Director's Report
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This has been a busy year for the Bureau of Competition, requiring extraordinary effort from our attorneys and support staff to keep up with the unprecedented litigation workload. As of today, we have four merger challenges in various stages of active litigation, as well as three federal court injunction cases involving anticompetitive conduct by pharmaceutical companies – two reverse patent settlement cases and one sham litigation case. These cases came quick on the heels of last year's preliminary injunction trials in Sysco/US Foods and Steris/Synergy, and the eve-of-trial resolution of *FTC v. Cephalon*, a landmark settlement of $1.2 billion in disgorged profits, our first monetary settlement in a reverse patent settlement case.

Once a year, the ABA Antitrust Section Spring Meeting presents the perfect occasion to take stock of the Bureau's work. This report allows me to acknowledge not only our litigation efforts, but all the ways in which the Bureau has worked to prevent consumer harm from anticompetitive conduct or mergers: through negotiated settlements, HSR enforcement, amicus briefs, and industry guidance, as well as behind-the-scenes projects that are designed to improve our process.

Merger activity is up, which means that merger review continues to require significant Bureau resources. This year, we applied merger analysis to a wide array of products, services and market conditions. We've examined competition among branded and generic pharmaceutical products, as well as products made of cement. We've reviewed mergers in which companies compete on a worldwide basis, and those in which rivals compete locally – inareas as small as a half-mile radius from their store. We've helped develop quantitative evidence through economic modeling, but have also been reminded by a federal court that qualitative indicia can be just as powerful in predicting a merger's potential for harm. While the year has been unusual for the amount of merger litigation, day-in and day-out merger review remains a mainstay of our work.

There have also been significant developments in our nonmerger work. Last year, during the week of the Spring Meeting, the Eleventh Circuit issued its decision upholding the Commission's monopolization decision in *McWane, Inc. v. FTC.*[2] Just last month, the Supreme Court denied review. The *McWane* circuit court decision adds a new dimension to monopolization law, especially as it applies to exclusive contracts. The case is a must-read for

[1] The views expressed are mine and do not necessary reflect the views of the Commission or any Commissioner.
[2] Opinion of the Commission, McWane, Inc., Dkt. 9351 (Feb. 6, 2014), https://www.ftc.gov/system/files/documents/cases/140206mcwaneopinion_0.pdf, *aff'd*, 783 F.3d 814 (11th Cir. 2015), *cert. denied*, 2016 U.S. LEXIS 2010 (Mar. 21, 2016).

antitrust practitioners. In the realm of reverse payment settlements, federal courts continue to apply the Supreme Court's teachings in *FTC v. Actavis*, not only in Commission cases but also in private litigation, where our active *amicus* program seeks to help federal courts develop antitrust law in the area of reverse payment settlements.

MERGERS

Litigated Mergers

Last June, after an eight-day hearing on our motion for a preliminary injunction, the U.S. District Court for the District of Columbia blocked the merger of the two largest foodservice distributors in the country, Sysco Corporation and US Foods, Inc.[3] The $231 billion industry supplies food and related products to restaurants, hotels and resorts, hospitals, government agencies, and school and workplace cafeterias. The court found that the FTC was likely to succeed in proving, after a full administrative trial, that the proposed acquisition would likely substantially lessen competition in two relevant markets – broadline foodservice distribution to national customers and broadline foodservice distribution to local customers. Shortly after the court's decision, Sysco announced it would not pursue the merger.

As I outlined in a speech last fall,[4] the court's decision in *Sysco* is a worthwhile read for anyone who wants to learn more about U.S. merger analysis. Every element of a Section 7 claim was in dispute: product and geographic market definition, market shares, effects, entry, and efficiencies. But as the judge noted, the "primary battlefield" was over market definition. The court spent nearly 40 pages discussing the evidence bearing on the product dimensions of competition among broadline foodservice distributors. Our view was that Sysco and US Foods were competitors in the market for *broadline* foodservice distribution, including separate markets for broadline foodservice distribution to national and local customers, while defendants argued that the market included other foodservice distributors, such as specialty distributors, systems distributors, and cash-and-carry stores,[5] a market in which their combined sales would account for only 25 percent.

What is clear from the court's decision is that qualitative evidence is still useful in assessing the market in which the merging companies compete. We presented evidence that the court found credible that broadline foodservice distribution has a number of distinct characteristics that distinguish it from other types of distribution, such as a wide selection of products, including private label products, next-day delivery, and value-added services, such as menu and nutrition planning. These attributes, in addition to other qualitative indicia such as distinct customers, distinct pricing, and industry recognition, suggested that broadline distributors offer a unique set of products and services that are not interchangeable with product

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[3] *FTC v. Sysco Corp*., --- F. Supp.3d ----, 2015 WL 3958568 (D.D.C. June 23, 2015).

[4] "*FTC v. Sysco*: Old-School Antitrust with Modern Economic Tools," remarks of Deborah L. Feinstein at GCR Live (Sept. 18, 2015) *available at* https://www.ftc.gov/system/files/documents/public_statements/802381/150918gcrspeech.pdf.

[5] Specialty distributors offer a limited number of products in a category, such as fresh produce, seafood or baked goods. Systems distributors primarily serve chain restaurants with fixed or limited menus. Cash-and-carry stores offer self-service purchasing for customers that transport purchased goods themselves.

and service offerings from other modes of distribution. The merging parties argued that there must be a broader market because broadline customers also buy from other types of distributors. But the district court found that "[t]hough the customers may be varied, . . . the industry, from the perspective of both sellers and buyers, perceives broadline to be a separate mode of food distribution."[6]

As important as the qualitative evidence weighing on market definition was the economic evidence. Our expert, Dr. Mark Israel, performed a SSNIP test using an aggregate diversion analysis. Such an analysis relies on calculations using gross margins to determine the percentage of customers that would need to stay in the market to make a price increase profitable. The defendants disagreed about the appropriate formula to use, the measure of gross margin, and the basis for calculating the diversions. In the end, while the court did not rely on our expert's precise calculations, it weighed all the evidence and found that our expert's conclusions were more consistent with the business realities of the broadline foodservice distribution market than were the views of defendants' experts.[7]

In *Sysco*, we were also confronted with defendants' effort to "litigate the fix." The parties argued that they had resolved any potential problems created by the merger by entering into a separate agreement to sell 11 of US Foods' 61 distribution centers to PFG, a regional broadline competitor with 24 distribution centers of its own. The agreement with PFG was signed during the Commission's investigation in an effort to avoid litigation. The Commission, however, determined that even with the divestitures to PFG, Sysco's acquisition of US Foods would likely result in anticompetitive harm. The court agreed, employing the same two-step approach that is familiar to those who have mergers reviewed by the Commission: the judge addressed the impact of the proposed divestitures as a rebuttal argument and only after he had determined that the original deal created a presumption of anticompetitive effects.[8]

Most significantly, the court found that the obstacles faced by a post-divestiture PFG created a significant risk that it would not replace the competition lost by the elimination of US Foods as an independent competitor. As the court's findings make clear, it did not believe that merely creating an additional competitor would be sufficient; rather the court considered whether "PFG will be on equal competitive footing with the merged firm."[9] Citing concerns that PFG would face significant competitive disadvantages in competing against the much larger Sysco, and would be dependent on Sysco for several years for transitional services, the court was not persuaded that the proposed divestiture would create a truly independent competitor to counter the anticompetitive effects of the merger.

Finally, on the issue of efficiencies, the court concluded that even if all of the cost savings were passed on to consumers, the savings were unlikely to outweigh the competitive harm to customers. This of course is yet another litigated case in which the court found that the

[6] *Sysco* Opinion at *17.
[7] *Id*. at *20.
[8] With regard to the market for national customers, the court looked at shares with and without adjusting for divestitures to PFG.
[9] *Sysco* Opinion at *50.

proffered efficiencies did not outweigh the potential for harm from the merger. However, given the very high levels of concentration involved in most litigated cases, and lingering doubts by some courts about the legal basis for an "efficiencies defense," I encourage practitioners to look beyond litigated cases. To understand how we analyze efficiencies, it is important to look to Section 10 of the Merger Guidelines for guidance, realizing that just as the elements of a merger claim must be proven by reference to information from a variety of sources, so too must efficiency claims be put to the test. As I noted recently in a blog post, another good source of guidance on efficiencies is contained in the ten-year old Commentary on the Merger Guidelines.[10] We routinely consider efficiencies claims during a merger investigation, and have made decisions to close investigations based, in part, on those claims. But as with all elements of merger analysis, facts matter, and when a merger results in high levels of concentration, there must be commensurate levels of efficiencies to ensure customers, not just shareholders, will benefit from the merger.

Our effort to block Steris Corporation's proposed $1.9 billion acquisition of Synergy Health on antitrust grounds was not a success when, in September, a federal district court denied our motion to enjoin the acquisition pending an administrative trial.[11] At the time of the merger, Steris and Synergy were the second- and third-largest providers of product sterilization services in the world. Sterilization is critical step in the manufacture of a number of healthcare products, and is required by the U.S. Food and Drug Administration. Steris and the market-leader Sterigenics offer gamma sterilization, which uses Cobalt 60, a radioactive isotope that is increasingly hard to find. Synergy offered e-beam and ethylene oxide gas sterilization services to U.S. customers, but had plans to open sterilization facilities offering x-ray sterilization in the United States.

