.

THE FUTURE OF THE PCSF

The first year of the PCSF was dedicated to outreach, education and partnership implementation. The PCSF has now established partnerships with many law enforcement agencies across the country. Beyond domestic interagency investigations, the PCSF has launched initiatives that will expand its reach and target acute problems in government procurement. Investigations initiated by the PCSF have taken time to be investigated (particularly with a global pandemic making certain investigative steps more challenging), but in some instances these investigations have reached the recommendation and/or charging stage. We expect to see additional PCSF cases in the coming year.

PCSF Global: The PCSF has launched PCSF Global, an initiative aimed at fostering partnerships with international enforcement authorities. The US government spends considerable funds abroad, particularly for military contracts. International partners lend their expertise with foreign markets and give the PCSF eyes and ears on the ground abroad.

Set-Aside Fraud: One of the PCSF enforcement priorities is combating fraud in government set-aside programs. Such programs set aside government contracting opportunities for special interest groups such as disabled veterans, small businesses and minority-owned businesses. In January 2021, President Biden signed "Advancing Racial Equity and Support for Underserved Communities Through the Federal Government," an executive order aimed at increasing equal access to government contracting and procurement opportunities. While the PCSF mandate to combat fraud on set-aside programs existed before the executive order, it is strengthened by the Biden administration's directive.

Data Analytics Project: The PCSF has hosted webinars attended by data scientists, analysts and auditors focused on using data analytics to detect procurement fraud. Data Analytics Project attorneys have engaged analytics shops to build tools for detecting collusion using bid data. Currently, the Data Analytics Project is focused on US procurement. In light of the PCSF Global initiative, it is possible that international partners will engage with the PCSF to develop cross-border tools.

Criminal Antitrust Anti-Retaliation Act (CAARA): CAARA, the first antitrust-specific whistleblower protection legislation, became law in December 2020. It prohibits employers from retaliating against employees, contractors, subcontractors and agents of employers for reporting antitrust violations or participating in antitrust government proceedings. The Securities and Exchange Commission (SEC), Internal Revenue Service

(IRS) and other government agencies saw increased reporting since implementing similar whistleblower protections. CAARA is a tool that can be used to encourage early reporting and cooperation because of the legal protection it offers to whistleblowers, furthering the PCSF's goals to deter and detect fraud.

GENERICS

For more than seven years, the generic pharmaceutical industry has been caught up in investigations and litigation asking whether the industry has engaged in a conspiracy to violate the antitrust laws.² In 2014 the Connecticut attorney general opened a civil investigation into whether manufacturers of generic pharmaceuticals had fixed prices and allocated markets. Shortly thereafter, the DOJ joined the mix, first opening a criminal investigation into these issues and then, a few years later, opening a civil False Claims Act (FCA) investigation into the same conduct. And by 2016, the plaintiffs' bar had joined the fray, filing the first complaints of what soon became a massive and unwieldy multidistrict litigation (MDL), ultimately consolidated in the United States District Court for the Eastern District of Pennsylvania.

Below, we provide a brief update on this massive MDL and the DOJ investigation that started it.

MULTIDISTRICT LITIGATION: IN RE: GENERICS PHARMACEUTICALS PRICING ANTITRUST LITIGATION, NO. 16-MD-2724 (E. D. PA. 2016)

In re: Generics, the broad and long-running MDL, remains at the center of the pharmaceutical cases this past year. In addition to the governments of 49 states, the District of Columbia, American Samoa, Guam, Puerto Rico, Northern Mariana Island and the US Virgin Islands, the MDL also includes three putative plaintiff classes (direct purchaser, end-payer and indirect reseller plaintiffs), and more than a dozen individual entities (including major retailers, healthcare insurers and even some local governments) that filed opt-out complaints (e.g., The Kroger Co. et al, Humana Inc., and United Healthcare Services, Inc.). At present, the MDL involves at least 85 complaints alleging misconduct regarding more than 285 drugs, 38 manufacturers and 25 individual defendants.

