ABA Health Care and Pharmaceuticals Committee
Recent Developments

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ABA SECTION OF ANTITRUST LAW

Promoting Competition Protecting Consumers

About Recent Developments

Recent Developments is published six times a year by the ABA Antitrust Section Health Care and Pharmaceuticals Committee and contains summaries of recent federal and state court cases, government enforcement actions, and other "recent developments" involving antitrust and privacy issues in the health care and pharmaceutical industries.

Please contact the editors, Kari Wallace (kwallace@ftc.gov) or Imran Ahmad (iahmad@casselsbrock.com), if you would like to get involved with the publication or if you have any comments or suggestions. This publication is being distributed via the Committee listserv (AT-HCIC) and will be available through the Recent Developments archive on the Committee website at: http://apps.americanbar.org/dch/committee.cfm?com=AT301000.

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FEDERAL COURT CASES

FTC Resumes Litigation against Phoebe Putney; Obtains Temporary Restraining Order

Fed. Trade Comm'n v. Phoebe Putney Health Sys., Inc. No., 1:11-cv-00058-WLS (filed Apr. 11, 2013)

Following the Supreme Court's recent decision to revive the agency's challenge to Phoebe Putney Health System's acquisition of Palmyra Park Hospital in Georgia, the Federal Trade Commission (FTC) obtained a temporary restraining order preventing the acquisition from moving forward.

The matter stems from an acquisition involving Georgia-based Phoebe Putney Health System and Palmyra Park Hospital. Phoebe Putney Health System had leased Phoebe Putney Memorial Hospital from a Georgia Public Hospital Authority in 1991. In April 2011, the Authority approved a plan by which the Authority would acquire nearby Palmyra Park Hospital with money provided by Phoebe Putney Health System. After acquiring Palmyra Park, the Authority would lease the hospital back to the system.

The FTC filed an administrative action and a federal complaint challenging the acquisition. According to the FTC, the two hospitals would control more than 85 percent of acute care services in the geographic market in which they operate. Finding the transaction immune under the state action doctrine, a district court and the Eleventh Circuit Court of Appeals refused to enjoin the transaction and the parties closed the deal. The Eleventh Circuit noted, however, that the transaction would substantially lessen competition, if not create a monopoly. The FTC sought and was granted certiorari from the Supreme Court.

The Supreme Court disagreed with the Eleventh Circuit. In a unanimous ruling, the Court found that while Georgia law authorized the creation of hospital authorities and permitted the acquisition of hospitals, the state had not clearly articulated and affirmatively expressed a policy to permit authorities to displace competition when they acquired hospitals.

Two months later, the FTC filed a renewed complaint in federal district court and moved to enjoin the parties from integrating further pending the outcome of the administrative proceeding. The FTC argued that the parties consummated the transaction "at their own peril" given the Eleventh Circuit's concern for their combined market power.

The district court agreed. Granting the FTC's request for a temporary restraining order, the court preserved the status quo and barred Phoebe Putney and Palmyra Park from further integration. The restraining order will remain in effect until the court rules on the FTC's pending request for a preliminary injunction, which is set for hearing on June 14, 2013.

AbbVie and Teva Hit with Two Pay-For-Delay Class Action Lawsuits

City of Providence v. AbbVie Inc. et al., No. 1:13-cv-00292, (D. R.I. filed Apr. 30, 2013); Painters Dist. Council No. 30 Health & Welfare Fund v. AbbVie Inc. et al., No. 2:13-cv-02343 (E.D. Pa. filed Apr. 30, 2013)

AbbVie Inc. and Teva Pharmaceutical Industries Ltd. are facing two antitrust class action suits challenging a pay-for-delay deal that has allegedly harmed consumers by keeping a generic version

of AbbVie's cholesterol drug Niaspan off the market.

The city of Providence, Rhode Island and a painters union's benefits fund commenced separate class actions. Both alleged that the agreement between AbbVie and Teva kept a less-expensive generic version of Niaspan off the market for several years and, as a result, harmed competition and consumers who have been forced to pay higher prices because of the agreement.

Providence alleges that after Barr Pharmaceuticals Inc. (now a Teva subsidiary) applied in 2001 to the U.S. Food and Drug Administration (FDA) to sell a generic form of Niaspan, AbbVie's predecessor company, Kos Pharmaceuticals Inc., sued the generics maker for patent infringement. The two sides eventually reached a settlement under which the generics maker agreed to keep its product off the market for eight years in exchange for payment.

According to Providence's complaint, the pay-for-delay deal prevented "a less-expensive generic version of Niaspan from entering the market in violation of federal and state antitrust laws, state consumer protection laws and state unjust enrichment laws."