The Commission alleged that after the merger, Steris planned to halt Synergy's x-ray development program – a program that, if successful, had the potential to substantially improve competition for contract sterilization services provided to U.S. customers. The essence of our case was that, prior to the merger, Synergy was in the process of entering the U.S. sterilization market with new disruptive technology that would have challenged the existing Steris/Sterigenics duopoly and benefitted customers. The Commission routinely relies on this "actual potential competition" theory of harm as the basis for requiring the divestiture of pharmaceutical products in development, as discussed below. As the judge noted in his decision denying the preliminary injunction, the case hinged on whether Synergy likely would have entered the U.S. with x-ray sterilization services within a reasonable period of time – soon enough to be considered a competitor worth preserving. While we agreed that this was the decisive question before the court, we disagreed on what the evidence showed. Despite this loss, preservation of future competition is important and something I believe is likely to remain an active part of the Commission's merger enforcement agenda.

I'll briefly mention the basic facts surrounding our four pending litigation matters (the results of our efforts will be for next year's report). For a second time, the Commission

[10] *Competition Matters* blog post, "When past is prologue," (Mar. 9, 2016), *available at* https://www.ftc.gov/news-events/blogs/competition-matters/2016/03/when-past-prologue.
[11] *FTC v. Steris Corp.*, --- F. Supp.3d ---, Case No. 1:15-cv-80 (N.D. Ohio Sept. 24, 2015).

unanimously authorized a challenge to Staples, Inc.'s proposed acquisition of Office Depot. Unlike 19 years ago, when the Commission's case focused on the effects of the merger on retail sales of consumable office supplies by office supply superstores, this time around we allege that the proposed acquisition would significantly reduce competition in the market for the sale and distribution of core consumable office supplies and paper sold to large business-to-business customers for their own use.[12] The complaint alleges that, in competing for contracts, both Staples and Office Depot can provide the low prices, nationwide next-day distribution and combination of services and features that many large business customers require.

We also have three pending hospital merger cases, each presenting its own unique set of facts. The first involves Cabell Huntington Hospital's proposed acquisition of St. Mary's Medical Center – two hospitals located three miles apart in Huntington, West Virginia. The FTC issued an administrative complaint alleging that the combination would create a dominant firm with a near monopoly over general acute care inpatient hospital services and outpatient surgical services in the adjacent counties of Cabell, Wayne, and Lincoln, West Virginia and Lawrence County, Ohio.[13] The Commission also issued an administrative complaint and authorized staff to file a preliminary injunction to block Penn State Hershey Medical Center's proposed merger with PinnacleHealth System. The complaint in this case alleges that combining the two health care providers would substantially reduce competition for general acute care inpatient hospital services sold to commercial health plans in four south-central Pennsylvania counties.[14] Late last year, the FTC issued an administrative complaint in the third hospital merger and authorized staff to seek a preliminary injunction in federal court to block Advocate Health Care Network's proposed merger with NorthShore University Health System.[15] The two firms are the leading providers of general acute care inpatient hospital services in the North Shore Area of Chicago.

Merger Settlements

While our litigated challenges grab headlines, most agency antitrust enforcement occurs through challenges settled by a consent order. Since last April, the Commission issued 16 consent orders requiring divestitures to maintain competition, as discussed below.

Pharmaceutical and Medical Device Markets

Merger activity remains high in the pharmaceutical sector, and we continue to require divestitures to maintain competition for existing products as well as for pipeline products in development where the merger would reduce competition in the future by eliminating a likely entrant.

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[12] FTC News Release, FTC Challenges Proposed Merger of Staples, Inc. and Office Depot, Inc. (Dec. 7, 2015), https://www.ftc.gov/news-events/press-releases/2015/12/ftc-challenges-proposed-merger-staples-inc-office-depot-inc.

[13] In the Matter of Cabell Huntington Hosp., Dkt. 9366 (complaint issued Nov. 6, 2015). On March 25, the Commission withdrew this matter from adjudication for 30 days to review the effect of recently enacted legislation on this proceeding.

[14] *FTC v. Penn State Hershey Medical Center*, No. 1:15-cv-2362 (M.D. Pa.).

[15] *FTC v. Advocate Health Care Network*, No. 1:15-cv-11473 (N.D. Ill.).

Pharmaceutical companies Endo International plc and Par Pharmaceuticals, Inc. agreed to divest all of Endo's rights and assets to two generic drugs in order to settle FTC charges that Endo's proposed $8 billion acquisition of Par would likely be anticompetitive.[16] Without the divestitures, the acquisition would have combined the two most significant suppliers in the market for generic glycopyrrolate tablets, which are used with other drugs to treat certain types of ulcers, and two of only four active suppliers in the market for generic methimazole tablets, which are used to treat the body's production of excess thyroid hormone. Rising Pharmaceuticals, an established drug marketer, acquired the divested assets. Under the settlement, Endo must supply Rising with the divested products for two years, while it transfers the manufacturing technology to Rising's chosen third-party manufacturer.

Lupin Ltd. and Gavis Pharmaceuticals LLC agreed to sell the rights and assets for two generic drugs to settle FTC charges that Lupin's proposed $850 million acquisition of Gavis would likely be anticompetitive.[17] Without a divestiture, the merger would have combined two of only four current competitors marketing two dosages of generic doxycycline monohydrate capsules, which are used to treat bacterial infections. Prior to the merger, both Lupin and Gavis were recent entrants in this market, introducing products in 2014 and 2015, respectively. In the market for generic mesalamine extended release capsules, used to treat ulcerative colitis, the merger also would have eliminated a future competitor. At the time of the merger, only the branded version of the product was available, and both Lupin and Gavis were working to develop a generic version. Given that Lupin and Gavis were two of only a few companies likely to enter the generic market in the near future, we alleged the merger would eliminate future generic competition that would otherwise have occurred if the merging firms remained independent, thereby delaying beneficial competition and the prospect of price decreases. The proposed consent order requires Gavis to divest its rights and assets to these products to generic pharmaceutical company G&W Laboratories.

The FTC also obtained negotiated settlements related to two acquisitions by Hikma Pharmaceuticals. To resolve concerns that its $2 billion acquisition of Roxane Laboratories, Inc. would likely be anticompetitive, Hikma agreed to sell the rights and assets for two generic drugs, and relinquish its U.S. marketing rights to a third generic drug, to the upfront buyer approved by the Commission, Renaissance Pharma, Inc.[18] The acquisition would have reduced the number of current suppliers of three strengths of anti-inflammatory and immunosuppressant prednisone tablets and all strengths of lithium carbonate capsules, used to treat bipolar disorder. The order also requires Hikma to relinquish to its drug development partner, India-based Unimark Remedies Ltd., the rights to market generic flecainide acetate tablets in the United States. Flecainide is used to prevent and treat abnormally fast heart rhythms. In the market for flecainide tablets, Roxane is currently one of only two firms with significant market share. Absent the merger, Hikma was expected to market generic flecainide tablets in the U.S. following the FDA approval that its partner, Unimark, is currently seeking. The proposed order also requires Hikma

[16] In the Matter of Endo International plc, Dkt. C-4539 (final order issued Nov. 19, 2015).
[17] In the Matter of Lupin Ltd., Dkt. C-4566 (complaint issued Feb. 19, 2016).
[18] In the Matter of Hikma Pharmaceuticals PLC, Dkt. C-4568 (modified order issued Mar. 31, 2016).

to divest its 23 percent ownership interest in Unimark so that Unimark will be an independent marketer of this drug.

The second transaction related to Hikma's $5 million acquisition of the rights to various drug products and related assets from BenVenue Laboratories, Inc. According to the complaint, without a remedy, Hikma's purchase of certain generic injectables assets from Ben Venue, a U.S. subsidiary of Boehringer Ingelheim Corporation, would likely harm future competition in five U.S. generic markets: (1) acyclovir sodium injections. an antiviral drug used to treat chicken pox, herpes, and other related infections; (2) diltiazem hydrochloride injections, a calcium channel blocker and antihypertensive used to treat hypertension, angina, and arrhythmias; (3) famotidine injections, a treatment for ulcers and gastroesophageal reflux disease; (4) prochlorperazine edisylate injections, an antipsychotic drug used to treat schizophrenia and nausea; and (5) valproate sodium injections, a treatment for epilepsy, seizures, bipolar disorder, anxiety, and migraine headaches.[19]

Boehringer had recently exited each of these markets as part of shutting down its manufacturing operations through BenVenue. Our competitive concern was that absent the acquisition, Boehringer would have had the incentive to sell its ANDAs to a third-party supplier who would likely bring these products to market. For each of the five markets, Hikma either was a current competitor or was likely to become one in the near future. Post-merger, Hikma would lack the incentive of an independent ANDA holder to sell those assets, and thus customers would be deprived of the price decreases that likely would have accompanied third-party entry into each of these concentrated markets. Under the proposed order, Hikma is required to divest the five generic injectable drug assets to Amphastar Pharmaceuticals, Inc., a California-based specialty pharmaceutical company that sells generic injectable and inhalation products.