The first civil complaints were filed in 2016, initially encompassing claims concerning just two drugs, digoxin and doxycycline. The Judicial Panel on Multidistrict Litigation later consolidated claims involving other drugs into the MDL. As the litigation has evolved, private plaintiffs and state attorneys general have since filed complaints involving numerous drugs, focusing on an alleged overarching conspiracy to fix prices, rig bids and allocate customers across the generic pharmaceutical industry. The state attorneys general, which have led the expansion of the MDL, have filed three such overarching conspiracy complaints: (1) a June 2018 complaint

 $^{^2} Christopher Rowland, \textit{Investigation of generic 'cartel' expands to 300 drugs, THE WASHINGTON POST (Dec. 9, 2018), https://www.washingtonpost.com/business/economy/investigation-of-generic-cartel-expands-to-300-drugs/2018/12/09/fb900e80-f708-11e8-863c-9e2f864d47e7_story.html.$

focused on Heritage Pharmaceuticals; (2) a May 2019 complaint focused on Teva Pharmaceuticals; and (3) a May 2020 complaint focused on dermatology products. Many plaintiffs are seeking joint and several liability for the alleged overarching conspiracy—the scope of which is unprecedent and untested in antitrust litigation.

In May 2021, US District Judge Cynthia M. Rufe selected the state attorneys general overarching conspiracy complaint centered on over 80 dermatology products to serve as a bellwether case in the MDL. Two drug-specific complaints filed by the direct purchaser and end payer plaintiffs will also proceed as bellwethers. The court originally selected the state attorneys general May 2019 Teva-centric overarching conspiracy complaint as the bellwether. A coalition of 44 state attorneys general led by Connecticut filed the Teva-centric case in May 2019. However, following the DOJ's August 2020 grand jury indictment of Teva on criminal price-fixing charges (*see below*), Teva petitioned to have the selection of its case as bellwether overturned. The pharmaceutical companies then sought to have the states' first filed case, which centered around Heritage Pharmaceuticals, chosen as a replacement bellwether because the case involved a smaller scope and was more manageable to litigate. The states advocated for the May 2020 dermatology action as the bellwether. Despite involving over 80 drugs, the states contended this complaint was more indicative of the alleged conspiracy and their investigation had evolved in the years since the Heritage complaint was filed. Judge Rufe found that "the dermatology action [wa] s more typical of the overarching conspiracy cases than the Heritage-centric action and w[ould] provide overall a more comprehensive view of the positions of more parties in the MDL."

The bellwether selection was just the first step in what will continue to be a long series of cases. At present, class certification briefing in the drug-specific bellwether cases is scheduled to be completed by mid-October 2023. The district court will schedule hearings on class certification for dates to be determined in November 2023.\(^4\) All motions for summary judgment regarding the states' bellwether case must be filed by October 16, 2023, and motions for summary judgment regarding the drug-specific bellwether cases must be filed no later than November 16, 2023.\(^5\) Pretrial conferences are not yet scheduled.

CRIMINAL LITIGATION: UNITED STATES V. TEVA PHARMACEUTICALS USA, INC. AND GLENMARK PHARMACEUTICALS, USA (E.D. PA. 2020)

While the MDL has proceeded, the DOJ has continued with its separate criminal investigation. In June 2020, the DOJ indicted Glenmark Pharmaceuticals, USA, alleging that it engaged in a conspiracy to fix prices for pravastatin and other undisclosed drugs from around May 2013 through December 2015. In August 2020, the DOJ filed a superseding indictment naming Teva as an alleged co-conspirator. Glenmark sought to sever the cases to proceed with separate trials, but US District Judge R. Barclay Surrick recently denied that motion and

⁵Pretrial Order No. 171 (Revised Bellwether Selection; Stay of Certain Discovery), MDL 2724 Dkt. 1769 (E.D. Pa. May 7, 2021), at p. 3.

⁴In re: Generics, Pretrial Order No. 188 (Schedule of Further Proceedings in Bellwether Cases), available at https://www.paed.uscourts.gov/documents/MDL/MDL2724/16md2724%20PTO188.pdf.

⁵See Id.

⁶U.S. v. Teva Pharmaceuticals USA, Inc. and Glenmark Pharmaceuticals, USA, U.S. DEP'T OF JUSTICE (Aug. 25, 2020), https://www.justice.gov/atr/case/us-v-teva-pharmaceuticals-usa-inc.

ruled that a joint trial could proceed.⁷ In June 2021, the Antitrust Division filed a scheduling order motion seeking a trial date of January 18, 2022; however, counsel for Glenmark and Teva found this date "unrealistic in light of the enormous volume of complex discovery in this case (more than 22 million documents and counting), as well as the backlog of trials in this District due to the pandemic." To date, no schedule has been set.