The complaint further alleged that "[t]he ultimate losers of the pay-for-delay agreement are American consumers who were denied the opportunity to more timely purchase a less expensive generic version and were, thereby, forced to continue to pay unnecessarily high prices for Niaspan for many years."

In addition to the City of Providence, the Painters District Council No. 30 Health & Welfare Fund filed a separate class action in Pennsylvania federal court contesting the alleged pay-for-delay deal struck between AbbVie and Teva.

These lawsuits come less than a month after AbbVie and Teva were hit with a similar suit in Pennsylvania federal court by another union benefits fund. In that class action, lodged in early April 2013 by the United Food & Commercial Workers Union and Midwest Health Benefits Fund, the union benefits fund made allegations nearly identical to those in the most recent lawsuits.

New Jersey Court Denies Sanofi's Counterclaims and Interlocutory Appeal in Class Action Suit Involving Vaccine Purchasers

Castro v. Sanofi Pasteur, Inc., No. 2:11-cv-07178-JLL-MAH (D. N.J. filed Dec. 9, 2011)

On April 9, 2013, New Jersey District Court Judge Linares denied two motions filed by Sanofi Pasteur Inc., thereby maintaining the court's previous decision to dismiss the vaccine producer's antitrust counterclaims.

Sanofi develops and distributes healthcare products, including pediatric vaccines. In a proposed class action filed on January 20, 2012, vaccine purchasers alleged that Sanofi engaged in a monopolization scheme to maintain market power by entering into contracts with physician buying groups (PBGs). Some of the contracts explicitly prohibited contracting with competitors. The plaintiffs further alleged that by bundling a portfolio of vaccines, Sanofi made it more expensive to purchase competitors' vaccines. The class action plaintiffs purchased vaccines directly from Sanofi and claim damages due to paying higher prices for the drugs.

Sanofi filed a counterclaim on February 27, 2012, stating that the plaintiffs and "unnamed co-conspirators" used PBGs to enter into cooperative agreements and demanded discounts that caused the prices of its vaccines "to fall below

competitive levels." The court found that Sanofi failed to allege facts to support a plausible inference that the PBGs fixed prices or restricted purchases. Moreover, the court found that PBGs are not, prima facie, anticompetitive and that Sanofi failed to allege facts sufficient to find that the buying groups had an anticompetitive effect.

As a result of the court's rulings, Sanofi made a motion for entry of a final judgment, or in the alternative, for leave to file an interlocutory appeal of the dismissal of its counterclaim. On April 9, 2013, the court denied both.

In disposing of the motion for entry of a final judgment, the court noted that both Sanofi and the plaintiffs' claims involved common questions, such as seeking to find the definition of "market power" and "anticompetitive practices." The court also denied leave to file an interlocutory appeal because it found that an immediate appeal would not advance the termination of the suit.

Union Sues Drug Manufacturers over Alleged Pay-For-Delay Agreements

United Food and Commercial Workers Local 1776 & Participating Emp'rs Health and Welfare Fund v. Warner Chilcott, LLC, No. 2:13-cv-01807 (E.D. Pa. filed Apr. 5, 2013)

United Food and Commercial Workers Local 1776 (United Food) sued branded-drug manufacturer Warner Chilcott and generic manufacturers Actavis and Lupin for allegedly entering into pay-for-delay agreements that stymied generic competition to Warner Chilcott's brand-name oral contraceptive.

On April 5, 2013, United Food filed a class action complaint against the defendants on behalf of a putative class of indirect purchasers who paid for Warner Chilcott's branded Loestrin 24 Fe and/or its AB-rated generic equivalents beginning September 1, 2009. According to the fund's complaint, Warner Chilcott "gamed" the Hatch Waxman Act regulatory system by suing Actavis and Lupin for patent infringement. The plaintiffs allege that Warner Chilcott knew that the patent covering its Loestrin 24 drug was weak, and sued the generic manufacturers solely to initiate the statutorily created thirty-month stay period during which the FDA will not grant final approval to generic companies and allow them to enter the market.

Specifically, United Food accuses Warner Chilcott of initiating meritless patent infringement litigation—first against Actavis and later against Lupin—and then settling both lawsuits by paying each generic manufacturer to delay entering the market until dates near or at the end of its patent expiration term in July 2014. In exchange for Actavis' delayed market entry, Warner Chilcott allegedly agreed to refrain from launching its own authorized generic version of Loestrin 24 during Actavis' first 180 days of marketing a generic equivalent and compensated Actavis via certain licenses and marketing rights to other lucrative pharmaceuticals. In exchange for Lupin's delayed market entry, Warner Chilcott allegedly granted Lupin licenses to make or sell generic versions of another oral contraceptive and, under certain circumstances, an inflammatory bowel disease drug.