Pfizer Inc. agreed to sell the rights and assets related to four pharmaceutical products in order to settle FTC charges that its proposed $16 billion acquisition of Hospira, Inc. would likely be anticompetitive.[20] According to the complaint, the combination would reduce the number of current suppliers for two of the generic drugs: acetylcysteine inhalation solution, used to treat respiratory disorders, and clindamycin phosphate injection, an antibiotic used to treat lung, skin, blood, bone, joint, and gynecological infections. Pfizer's clindamycin phosphate is marketed under its branded label, but is priced to compete with generic products. Without the divestiture, the merger would have reduced the number of current suppliers from four to three, making it likely that prices would rise.

For two other generic markets, the acquisition was likely to reduce future competition: voriconazole injections, an antifungal medication used in hospitals, and melphalan hydrocholoride injections, a chemotherapy agent used to treat multiple myeloma and ovarian cancer. Pfizer markets the branded voriconazole injection Vfend, which competes on price with the one generic version currently on the market. At the time of the merger, Hospira expected FDA approval for its voriconazole injection drug in May 2016. In the market for melphalan hydrochloride injection products, a branded and a generic version of this chemotherapy agent

[19] In the Matter of Hikma Pharmaceuticals PLC, Dkt. C-4572 (complaint issued Feb. 25, 2016).
[20] In the Matter of Pfizer Inc., Dkt. C-4537 (final order issued Oct. 19, 2015).

compete against each other on price in the U.S. market. Pfizer and Hospira both have generic versions under development, and no other company is as well positioned as these two firms are to enter this market. Without the divestiture, the merger would have eliminated one of a limited number of firms likely to enter the U.S. market with this product in the near future, thereby delaying beneficial competition and further price decreases.

Mylan N.V. agreed to sell the rights and assets related to seven generic drugs in order to settle FTC charges that its proposed hostile takeover of Perrigo Company plc would reduce competition in U.S. markets for seven generic pharmaceutical products.[21] Specifically, our complaint alleged that, if consummated, the proposed acquisition would likely have harmed current competition in U.S. markets for four generic drugs: (1) bromocriptine mesylate, used to treat conditions including type 2 diabetes and Parkinson's disease; (2) clindamycin phosphate/benzoyl peroxide, used to treat acne; (3) liothyronine sodium, used to treat hypothyroidism; and (4) polyethylene glycol 3350, a laxative used to treat occasional constipation.

Our settlement also sought to preserve future competition for three generic drugs for which the proposed acquisition would eliminate at least one likely future entrant from a very limited pool. For instance, acyclovir ointment is used to slow the growth and spread of the herpes virus in the body; Mylan holds an ANDA is only one of three current generic suppliers, while Perrigo is one of a limited number of suppliers likely to enter in the near future. Hydromorphone hydrochloride is used to treat moderate to severe pain in narcotic-tolerant patients; Perrigo holds an ANDA and Mylan is one of a limited number of future entrants. In scopolamine transdermal patches, which prevent symptoms associated with motion sickness and help patients recover from anesthesia and surgery, Perrigo has the only approved ANDA for a generic version of the currently available branded product, and Mylan is one of a limited number of firms like to enter in the near future. Because no generic version is yet available, the onset of generic competition is likely to significantly reduce prices for this product.

To remedy competitive concerns in these seven markets, Mylan agreed to divest rights and assets to Alvogen Group, Inc. The divestiture provisions, as well as several other provisions of the Commission's proposed order, were contingent on the success of Mylan's tender offer. For instance, if Mylan did not acquire more than 50 percent of Perrigo voting securities by the expiration date of its tender offer, then Mylan was obligated to divest all of its ownership interests in Perrigo, such as Perrigo shares. If Mylan sold these shares through anything other than open-market transactions, Mylan would have to seek Commission approval of the buyer, including selling shares to Perrigo if the consideration included anything other than cash. Other order provisions were unique to the hostile nature of the proposed acquisition. For instance, with respect to the divestiture of acyclovir ointment assets, the proposed order required Mylan to divest its own on-market acyclovir product because the buyer would be unable to conduct due diligence on the Perrigo product in development. The order provided Mylan with a limited license-back so that it could continue to market its product until launching a new product based on Perrigo's technology, but no longer than three years. The reasoning behind this provision was to permit Mylan to remain an active market participant pending the approval of Perrigo's acyclovir

[21] In the Matter of Mylan N.V., Dkt. C-4557 (modified order issued Feb. 22, 2016).

ointment ANDA while at the same time ensuring Mylan's continued incentive to develop and launch the Perrigo product. When Mylan failed to obtain the required threshold of Perrigo shares to succeed in its unsolicited offer, it abandoned the proposed acquisition. As a result, the Commission issued a modified final order that relieved the interim monitor of his duties and reduced Mylan's reporting obligations from ten years to three years.

The Commission also obtained negotiated settlements in two acquisitions involving medical devices. Like pharmaceutical products, medical devices require FDA approval for sales in or into the United States. Medical device company Zimmer Holdings, Inc. agreed to divest U.S. rights and assets related to unicondylar knee implants, total elbow implants, and bone cement in order to settle charges that its proposed $13.35 billion acquisition of Biomet Inc. would likely be anticompetitive.[22] According to the complaint, Zimmer and Biomet are two of the only three substantial competitors in the U.S. markets for unicondylar knee implants and total elbow implants, and two of only four significant competitors in the U.S. market for bone cement. The order requires Zimmer to divest to Smith & Nephew the U.S. intellectual property, manufacturing technology, and existing inventory relating to its unicondylar knee implant, and to provide transitional services to help them establish manufacturing capabilities and secure necessary FDA approvals. The order also requires Zimmer to waive any non-compete provisions in employee contracts and to facilitate interviews between key employees and sales reps from Zimmer distributors. The order also requires Biomet to divest to a second buyer, DJO, the U.S. intellectual property, manufacturing technology, and existing inventory relating to its total elbow implant and bone cement products.

Wright Medical Group, Inc. and Tornier N.V. agreed to sell Tornier's U.S. rights and assets related to its total ankle replacements and total silastic toe joint replacements to resolve charges that the proposed $3.3 billion merger would illegally reduce competition for these devices.[23] Under the settlement, Wright and Tornier will divest the rights and assets to these devices to Integra Lifesciences Corporation and provide Integra with intellectual property, manufacturing technology, and existing inventory, as well as other assets and assistance to ensure that Integra can effectively compete in the markets. The order also requires Wright and Tornier to supply Integra with total ankle replacements for up to three years and total silastic toe joint replacements for up to a year, while Integra transitions to become an independent competitor in these markets.[24]

Consumer Goods

The Commission also accepted negotiated settlements in mergers involving products that consumers buy every day. For instance, the Commission reviewed the effects of two competing

[22] In the Matter of Zimmer Holdings, Inc., Dkt. C-4534 (final order issued Aug. 20, 2015).
[23] In the Matter of Wright Medical Group, Dkt. C-4559 (final order issued Nov. 17, 2015).
[24] The Commission obtained settlements in two additional health care-related mergers. In the Matter of Keystone Orthopaedic Specialists, LLC, Dkt. C-4562 (final order issued Dec. 18, 2015) (orthopedic practice formed through a combination of six independent orthopedic practices allegedly reduced competition for orthopedic services in Berks County, Pennsylvania); In the Matter of Rangers Renal Holding, LP, Dkt. C-4570 (final order issued Mar. 18, 2016) (U.S. Renal required to sell three dialysis clinics to settle charges that its acquisition of DSI Renal would substantially lessen competition for outpatient dialysis services in Laredo, Texas).

proposals by Dollar Tree and Dollar General to take over Family Dollar Stores. These companies each operate small-format, deep-discount retail outlets that sell an assortment of consumables and non-consumables, including food, home products, apparel and accessories, and seasonal items, at prices under $10. Dollar General attempted a hostile takeover of Family Dollar in competition with Dollar Tree. Like the Mylan-Perrigo transaction, which happened at the same time as Teva's attempted hostile takeover of Mylan, we analyze each transaction on its merits. Our goal is not to pick winners and losers in the battle for corporate control; rather it is to protect competition and consumers. After Dollar Tree emerged as the successful bidder, the Commission required it to divest 330 Family Dollar stores to remedy likely anticompetitive effects in local markets in 35 states.

By starting the analysis with a focus on whether the elimination of an independent Family Dollar was likely to reduce competition in any relevant antitrust market, we found that unlike supermarkets, which offer a selection of products and services for a "one-stop shopping experience," dollar stores compete for "fill-in" shopping by offering a broad assortment but limited variety of general merchandise sold at deeply-discounted prices. We found that the extent to which other retailers (such as Wal-Mart, supermarkets, pharmacies, mass merchandisers, and discount specialty merchandise retail stores) constrained pricing at the merging parties' stores differs by area. For that reason, we indicated that (i) the relevant line of commerce in which to analyze the acquisition is no narrower than discount general merchandise retail stores, and (ii) in certain geographic markets the relevant line of commerce may be as broad as the sale of discounted general merchandise in retail stores.