GENERIC DRUG COMPANY PENALTIES AND SETTLEMENTS

DOJ Investigations

Nonetheless, the DOJ has already obtained several settlements in both the criminal and civil FCA investigations, including securing several deferred prosecution agreements (DPAs) from the targets of its investigations. In fact, the DOJ's Antitrust Division and Civil Division have already collected more than \$1 billion in penalties as a result of their investigations into the generic drug industry, as detailed below.

Most recently, in October 2021, Taro Pharmaceuticals USA, Inc., Sandoz Inc., and Apotex Corporation agreed to pay \$213.2 million, \$185 million and \$49 million, respectively, to settle alleged False Claims Act violations stemming from conspiracies to fix prices of multiple generic drugs. The Civil Division alleges that the three companies illegally paid and received compensation between 2013 and 2015 resulting from alleged agreements on price, supply and allocation of customers with other generic pharmaceutical manufacturers for 20 generic drugs, including etodolac, nystatin-triamcinolone cream and ointment, benazepril HCTZ and pravastatin. In addition, the companies entered into five-year corporate integrity agreements with the Health and Human Services Office of the Inspector General, which provides oversight for federal healthcare programs like Medicare and Medicaid. These agreements require internal monitoring and price transparency.

Multidistrict Litigation

In connection with the *In re: Generics* MDL, the first civil settlements with certain plaintiffs were announced in 2021. In June 2021, Teva announced it settled, for \$925,000, all claims brought by the state of Mississippi. In November 2021, two US subsidiaries of Sun Pharma—Taro Pharmaceuticals U.S.A., Inc., and Sun Pharmaceutical Industries, Inc.—agreed to pay a total of \$85 million to a proposed class of direct purchaser plaintiffs (DPPs) in the MDL. The settlement can be reduced, however, by \$10 million if the direct purchasers that opt out of the putative class collectively account for 20% or more of Taro's and Sun Pharmaceutical Industries, Inc.'s aggregate dollar sales of the generic drugs at issue in the direct purchaser action.

US v. Teva Pharmaceuticals USA, Inc. and Glenmark Pharmaceuticals, USA, No. 20-200 Dkt. 146 (E. D. Pa. Jan. 14, 2022).

⁸Letter from D. Axelrod and K. Stojilkovic to Judge Surrick re: United States v. Glenmark Pharmaceuticals Inc., USA et al., 20-cr-200 (RBS), No. 2:20-cr-00200-RBS Dkt. 94 (June 10, 2021).

⁹Normally, in a cartel investigation, guilty pleas would be used; however, because a guilty plea would bar these companies from participating in certain government healthcare programs, which would effectively terminate business for some of the companies involved and deprive millions of Americans of important, often life-saving medication, the DOJ used DPAs in these settlements.

¹⁰Pharmaceutical Companies Pay Over \$400 Million to Resolve Alleged False Claims Act Liability for Price-Fixing of Generic Drugs, U.S. DEP'T OF JUSTICE (Oct. 1, 2021), https://www.justice.gov/opa/pr/pharmaceutical-companies-pay-over-400-million-resolve-alleged-false-claims-act-liability.