United Food further claims that Warner Chilcott used the period of exclusivity it obtained from its agreements with Actavis and Lupin to "product hop"—that is, patent minor modifications to Loestrin 24 and persuade doctors to switch their patients to Warner's follow-on product called Lo Loestrin Fe (that would ostensibly be protected by patent until 2029). The plaintiff asserts that Warner Chilcott's patent settlement payments combined with its product hop strategy has both delayed generic competition to its Loestrin 24 drug and ensured that, by the time such entry does occur, the demand for Loestrin 24 will be

supplanted by demand for Warner's follow-on drug for which there will be no effective generic competition.

The suit comes at a time when pay-for-delay agreements, product hopping, and "no authorized generic" agreements continue to garner significant attention from the FTC and private litigants. Actavis, formerly known as Watson, is a party to an FTC pay-for-delay challenge upon which the U.S. Supreme Court will rule this term.

Years of Litigation Ends with $5 Million Settlement with Nurses in Trinity Health Lawsuit

Cason-Merendo et al. v. Detroit Med. Ctr., et al., No. 2:06-cv-15601-GER-DAS (E.D. Mich. filed Dec. 14, 2006)

A class action lawsuit brought by registered nurses in the Detroit area against eight hospitals has resulted in a settlement with one of the alleged conspirators—Trinity Health Corporation. Trinity, a home healthcare service provider that operates multiple facilities in the Detroit area, allegedly conspired with the other defendant hospitals by exchanging information related to the wage rates for nurses, resulting in lower and anticompetitive wages in violation of the Sherman Act. The defendant hospitals and healthcare centers allegedly discussed and exchanged non-public data about employee compensation, resulting in the registered nurses receiving nearly identical wages despite working for different hospitals.

After years of litigation, Judge Rosen of the Eastern District of Michigan granted preliminary approval of the settlement with Trinity on May 16, 2013. Once members of the class are given notice of the settlement and the court conducts a hearing, the court can give its final approval. The settlement provides more than $5 million in cash to plaintiffs in exchange for a release of all claims against Trinity. The settlement class includes all registered nurses employed by the defendant within the Detroit area from December 12, 2002 through June 15, 2007, who provided direct patient care in short-term acute facilities. The class excludes registered nurses who worked in a supervisory or managerial role.

Plaintiffs previously settled with three defendants, while another three settlements are still pending approval. Plaintiffs found the proposed settlement with Trinity fair and reasonable, stating it was based on arms-length negotiations and noting "a recovery equivalent to two percent of the total [registered nurse] wages paid by Trinity is the same result as multiple settlements approved" by the court.

Notably, of the eight healthcare systems sued by plaintiffs, Trinity was the only one that moved to dismiss plaintiff's complaint. In August 2007, Trinity argued that the case should be dismissed because plaintiffs failed to allege how Trinity was involved in the alleged conspiracy, and that the complaint failed to give Trinity notice of "critical facts necessary to evaluate the case and prepare a defense." Judge Rosen found these arguments unavailing and denied the motion to dismiss on March 31, 2008, noting that in the alleged conspiracy to provide lower wage compensation was "operated through essential identical conduct on the part of all participants," eliminating the need for plaintiffs to identify actions unique to Trinity.

Consumers Bring Class Actions against Shire over Adderall XR

Barba et al v. Shire U.S. Inc. et al, No. 1:13-cv-21158 (S.D. Fla. filed Apr. 2, 2013)
Netwall v. Shire U.S., Inc. et al, No. 2:13-cv-01669 (E.D. Pa. filed Apr. 1, 2013)

Shire U.S., Inc. faces two consumer class action lawsuits alleging that the company engaged in a

fraudulent scheme to delay the market entry of generic versions of its drug Adderall XR. According to one complaint, filed on behalf of consumers of Adderall in Pennsylvania and nationwide indirect purchasers, Shire allegedly "filed a sham patent litigation, constructed anticompetitive reverse payment agreements with generic competitors, and then proceeded to unlawfully breach agreements to supply competitors with materials to manufacture generic [Adderall]." The plaintiffs argued that Shire's alleged conduct resulted in an illegal restraint of trade and/or an attempt at monopolization that violated antitrust statutes. The complaint further alleged that Shire's conduct restricted consumers' supply of the generic version drug and forced them to buy the brand name version of the drug instead. This conduct allegedly violated the state's consumer protection laws and resulted in unjust enrichment to Shire.

Consumers alleged identical conduct in a second complaint filed in the U.S. District Court in the Southern District of Florida. However, that complaint was only brought on behalf of in-state consumers.