There has been a lot of interest in the use of the Gross Upward Pricing Pressure Index (GUPPI) analysis in Dollar Tree/Family Dollar. As the Commission explained in a statement released with our consent,[25] GUPPI analysis can serve as a useful indicator of whether a merger involving differentiated products is likely to result in unilateral anticompetitive effects. Using the value of diverted sales as an indicator of the upward pricing pressure resulting from the merger, a GUPPI is defined as the value of diverted sales that would be gained by the second firm measured in proportion to the revenues that would be lost by the first firm. During the investigation, GUPPI analysis served as a useful initial screen to flag those markets where the transaction might likely harm competition and those where it might pose little or no risk to competition. As a general matter, Dollar Tree and Family Dollar stores with relatively high GUPPIs suggested that the transaction was likely to harm competition, subject to evidence or analysis indicating that the GUPPIs may have overstated the potential for anticompetitive effects. Conversely, low GUPPIs for overlap stores suggested that the transaction was less likely to harm competition, subject to evidence or analysis indicating that the GUPPI may have understated the potential for anticompetitive effects.

While the GUPPI analysis was an important screen for the Commission's inquiry, it was only a starting point. The Commission considered several other sources of evidence in assessing the transaction's likely competitive effects, including additional detail regarding the geographic

[25] In the Matter of Dollar Tree, Inc., Dkt. C-4530, Statement of the Commission, (July 13, 2015), *available at* https://www.ftc.gov/public-statements/2015/07/statement-federal-trade-commission-matter-dollar-tree-inc-family-dollar.

proximity of the merging parties' stores relative to each other and to other retail stores, ordinary course of business documents and data supplied by Dollar Tree and Family Dollar, information from other market participants, and analyses conducted by various state attorneys general who were also investigating the transaction. After considering all of this evidence, the Commission identified specific local markets where the acquisition would be likely to harm competition and arrived at the list of 330 stores slated for divestiture.[26]

We also reviewed a merger involving branded consumer products, Reynolds American Inc.'s proposed $27.4 billion acquisition of Lorillard Inc. Prior to the merger, Reynolds and Lorillard were the second- and third-largest U.S. cigarette makers, behind industry leader Altria Group Inc., which sells Marlboro cigarettes. Reynolds had the second-largest cigarette manufacturing and sales business in the United States that included two of the best-selling cigarettes brands: Camel and Pall Mall. Pre-merger, Reynolds also managed a number of smaller cigarette brands that it did not promote as much, including Winston, Kool, and Salem. Lorillard was the third-largest U.S. cigarette manufacturer, and its flagship brand, Newport, was the best-selling menthol cigarette in the country, and the second-best-selling cigarette brand overall. In addition to recently introduced nonmenthol styles of Newport, Lorillard made and sold a few smaller discount-segment brands, such as Maverick. According to the complaint, since 1981, the U.S. cigarette market has faced declining demand. With strict prohibitions on advertising and marketing cigarette products in the U.S., the predominant form of promotion among U.S. cigarette producers is retail price reductions.

The transaction was brought to us as a three-way deal, whereby Reynolds had already agreed to sell to Imperial Tobacco Group four brands – Reynolds's Winston, Kool and Salem brands along with Lorillard's Maverick – plus Lorillard's manufacturing and headquarters facility in North Carolina. The Commission accepted the proposal, with additional conditions.[27] Unlike Reynolds, in the post-merger world Imperial would have the incentive to promote and grow sales of the divested brands because the incremental sales are unlikely to cannibalize sales from Imperial's portfolio. With the divested assets, Imperial – which had a limited presence in the United States – would have the ability and incentive to counter any competitive concerns raised by the merger. In addition, Reynolds provided Imperial with existing visible retail shelf space for five months following the close of the transaction in order to quickly turn around sales of the acquired brands.

Finally, the Commission also accepted a settlement involving gasoline terminaling, an upstream service that affects the cost, and therefore the price, of light petroleum products such as gasoline. Terminals receive bulk quantities of LPPs from a pipeline or vessel, hold the products in storage tanks, and dispense them in smaller quantities onto tanker trucks for local delivery to retail locations and commercial customers. According to the complaint, there is no cost-effective substitute for terminals and the services they provide.

The Commission alleged that the acquisition of Gulf Oil Limited Partnership by ArcLight Energy would increase concentration in three Pennsylvania terminal markets that are already

[26] In the Matter of Dollar Tree, Inc., Dkt. C-4530 (final order issued Sept. 17, 2015).
[27] In the Matter of Reynolds American Inc., Dkt. C-4533 (final order issued July 31, 2015).

highly concentrated: Altoona, where ArcLight would own the only terminal handling gasoline and one of two terminals handling distillates; Scranton, where ArcLight would own one of two terminals handling gasoline and distillates; and Harrisburg, where ArcLight would own one of two terminals handling gasoline and one of three terminals handling distillates. To maintain competition in these markets, the parties agreed to divest to Arc Logistics four of Gulf's Pennsylvania LPP terminals: one in Altoona; one in Pittston Township in the Scranton market; and one each in Mechanicsburg and Williamsport in the Harrisburg market. To ensure that the divested terminals will remain viable and competitive during their transition in ownership, the order requires ArcLight to maintain minimum throughput volumes at the terminals for two years; to supply Arc Logistics with renewable fuels that may be blended with LPPs for five years; and to allow any ArcLight and Gulf customers in the Altoona, Scranton, and Harrisburg markets to cancel their terminaling service contract without penalty for six months after the divestiture, so that Arc Logistics can compete for these customers.[28]

International Cooperation in Merger Review

The number of mergers that are subject to review in multiple jurisdictions has increased significantly in the past several years – which means that the risks and costs for businesses stemming from multiple regulatory reviews have also increased. Cooperation with antitrust officials in other countries during our merger review helps us reach compatible results, increases the predictability of outcomes, and facilitates more efficient use of limited agency resources. As a result, communicating with staff in other reviewing jurisdictions has become standard practice in merger reviews involving multinational companies.

In our experience, the risk of inconsistent outcomes can be reduced by communicating with other competition authorities from the very early stages of the investigations. This dialogue may include participating in joint conference calls with the merging companies or with third parties, discussing the industry context and background, comparing substantive approaches to market definition or competitive effects, sharing and discussing documents and other information obtained from merging parties or from third parties, as well as coordinating on merger remedies.

Cross-border cooperation is greatly aided by international waivers of confidentiality from companies under investigation. I would encourage all parties to investigations that involve non-U.S. competition authorities to consider granting a waiver of confidentiality restrictions. Waivers enable more complete communication and coordination among the competition agencies, which expedites the review and leads to well informed, consistent decisions – for all the competition enforcers. Without these waivers, FTC staff cannot share confidential information with non-U.S. competition authorities also reviewing the merger or conduct. We are limited to discussing publicly available information and sharing staff views on different elements of competition analysis, such as market definitions, competitive effects, and possible remedies.

We had three examples of successful international cooperation leading to compatible remedies in the past year, and the first one involved the merger of two global auto parts makers,

[28] In the Matter of ArcLight Energy Partners Fund VI, L.P., Dkt. C-4563 (final order issued Feb. 9, 2016).

ZF Friedrichshafen AG and TRW Automotive Holdings.[29] Both companies manufactured a wide variety of car and truck components, such as chassis, powertrains, and suspension systems, and had production facilities located throughout the United States, Canada and Mexico. In our review, we cooperated with Mexican authorities, the Canadian Competition Bureau, and the European Union's Directorate-General for Competition. Our cooperation began early in the investigation and included biweekly phone calls. We also received a number of waivers.

Based on our review, the FTC concluded that customers located in North America typically rely on manufacturers with production facilities located in the United States, Canada and Mexico, and that ZF and TRW, together with the Mexican firm USK Internacional (also known as Urresko), accounted for virtually all of the sales of heavy vehicle tie rods in North America. As part of its review, the European Commission determined that the merger would reduce competition in a different market in Europe – chassis components for cars and trucks. To resolve concerns in both countries, ZF decided to sell TRW's entire suspension business in North America and Europe, a single divestiture that satisfied concerns raised in both regions. The divestiture included five manufacturing plants located in the United States, Canada, the Czech Republic and Germany, as well as a German research lab. While the FTC on its own might not have required such an extensive divestiture package, the companies opted to sell a broader package of assets in order to resolve all outstanding competition reviews and proceed with their merger.[30]

Another example of successful international merger cooperation highlights a different issue that is more likely to occur in markets where there are substantial cross-border sales. The case involved the proposed $25 billion merger of cement manufacturers Holcim Ltd. and Lafarge S.A.[31] Before the merger, Holcim was a vertically integrated global supplier of building materials based in Switzerland. Lafarge was based in France, and sold many of the same products, including cement. The combined company would have operations in 90 countries and sales of $35 billion worldwide. Early on, we were in contact with our counterparts at the Canadian Competition Bureau and DG-Comp of the European Commission. The FTC's investigation revealed that because cement products are heavy and relatively cheap, transportation costs limit their markets to local or regional areas. In addition, we determined that there is significant cross-border trade in cement with sources in Canada supplying customers in U.S. border states, and vice-versa.

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[29] In the Matter of ZF Friedrichshafen and TRW Automotive, Inc., Dkt. C-4520 (final order issued June 18, 2015).