ENTITY/INDIVIDUAL	DATE	CHARGES/RESOLUTION	SETTLEMENT AMOUNT
Jeffrey Glazer and Jason Malek (former Heritage Pharmaceuticals executives)	Dec. 2016	Pleaded guilty to conspiring to fix prices, rig bids, and allocate customers for doxycycline hyclate and glyburide. Both awaiting sentencing.	TBD
Heritage Pharmaceuticals	May 2019	Entered into a DPA with the Antitrust Division to resolve the DOJ's charges relating to glyburide, a drug used to treat diabetes, agreeing to pay a criminal penalty and cooperate fully with the ongoing criminal investigation. In a separate civil resolution with the Civil Division, Heritage agreed to pay to resolve allegations under the FCA related to the alleged price-fixing conspiracy.	\$225K criminal penalty and \$7.1M civil settlement
Rising Pharmaceuticals	Dec. 2019	Entered into a DPA with the Antitrust Division to resolve the DOJ's charges regarding an alleged conspiracy to fix prices for a hypertension medication.	\$3.5M criminal fine and civil penalty combined
H. Armando Kellum (former Sandoz executive)	Feb. 2020	Pleaded guilty to fixing prices, rigging bids and allocating customers for several drugs, including clobetasol and nystatin triamcinolone cream. Kellum is awaiting sentencing.	TBD
Sandoz Inc.	Mar. 2020 and Oct. 2021	Agreed to pay a criminal penalty for allegedly conspiring to fix prices on several generic drugs, including, but not limited to, drugs used to treat brain cancer, cystic fibrosis, arthritis and hypertension. Agreed to pay a civil penalty for aiding and receiving compensation prohibited by the Anti-Kickback Statute through arrangements on price, supply, and allocation of customers for drugs such as benazepril HCTZ and clobetasol.	\$195M criminal penalty and \$185M civil settlement
Apotex Corporation	May 2020 and Oct. 2021	Agreed to pay a criminal penalty to resolve allegations that it conspired to fix prices for pravastatin.	\$24.1M criminal penalty and \$49M civil settlement
Taro Pharmaceutical USA, Inc.	July 2020 and Oct. 2021	Entered into a DPA with the Antitrust Division to resolve the DOJ's charges regarding an alleged conspiracy related to several drugs with affected sales of over \$500 million.	\$205.6M criminal fine and \$213.2M civil penalty

TAKEAWAYS

Although the district court has allowed several cases to proceed past the motion to dismiss stage, it remains unclear if the plaintiffs' expansive allegations will survive summary judgment and later proceedings. In the months to come, there will continue to be interplay between the criminal trial proceeding against Teva and Glenmark and the civil cases proceeding in the MDL. For example, the MDL court is currently considering whether the DOJ should be allowed to extend a continued stay of depositions in the civil cases of specific individuals it views as "key" to its criminal investigation.

This investigation and litigation has brought significant attention to the generic drug and pharmaceutical industry at large, including increased scrutiny and calls for action by Congress (such as the US House of Representatives Committee on Oversight and Reform's three-year Drug Pricing Investigation, which culminated in a majority staff report released in December 2021). Several pieces of legislation aimed at reigning in pharmaceutical prices have also been introduced. In all, these investigations and litigation, coupled with the increases in oversight and willingness to investigate by state and federal governments, suggest that the pharmaceutical industry will remain subject to heightened scrutiny of its business practices for many years to come.

CONCLUSION

As we move into the second quarter of 2022, one thing is abundantly clear: The DOJ's aggressive criminal antitrust enforcement will only continue to increase. The Division ended the last fiscal year with 146 open grand jury investigations—the most in 30 years. President Biden has made competition a priority for his administration. Attorney General Garland has specifically identified "reinvigorating antitrust enforcement" as at the center of the DOJ's mission. In its FY 2022 budget request, the DOJ requested a 9% increase in spending, amounting to an additional \$200 million.

At the same time, there seems to be a shift in tone and approach at the Division. The Division has started to push the boundaries of criminal antitrust enforcement. As noted above, it has pursued naked no-poach agreements criminally, something that it had never done prior to 2020. In recent remarks to the ABA Institute on White Collar Crime, Richard Powers, the US Deputy Assistant Attorney General for Criminal Enforcement in the Division, noted that the Division is also prepared to criminally charge individual executives for violations of Section 2 of the Sherman Act, the provision that prohibits market monopolization—another exceedingly aggressive and controversial approach and something that the Division has not done in decades. To cap it off, the Division has shown a tendency, of late, to take cases to trial, rather than negotiate resolutions. And, it has hired a number of prominent Criminal Division alumni, several with significant trial experience, to help with this effort. All of this suggests that the Division is prepared to stretch the law in places and go the distance to pursue what it views as criminal violations of the antitrust laws.

¹¹Id.

 $^{^{12}} https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/07/09/remarks-by-president-biden-at-signing-of-an-executive-order-promoting-competition-in-the-american-economy/$

 $^{^{15}}https://www.appropriations.senate.gov/imo/media/doc/Statement\%20of\%20Attorney\%20General\%20Merrick\%20Garland\%20-\%20June\%209,\%2020215.pdf$

¹⁴Id.



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