[30] It is not unusual for the Commission to require broader divestitures to maintain or restore competition. For instance, the Commission may require divestiture of assets outside the market of concern to ensure that the buyer is able to compete effectively with incumbent competitors. In *Polypore*, in order to restore competition in four North American markets for battery separators, the Commission ordered Polypore to divest a plant in Piney Flats, Tennessee as well as one in Feistritz, Austria because the buyer needed the foreign plant in order to manage its capacity and compete effectively in North America. *See* Opinion of the Commission, In the Matter of Polypore International, Inc., Dkt. 9327, at 38 (Dec. 13, 2010), *available at* http://www.ftc.gov/sites/default/files/documents/cases/2010/12/101213polyporeopinion.pdf,. *aff'd*, 686 F. 3d 1208, 1219 (11th Cir. 2012). *See also Competition Matters* blog post, "Divestitures may include assets outside the market," (Apr. 24, 2015), *available at* https://www.ftc.gov/news-events/blogs/competition-matters/2015/04/divestitures-may-include-assets-outside-market.

[31] In the Matter of Holcim Ltd. and Lafarge S.A., Dkt. C-4519 (final order issued June 16, 2015).

After an extensive investigation, the Commission concluded that the merger was likely to harm competition in 12 U.S. regional markets for portland cement, an essential ingredient in making concrete, and in two U.S. regional markets for slag cement, a specialty cement used in certain building applications. The FTC remedy required divestitures of specific plants and terminals in both the U.S. and Canada. The Canadian Competition Bureau also determined that the merger would cause harm to Canadian customers. To resolve those concerns, the companies entered into an agreement with Canada requiring divestitures of a larger group of Holcim assets, most located in Canada but including some facilities in the United States. The FTC's order and the CCB's order were compatible because our asset package was a subset of what was required to be divested by Canada. In addition, although most of the U.S. divestitures were made to upfront buyers, we were willing to accommodate the Canadian authorities in the timing of their divestitures. We allowed the assets that were included in the Canadian package to be sold after the FTC order was entered, subject to a hold separate agreement and with the FTC's approval of the post-order buyer.

The Holcim/Lafarge case is an excellent example of how cooperation allows each country to prevent mergers that are likely to cause harm to its consumers and businesses while at the same time avoiding an outcome in which one country's remedy undermines another's. It also illustrates how cooperation benefits the merging companies, which can get to a final decision in all the reviewing countries when the enforcers are flexible and have established procedures to obtain an effective remedy.

The third merger investigation with significant international cooperation involved technology products. To remedy competitive concerns, NXP Semiconductors N.V. agreed to sell its RF power amplifier assets in order to settle charges that its proposed $11.8 billion acquisition of Freescale Semiconductor Ltd. would substantially lessen competition in the worldwide market for RF power amplifiers.[32] The worldwide market for RF power amplifiers – high-powered semiconductors that amplify radio signals used to transmit information between electronic devices such as cellular base stations and mobile phones – is extremely concentrated, with Freescale and NXP supplying more than 60 percent, and Infineon Technologies AG as the only other significant competitor. The proposed consent order preserves competition by requiring NXP to divest all its assets that are used primarily for manufacturing, research, and development of RF power amplifiers to the Chinese private equity firm Jianguang Asset Management Co. Ltd. These assets include a manufacturing facility in the Philippines, a building in the Netherlands to house management and some testing labs, as well as all patents and technologies used exclusively or predominantly for the RF power amplifier business, and a royalty-free license to use all other NXP patents and technologies required by that business. The order also includes provisions to ensure the viability of the buyer, such as requiring NXP to assist the buyer in hiring its RF power amplifier employees. Throughout the investigation, Commission staff cooperated with staff of the antitrust agencies in the European Union, Japan and Korea, including on the analysis of the proposed transaction and potential remedies, to reach compatible approaches on an international scale.

[32] In the Matter of NXP Semiconductors N.V., Dkt. C-4560 (final order issued Jan. 29, 2016).

These cases are also a reminder that worldwide operations do not always equate with worldwide markets. Cement is a good example of a cheap, heavy product that is sold in local and regional markets in which customers pick up product from a plant or terminal nearby. Similarly, heavy equipment such as truck tie-rods can travel farther, but their size and weight still cause customers to look no farther than North America for supply. But in a merger involving high-technology specialized semiconductors, we found the relevant geographic market for RF power amplifiers is worldwide. The three major RF power amplifier suppliers manufactured the products in facilities around the world, and shipped the products from those facilities to customer locations worldwide. There are currently no regulatory barriers, tariffs, or technical specifications that impede worldwide trade, and transportation costs are low. As a result, RF power amplifier customers in the United States looked to suppliers from around the world.

NONMERGER MATTERS

There were also a number of important developments on the nonmerger side this year. Last summer the Commission issued a Statement of Enforcement Principles for the use of FTC Act Section 5 when the harmful conduct lies beyond the reach of Sherman Section 1 or 2.[33] The bipartisan policy statement reaffirms that the promotion of consumer welfare is the cornerstone of antitrust enforcement, and in deciding whether to bring a standalone Section 5 claim, the Commission will consider three principles on which there is broad consensus:

- the Commission will be guided by the public policy underlying the antitrust laws, namely, the promotion of consumer welfare;

- the act or practice will be evaluated under a framework similar to the rule of reason, that is, an act or practice challenged by the Commission must cause, or be likely to cause, harm to competition or the competitive process, taking into account any associated cognizable efficiencies and business justifications; and

- the Commission is less likely to challenge an act or practice as an unfair method of competition on a standalone basis if enforcement of the Sherman or Clayton Act is sufficient to address the competitive harm arising from the act or practice.

The Section 5 Statement confirms that Section 5's ban on unfair methods of competition covers not only those acts and practices that violate the Sherman Act or the Clayton Act, but also those that violate the spirit of the antitrust laws and those that, if left unaddressed, could violate the other antitrust laws. As an example of this last type of behavior, the Commission invoked its standalone authority in two cases this year involving invitations to collude.[34] The Commission

[33] Statement of Enforcement Principles Regarding "Unfair Methods of Competition" Under Section 5 of the Federal Trade Commission Act, 80 Fed. Reg. 57056 (Sept. 21, 2015); Statement of the Federal Trade Commission on the Issuance of Enforcement Principles Regarding "Unfair Methods of Competition" Under Section 5 of the FTC Act (Aug. 13, 2015).

[34] In the Matter of Drug Testing Compliance Group, LLC, Dkt. C-4565 (complaint issued Jan. 29, 2016); In the Matter of Step N Grip, LLC, Dkt. C-4561 (final order issued Dec. 16, 2015).

has long held that an invitation to collude violates Section 5 even where there is no proof that the competitor accepted the invitation, and is likely to continue to enforce Section 5 in this manner in keeping with the framework outlined in the Section 5 Statement.

Reverse-Payment Settlements Post-Actavis

As Chairwoman Ramirez reaffirmed recently in testimony before Congress,[35] stopping anticompetitive reverse payment settlements remains one of the Commission's top priorities. The Commission continues to devote significant resources to this effort, with three matters pending in federal court: *FTC v. Actavis*, which the Supreme Court returned to the federal court in Atlanta for trial,[36] and *FTC v. AbbVie, Inc.* [37] and *FTC v. Endo Pharmaceuticals Inc.*,[38] both of which are pending in Philadelphia.

The past year produced a break-through in the Commission's efforts: in June, seven years after filing the complaint and one week before the trial in *FTC v. Cephalon,*[39] Cephalon's new owner, Teva Pharmaceuticals, agreed to stop using certain types of anticompetitive patent settlements and paid $1.2 billion in ill-gotten gains to reimburse drug wholesalers, pharmacies, insurers, and others who overpaid for the blockbuster sleep disorder drug Provigil due to Cephalon's conduct. This landmark settlement represents the first monetary relief the Commission has obtained for purchasers harmed by reverse payment settlement agreements. Just as important, it contains broad injunctive relief restricting Teva, the world's largest generic company, from entering into these illegal settlements in the future.[40]

Under the stipulated order for permanent injunction, Teva is prohibited from engaging in certain types of reverse payment agreements – in particular, business transactions entered at the same time as the patent settlement. In this case, we were prepared to prove at trial that Cephalon agreed to pay the generics principally for active pharmaceutical ingredients and intellectual property, business deals that made no economic sense for Cephalon except as payments not to compete. The order bars Teva from entering into a business deal with a competitor within 30 days of, or expressly conditioned on, a patent litigation settlement that restricts that competitor's generic entry. This provision will not prevent Teva from entering into truly independent business transactions, and it preserves Teva's ability to enter other types of settlement agreements in which the value transferred is unlikely to present antitrust concerns, such as those providing payment for saved future litigation expenses (up to $7 million). This broad injunctive relief

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[35] Prepared Statement of Federal Trade Commission on "Oversight of the Enforcement of the Antitrust Laws," before the Subcommittee on Antitrust, Competition Policy and Consumer Rights of the Committee on the Judiciary, United States Senate (Mar. 9, 2016).
[36] *FTC v. Actavis, Inc.*, No. 1:09-cv-00955 (N.D. Ga. Apr. 10, 2009).
[37] *FTC v. AbbVie, Inc.*, No. 2:14-cv-5151 (E.D. Pa. Sept. 8, 2014).
[38] *FTC v. Endo Pharmaceuticals Inc*., No. 2:16-cv-01440 (E.D. Pa. Mar. 30, 2016).
[39] *FTC v. Cephalon, Inc*., No. 08-cv-2141 (E.D. Pa. complaint filed Feb. 13, 2008).
[40] FTC News Release, "FTC Settlement of Cephalon Pay for Delay Case Ensures $1.2 Billion in Ill-Gotten Gains Relinquished; Refunds Will GoTo Purchasers Affected by Anticompetitive Tactics" (May 28, 2015), https://www.ftc.gov/news-events/press-releases/2015/05/ftc-settlement-cephalon-pay-delay-case-ensures-12-billion-ill.

against the world's largest generic pharmaceutical company is an important milestone for the Commission's efforts to curtail anticompetitive reverse payment settlements.

Just last week, the Commission filed its first case challenging an agreement not to market an authorized generic, also known as a "no-AG commitment," as a form of reverse payment. In a complaint filed in federal court in Philadelphia, we allege that Endo Pharmaceuticals paid first-filers Impax Laboratories and Watson Laboratories to delay entry with a promise not to launch authorized generic versions of Endo's Opana ER and Lidoderm. Under the Hatch-Waxman framework, the first applicant to challenge a branded pharmaceutical's patent may be entitled to 180 days of exclusivity as against any other generic applicant upon final FDA approval. But a branded drug manufacturer is permitted to market an authorized generic version of its own brand product at any time, including during the 180 days after the first generic competitor enters the market. As we have previously argued in amicus briefs – a position now adopted by the First and Third Circuits – a no-AG commitment can raise the same competitive concerns addressed by the Supreme Court in *FTC v. Actavis* because it ensures that the first-filer will capture all generic sales and be able to charge higher prices during the exclusivity period.[41]

In *Endo*, we are seeking a permanent injunction as well as equitable monetary relief in the form of restitution or disgorgement. At the same time, we also filed a proposed stipulated order resolving allegations against Teikoku Seiyaku Co. Ltd. and Teikoku Pharma USA, Inc., Endo's partner for Lidoderm patches. We alleged that in May 2012, Endo and the Teikoku entities illegally agreed with Watson that Watson would not compete with Endo and Teikoku by marketing a generic version of Endo's Lidoderm patch until September 2013. In exchange, Endo paid Watson hundreds of millions of dollars, including $96 million in free branded Lidoderm products that Endo and Teikoku gave to Watson. As a result, Endo illegally maintained its monopoly over Lidoderm. The stipulation enjoins Teikoku Seiyaku Co. Ltd. and Teikoku Pharma USA, Inc. for 20 years from entering certain types of reverse payment agreements, including settlements containing no-AG commitments, but permits the companies to enter other types of settlement agreements in which the value transferred is unlikely to present antitrust concerns, such as those providing payment for saved future litigation expenses.

The Commission is also attentive to agreements that are not part of a patent settlement but nonetheless have the effect of reducing generic competition. For instance, the FTC charged Concordia Pharmaceuticals Inc. and Par Pharmaceutical, Inc. with entering into an unlawful agreement not to compete in the sale of generic versions of Kapvay, a prescription drug used to treat Attention Deficit Hyperactivity Disorder. One week before Concordia's patent covering branded Kapvay ended, Concordia and Par were the only two firms permitted by the FDA to market generic Kapvay. Rather than competing against each other, Concordia agreed not to sell

[41] *King Drug Co. of Florence Inc. v. Smithkline Beecham Corp*., 791 F.3d 388 (3d Cir. 2015); *see* FTC Brief as Amicus Curiae, *In re Lamictal Direct Purchaser Antitrust Litig*., No. 14-1243 (3d Cir. Apr. 28, 2014), https://www.ftc.gov/system/files/documents/amicus_briefs/re-lamictal-direct-purchaser-antitrust-litigation/140428lamictalbrief.pdf; *In re Loestrin 24 FE Antitrust Litig*., --- F. 3d. --- , 2016 WL 698077 (1st Cir. Feb 22, 2016); FTC, Brief as Amicus Curiae, *In re Loestrin 24 FE Antitrust Litig*., No. 14-2071 (1st Cir. June 16, 2015), https://www.ftc.gov/system/files/documents/amicus_briefs/american-sales-co.et-al.plaintiffs-appellants-v.warner-chilcott-co.llc-et-al.defendants-appellees/1506warner-chilcottamicusbrief.pdf.

an authorized generic version of Kapvay for five years in exchange for a share of Par's profits on its generic sales.

Under the terms of the settlements with each company, Concordia is prohibited from enforcing the anticompetitive provisions of its agreement with Par, including the profit-sharing provisions, and Par is prohibited from enforcing provisions that bar Concordia from agreeing not to sell an authorized generic version of Kapvay. The settlements also prohibit Concordia and Par from entering into similar agreements with each other and with any other entities in the future. Concordia began selling generic Kapvay after learning of the FTC's investigation.[42]

We believe we are beginning to see positive signs in the types of agreements penned in the wake of *Actavis*. Based on our annual review of patent settlements filed with the antitrust agencies under the Medicare Modernization Act, the number of potentially anticompetitive reverse payment settlements in pharmaceutical patent settlement agreements declined in FY2014, the first full fiscal year after the *Actavis* decision, as compared to any of the previous four years. Although more patent disputes were settled in FY 2014 than in any prior fiscal years, more than 80 percent of the MMA filings in FY 2014 did not involve any compensation paid by the branded company to the generic company. It is too early to tell if these figures represent a more permanent decline in this activity, but the numbers are encouraging. At the same time, the data also show a need for the FTC to continue to investigate and challenge agreements that delay generic drugs and impose substantial costs on consumers, employers, and taxpayers.

Exclusive Dealing: McWane and Cardinal Health

Other nonmerger litigation news from this year includes the end of our monopolization case involving McWane, Inc. The case is important because it is one of the few litigated monopolization decisions involving vertical restraints. It is well-settled antitrust doctrine that exclusive dealing arrangements are generally procompetitive and can benefit competition by improving interbrand competition. Yet both the Commission and the Eleventh Circuit found that when used by a company with monopoly power, exclusive dealing can be harmful when it enables the firm to maintain its monopoly by impairing the ability of rivals to develop into effective competitors.

The basic facts of this case are not in dispute. McWane manufactures ductile iron pipe fittings used in waterworks projects, and is the only producer with a foundry located in the United States. Pipe fittings are sold by distributors to end-users, and in 2009, federal legislation provided funds for infrastructure projects that used products made in the U.S. Shortly thereafter, Star Pipe Products tried to enter the market for domestically manufactured fittings, contracting with third-party jobbers while it looked at options for acquiring a foundry of its own. Star did not sell a full line of fittings, supplying only the most commonly used sizes through distributors.

[42] In the Matter of Concordia Pharmaceuticals, Inc. and Par Pharmaceutical, Inc., Dkts. C-4553 and C-4554 (final orders issued Oct. 30, 2015).

In late 2009, McWane responded to Star's entry by announcing its "Full Support Program" under which distributors that did not buy all of their domestic fittings from McWane would lose their already-accrued rebates and be cut off from McWane's products. Even though Star was able to make some sales through distributors, McWane's market share in domestic fittings never fell below 90 percent.

The Commission determined that McWane's Full Support Program operated as a *de facto* exclusive dealing policy by effectively requiring distributors to buy domestic fittings only from McWane. As a result, the program foreclosed Star's access to distributors, raised its costs, and denied customers meaningful choice for domestic fittings. Using a full-blown rule of reason analysis, the Commission determined that McWane's exclusive dealing policy enabled McWane to maintain its monopoly power by preventing a rival pipe fittings firm from achieving sufficient scale to be an efficient competitor. McWane argued that its full-line requirement was needed to maintain high levels of capacity utilization; the Commission rejected this justification, observing that a monopolist's mere desire to maintain market share is not a procompetitive benefit that can outweigh anticompetitive effects.[43]

The Eleventh Circuit endorsed the structured balancing approach used by the Commission and the D.C. Circuit in *Microsoft,* finding that the Commission's factual and economic conclusions were supported by substantial evidence, and its legal conclusions supported by governing law. The court rejected McWane's argument that Star's entry precluded a finding of monopoly power, citing McWane's persistent 90 percent market share, the high capital costs associated with entry, and McWane's "undeniable continued power over domestic fittings prices."[44] In response to arguments that the Full Support Program was voluntary and merely reduced rebate levels (*i.e.*, raised prices for disloyal customers), the court found that the distributors understood that they would be cut off if they bought from others and so continued to buy from McWane exclusively rather than shifting sales to Star.

In effect, the Full Support Program was a "take-it-or-leave-it" proposition for distributors that neither reduced price nor expanded output:

> [T]he nature of the Full Support Program arguably posed a greater threat to competition than a conventional exclusive dealing contract, as it lacked the traditional procompetitive benefits of such contracts. As we've noted, courts often take a permissive view of such contracts on the grounds that the firms compete for exclusivity by offering procompetitive inducements (e.g., lower prices, better service). But not here. The Full Support Program was "unilaterally imposed" by fiat upon all distributors, and the ALJ found that it resulted in "no competition to become the exclusive supplier" and no "discount, rebate, or other consideration" offered in exchange for

[43] Opinion of the Commission, In the Matter of McWane, Dkt. 9351 (Feb. 6, 2014), *available at* https://www.ftc.gov/system/files/documents/cases/140206mcwaneopinion.pdf.
[44] 783 F.3d at 834.

exclusivity. This is consistent with evidence that McWane's prices rose, rather than fell, in the wake of the program.[45]

The Commission also reached a settlement in another case involving *de facto* exclusive agreements – this time involving supplier commitments that prevented downstream entrants from obtaining key inputs. Last April, the FTC charged Cardinal Health, Inc. with illegally monopolizing 25 local markets for the sale and distribution of low-energy radiopharmaceuticals.[46] Cardinal owns the nation's largest chain of radiopharmacies, which sell and distribute drugs known as low-energy radiopharmaceuticals. These radiopharmaceuticals are used by hospitals and clinics to diagnose a range of medical conditions, including heart disease. Due to the short half-life of the radioactive isotopes used in these drugs, hospital and clinics rely on radiopharmacies located nearby, resulting in highly localized markets.

As alleged in the FTC's complaint, between 2003 and 2008, Bristol-Myers Squibb and General Electric Co. were the only U.S. manufacturers of heart perfusion agents (or HPAs), radiopharmaceuticals used to perform heart stress tests. Over that period, Cardinal became the largest chain of radiopharmacies in the United States and the sole radiopharmacy operator in 25 metropolitan areas. Cardinal employed various tactics to coerce and induce both BMS and GE to refuse to grant distribution rights for their respective HPA products to new competitors in the relevant markets. These coercive tactics included canceling (or threatening to cancel) purchases; switching customers from one manufacturer's products to the other to pressure the supplier not to license new competitors; threatening to compete as a future generic supplier; and conditioning Cardinal's future relationship with GE on GE's refusal to grant HPA distribution rights to new competitors in the relevant markets. As a result of these tactics, BMS and GE did not offer HPA distribution rights to several potential entrants in the local radiopharmacy markets, and gave Cardinal *de facto* exclusive rights to distribute both products.

Cardinal's simultaneous maintenance of exclusive distribution rights to the only two HPAs lacked any legitimate business or efficiency justification because locking up both brands of HPAs *suppressed* rather than *promoted* interbrand competition. Moreover, given the thwarted attempts of the suppliers to license new distributors, Cardinal's conduct was output-reducing rather than output-enhancing.[47] Our investigation also revealed that Cardinal charged higher prices in its monopoly markets – as much as 20 percent more.

To settle these charges, Cardinal agreed to a stipulated injunction tailored to prevent future violations, restore the competition that was lost, and disgorge $26.8 million in ill-gotten gains to be placed into a fund to compensate affected customers. The order also includes provisions to prevent future violations and restore competition in six markets where Cardinal remains the dominant radiopharmacy.

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[45] Id.
[46] *FTC v. Cardinal Health Inc*., No. 15-cv-3031 (S.D.N.Y. 2015) (final order and stipulated permanent injunction).
[47] *See* Statement of the Commission at 4, In the Matter of Cardinal Health, Inc. (Apr. 17, 2015), *available at* https://www.ftc.gov/system/files/documents/public_statements/637781/150420cardinalhealthcommstmt.pdf.

State Action Guidance in the Wake of North Carolina Dental

After the Supreme Court's February 2015 decision in N.C. State Bd. of Dental Examiners v. FTC,[48] we received requests from state officials and others for advice on how to comply with the Court's decision. By way of background, the Board of Dental Examiners is a state agency established under North Carolina law and charged with setting and enforcing licensing standards for dentists. The Board acted to exclude non-dentists from providing teeth whitening services. The Board argued that as a state agency, it was exempt from federal antitrust laws under the state action doctrine. The FTC, the Fourth Circuit, and ultimately the Supreme Court disagreed, finding that the state action defense does not apply to the actions of a licensing board controlled by market participants unless its conduct is actively supervised by the state.

After *North Carolina Dental*, licensing boards may continue to regulate professionals in their respective states and be exempt from antitrust laws, so long as they act pursuant to a clearly articulated state policy and, if they are controlled by market participants, under active supervision by the state. The Court did not specify exactly what would constitute "active state supervision," explaining that that inquiry was "flexible and context-dependent." Further, it need not "entail day-to-day involvement in any agency's operation or micromanagement of its every decision." Rather, the touchstone is "whether the State's review mechanisms provide 'realistic assurance' that a non-sovereign actor's anticompetitive conduct 'promotes state policy, rather than merely the party's individual interests.'"[49]

In October, the Bureau issued staff guidance on two basic questions of concern to state officials in the wake of the Court's decision. First, when does a state regulatory board require active supervision to invoke the state action doctrine? Second, what factors are relevant to determining whether that requirement is met?[50] The staff guidance emphasizes that antitrust analysis – including the applicability of the state action defense – is fact-specific and context-dependent. A one-size-fits-all approach to active supervision is neither possible nor warranted. Moreover, deviation from this guidance does not necessarily mean that the state action defense is inapplicable, or that a violation of the antitrust laws has occurred.

The topic of occupational licensing has gotten more attention of late, given the growing list of professions subject to licensing and regulation by the states – including beekeepers, tour guides, and shampooers.[51] In advocacy comments, we often encourage states to avoid unneeded and burdensome regulation of service providers and empower regulatory boards to restrict competition only when necessary to protect the health or safety of consumers. Or the state may create a board that serves only in an advisory capacity or is made up of persons who have no

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[48] *N.C. State Bd. of Dental Exam'rs v. FTC*, 135 S. Ct. 1101 (2015).
[49] *Id*. at 1116 (quoting *Patrick v. Burget*, 486 U.S. 94, 100-1 (1988)).
[50] FTC Staff, Guidance on Active Supervision of State Regulatory Boards Controlled by Market Participants (Oct. 2015), https://www.ftc.gov/system/files/attachments/competition-policy-guidance/active_supervision_of_state_boards.pdf.
[51] *See* Prepared Statement of the Federal Trade Commission before the Subcommittee on Antitrust, Competition Policy and Consumer Rights, Committee on the Judiciary, United States Senate, "License to Compete: Occupational Licensing and the State Action Doctrine," Feb. 2, 2016, *available at* https://www.ftc.gov/system/files/documents/public_statements/912743/160202occupationallicensing.pdf.

financial interest in the occupation that is being regulated. In addition, a state may forgo active supervision and choose to have its boards subject to federal antitrust standards. In that case, the state need not provide for active supervision, and we can enforce antitrust standards to prevent regulatory boards from restraining competition without justification, as we did in the N.C. Dental case.

Amicus Brief on Promotional Allowances under the Robinson-Patman Act

Last fall, the Commission filed an amicus brief in the U.S. Court of Appeals for the Seventh Circuit urging the court to reverse a district court decision finding that the mere sale of large-sized packages of certain products to one merchant – but not to another that was purchasing the same products in smaller packages – could violate Section 2(e) of the Robinson-Patman Act.[52] In the underlying lawsuit, Woodman's Food Market alleges that Clorox violated the Robinson-Patman Act by selling Woodman's smaller packages of various consumer products (including bleach), but refusing to sell it large-sized packages while selling them to membership-based retailers Sam's Club, Costco, and BJ's Wholesale Club. The district court's decision relied on two FTC administrative decisions from 1940 and 1956 holding that the Act requires a seller to provide its products in packages of the same size and style to all competing buyers who demand them.

Our November 2015 amicus brief argues that these administrative decisions are no longer good law because they are out of step with more recent FTC and federal court cases that interpret the Robinson-Patman Act narrowly and in a manner consistent with other antitrust laws. Section 2(a) prohibits direct or indirect price discrimination in sales for resale only when the likely effect is to substantially lessen competition. By contrast, Section 2(e) categorically bans discrimination disguised as promotional services regardless of the effect on competition. Even though the FTC has not brought a case alleging violations of this provision of the Robinson-Patman Act since 1988, we recently updated our interpretive guides for Advertising Allowances and Other Merchandising Payments and Services, known as the Fred Meyer Guides, because public comments supported their continuing relevance in interpreting the Act.[53] As the Guides explain, special packaging or package sizes may be a promotional service within the reach of Section 2(e). But as we explained in our amicus brief, without evidence that the packaging conveyed a promotional message to consumers, plaintiff's claims should be dismissed.

HSR ENFORCEMENT

The FTC administers the Hart-Scott-Rodino premerger notification program and enforces the filing rules. There is a significant public interest in enforcing the filing rules in an even-

[52] FTC Brief as *Amicus Curiae*, *Woodman's Food Market, Inc. v. The Clorox Co*., 15-3001 (7th Cir. Nov. 2, 2015), *available at* https://www.ftc.gov/system/files/documents/amicus_briefs/woodmans-food-market-inc.plaintiff-appellee-v.clorox-co.clorox-sales-co.defendants-appellants/151102woodmanvscloroxamicusbrief.pdf.
[53] FTC News Release, "FTC Approves Final Amendments to Guides to Help Businesses Comply with Law Regarding Promotional Allowances and Services" (Sept. 24, 2014), *available at* https://www.ftc.gov/news-events/press-releases/2014/09/ftc-approves-final-amendments-guides-help-businesses-comply-law.

handed manner and deterring would-be violators from ignoring HSR rules and requirements. Staff of the Bureau's Premerger Notification Office are available to answer questions about how and when to file to aid counsel in complying with the HSR Act.

This year, we took three HSR enforcement actions, including one alleging misuse of the "investment-only" exemption. The HSR Act exempts certain acquisitions of voting securities if made "solely for the purpose of investment." The HSR Rules state that acquisitions of less than 10 percent are exempt from filing if the investor has "no intention of participating in the formulation, determination, or direction of the basic business decisions of the issuer." (Rule 801.1(i)(1).) The Statement of Basis and Purpose issued at the time the Commission promulgated the HSR Rules further explains that certain conduct is inconsistent with a claim of investment purpose, and contains the following examples: nominating a candidate for the board of directors, holding a board seat or being an officer, proposing corporate action that requires shareholding approval, soliciting proxies, or being a competitor of the issuer. The exemption does not apply if the acquirer will hold stock over 10 percent of the issuer's voting securities, regardless of any intention to participate in management.

In August, we charged three affiliated hedge fund companies and their management company, Third Point LLC, with violating the premerger reporting laws in connection with their 2011 acquisitions of stock in Yahoo! Inc. The complaint alleges that Third Point Partners (Qualified L.P., Third Point Ultra, LTD, and Third Point Offshore Fund, LTD) erroneously relied on the investment-only exemption when they failed to observe the filing and waiting requirements of the Hart-Scott-Rodino Act before purchasing shares in Yahoo. At the time of the stock purchases, however, defendant Third Point LLC, which made investment decisions on behalf of the funds, was taking actions inconsistent with an investment-only intent, such as:

- contacting certain individuals to gauge their interest and willingness to become the CEO of Yahoo or a potential board candidate of Yahoo;
- assembling an alternate slate for the Yahoo Board;
- drafting correspondence to Yahoo announcing that Third Point was prepared to join the Yahoo Board;
- internally discussing the possible launch of a proxy battle for directors of Yahoo; and
- stating publicly that it was prepared to propose a slate of directors at Yahoo's next annual meeting.

In a blog post explaining our action, we noted that the investment-only exemption is narrow.[54] Our settlement with Third Point contains valuable information for investors as well as CEOs or board members about conduct that is inconsistent with an intent to be a passive investor. Investors should note, however, that the test for the investment-only exemption is the acquirer's intention, and that determination may not turn on any particular conduct. While the conduct specified in the injunction is evidence that an investor is not passive, other evidence, and other conduct, also may reveal non-passive intent.

[54] Competition Matters blog post, "'Investment-only' means just that" (Aug. 24, 2015), *available at* https://www.ftc.gov/news-events/blogs/competition-matters/2015/08/investment-only-means-just.

Although the HSR Act provides for civil penalties of up to $16,000 for each day an acquirer is in violation of the Act, the Commission, in consultation with our colleagues at the Antitrust Division, decided to seek only injunctive relief in this case. Here, Third Point soon filed the required HSR forms, so it was out of compliance with the HSR Act for only a short period, and it observed the required waiting periods for subsequent purchases of Yahoo shares during the waiting periods. This was also Third Point's first violation of the HSR Act, which can be a factor in determining the appropriate consequences when parties mistakenly rely on an HSR exemption.

In another HSR case from this year, investor Len Blavatnik agreed to pay $656,000 in civil penalties to resolve allegations that he violated federal premerger reporting laws by failing to report voting shares that he acquired in a California technology startup called TangoMe in August 2014. According to our complaint, Blavatnik, via his company Access Industries, purchased shares of TangoMe that brought the value of his stake in the company to approximately $228 million without filing the requisite premerger notification and observing the waiting period. Blavatnik eventually made a filing for the acquisition, acknowledging that the acquisition was reportable and that his failure to report the transaction in a timely fashion was inadvertent. This was the investor's second HSR violation. Despite making representations after his first violation that he would discuss reportability with HSR counsel prior to any future acquisitions, he failed to do so, resulting in the second violation.

In a separate action, holding company Leucadia National Corporation agreed to pay $240,000 in civil penalties for its failure to file premerger notifications for a conversion of its ownership interest in the financial services company Knight Capital Group, Inc. In July 2013, Knight Capital consolidated with another financial services company, GETCO Holding Company, LLC, to become KCG Holdings, Inc. That transaction converted Leucadia's ownership interest in Knight Capital into nearly 16.5 million voting shares of the new entity, KCG Holdings, worth approximately $173 million. Leucadia did not report the transaction, according to the complaint, because it thought that it qualified for an exemption applicable to institutional investors. Although Leucadia consulted experienced HSR counsel in connection with the transaction, its counsel erroneously concluded that the exemption applied. Leucadia made a corrective filing in September 2014, acknowledging that the acquisition was reportable under the HSR Act. This was Leucadia's second HSR violation. Although the FTC did not pursue a civil penalty against Leucadia for the previous violation, the Premerger Notification Office informed Leucadia at that time that it "still must bear responsibility for compliance with the Act," and that it was accountable for instituting a program to comply with the HSR Act.

Finally, the Commission successfully defended a court challenge to a change to the HSR rules that requires pharmaceutical companies to file premerger notification reports for certain proposed acquisitions of exclusive patent rights.[55] In 2013, the Commission revised Rules 801.1 and 801.2 to reflect the longstanding staff position that a transaction involving the transfer of

[55] *See* FTC News Release, "FTC Finalizes Amendments to the Premerger Notification Rules Related to the Transfer of Exclusive Patent Rights in the Pharmaceutical Industry" (Nov. 6, 2013), *available at* https://www.ftc.gov/news-events/press-releases/2013/11/ftc-finalizes-amendments-premerger-notification-rules-related.

exclusive rights to a patent in the pharmaceutical industry, which typically takes the form of an exclusive license, is potentially reportable under the Act, and to clarify the treatment of retained manufacturing rights. Under the revised rules, the retention of limited manufacturing rights and co-rights does not affect whether the transfer of all commercially significant rights has occurred.[56]

A pharmaceutical trade association filed an action in federal court to set aside the revised rules, challenging the FTC's authority to issue an industry-specific rule under the Administrative Procedure Act. Last June, the D.C. Circuit affirmed the lower court's ruling that the Commission was entitled to *Chevron* deference in adopting an industry-specific rule. Moreover, the appellate court found that the revised rule was "obviously consistent" with the purpose of the HSR Act, and "the FTC's explanation for its promulgation of the Rule is perfectly reasonable and supported by the record."[57]

MERGER REMEDY STUDY AND MERGER PROCESS REFORMS

I also want to mention the ongoing Remedy Study. Last year, the Commission announced that it would conduct a study of all merger orders issued from 2006 through 2012 to determine how well they have met the goal of maintaining or restoring competition that would be lost due to a merger.[58] Once we received OMB approval, we assembled a team of lawyers, economists, paralegals and research analysts to take a look back at the nearly 90 merger orders issued during that period. This is a big undertaking for the Bureau, with lawyers from every merger shop participating in the interviews with competitors and customers. In addition, we have issued nearly 200 requests for data under Section 6(b) of the FTC Act, seeking limited sales information from the period pre- and post-divestiture. We appreciate the companies' willingness to participate in the study and to share their insights and knowledge, sometimes involving events from more than a decade ago. I can report that we are more than halfway through with interviews and data collection, and I am looking forward to the learning that will come out of this project.

Another internal project that I initiated shortly after I became Director aimed at streamlining certain internal merger processes and identifying best practices from among the different approaches used by the merger shops. My hope was not only to provide more transparency to businesses and their counsel about what they can expect if they are involved in a merger under review at the Commission, but also to increase consistency across merger investigations to the extent possible, especially in light of the increased use of pull-and-refile as well as advances in electronic discovery. Last August, I announced the findings of our internal review and issued updated guidance.[59] In addition to internal improvements, we revised the Model Second Request in the areas relating to requests for datasets, pricing information, and the

[56] 78 Fed. Reg. 68705 (Nov. 15, 2013).
[57] *PhRMA v. FTC*, 790 F.3d. 198, 200 (D.C. Cir. 2015).
[58] *See* FTC News Release, "FTC Proposes to Study Merger Remedies" (Jan. 9, 2015), *available at* https://www.ftc.gov/news-events/press-releases/2015/01/ftc-proposes-study-merger-remedies.
[59] *Competition Matters* blog post, "A fine balance: toward efficient merger review" (Aug. 4, 2015), *available at* https://www.ftc.gov/news-events/blogs/competition-matters/2015/08/fine-balance-toward-efficient-merger-review.

instructions regarding search terms and the use of predictive coding. We also updated our BC Production Guide, which contains information on suggested formats when submitting information electronically. And finally, we provided guidance to parties on steps they can take to work cooperatively with Bureau staff to minimize the burden of responding to a Second Request, such as early voluntary submission of information and effective use of pulling and refiling an HSR filing, as well as tips on negotiating the Second Requests to avoid unnecessary burden for both sides.