Shire has been involved in other antitrust litigation in recent months as well. In February 2013, the company agreed to pay Impax $48 million to settle claims that it was not meeting its obligations under a supply agreement relating to its ADHD treatment. In March, the U.S. District Court in the Southern District of New York dismissed a similar putative class action brought by Louisiana Wholesale Drug Co., Inc.

Generic Drug Manufacturer Sues Brand-Name Producer over Access to Drug Ampyra

Accord Healthcare, Inc. v. Acorda Therapeutics Inc., No. 0:13-cv-60742 (S.D. Fla. filed Apr. 1, 2013)

On April 1, 2013, generic-drug maker Accord Healthcare, Inc. filed a suit against brand-name drug manufacturer Acorda Therapeutics, Inc. alleging that Acorda violated antitrust laws by refusing to sell samples of its drug Ampyra to competitors seeking to develop a generic version of the drug. This suit is an example of a larger dispute between generic and brand-name manufacturers over access to brand-name drugs for the purposes of bioequivalence testing and FDA approval.

Ampyra improves walking for patients with multiple sclerosis. According to the complaint, because of a restricted distribution framework imposed by the FDA, the only option for Accord to gain access to the drug is through Acorda's distributor, H.D. Smith. Accord claims that in order to apply for FDA approval in January 2014, the company needs to obtain samples of Ampyra no later than June 2013.

Acorda's response to the lawsuit has been that the company is under no obligation to satisfy Accord's purchase request and essentially assist a competitor develop a competing product. For reasons currently unknown, Accord voluntarily withdrew the lawsuit on May 2, 2013 before Acorda filed a responsive pleading.

Maryland Federal Judge Dismisses Antitrust Suit over Baby-Formula Additives

SARL v. Martek Biosciences Corp. No. 1:11-cv-00446 (D. Md. filed Feb. 17, 2011)

Belgium-based BNLfood Investment SARL filed an antitrust lawsuit in February 2011 alleging that Martek Biosciences Corp. entered into anticompetitive contracts that kept BNLfood out of the U.S. market for certain additives to infant formula. On March 28, 2013, a Maryland federal court dismissed BNLfood's claims holding that the claims were too speculative to show an antitrust injury resulting from Martek's contracts with formula makers.

BNLfood and Martek both produce and sell Omega-3 docosahexaenoic acid, or "DHA," and Omega-6 arachidonic acid, or "ARA." Among other uses, DHA and ARA are utilized as additives in baby formula. Prior to its efforts to enter the U.S. market, BNLfood sold its products to Asian and European formula producers for over fifteen years. The company alleged that it spent more than 10 million euros (approximately $14 million) to build or expand facilities to produce DHA and ARA for U.S. customers. However, after being rejected by several of the major U.S. baby formula manufacturers, BNLfood sued Martek asserting that the Columbia-based company engaged in monopolistic conduct through the use of sole source, long-term contracts that stretched through 2016.

Martek responded that even absent the long-term contracts, Martek retained customer loyalty by being one of the first in the market to produce these additives shown to improve infants' mental development and vision. In dismissing BNLfood's complaint, U.S. District Judge William D. Quarles Jr. stated that there were other reasons, aside from price fixing and exclusive contracts, for why U.S. formula makers had chosen Martek's products over those of BNLfood.

Hospital Faces Setback in Astellas Tying Suit as Court Denies Certification

Lakeland Reg'l Med. Ctr. Inc. v. Astellas Pharma US Inc. et al, No. 8:10-cv-02008 (M.D. Fl. 2010)

Lakeland Regional Medical Center's effort to represent a nationwide class in an $867 million antitrust suit against Astellas Pharma Inc. ended on May 2, 2013 when the Eleventh Circuit declined to hear its appeal regarding the denial of class certification. Lakeland plans to pursue the antitrust claim individually, alleging that Astellas unlawfully tied the use of its Adenoscan drug with its patented cardiac tests.

Lakeland's attempt to represent a nationwide class failed twice in district court under *Illinois Brick Co. v. Illinois*, which bars indirect purchaser antitrust suits. Although it purchased Adenoscan, the allegedly tied product, from a wholesaler, Lakeland had argued that *Illinois Brick* should not apply as it directly licensed the stress test, a diagnostic procedure for coronary heart disease, from Astellas and was required to buy Adenoscan for use in that procedure. Lakeland argued that the direct purchasers of Adenoscan were not harmed by Astellas conduct because they had not been subjected to the alleged tying arrangement. The district court denied Lakeland's class certification in September 2012 and refused to reconsider in January 2013.

According to Lakeland, Adenoscan is used in 90 percent of all cardiac stress tests and Astellas abused this position to drive up prices on Adenoscan by 450 percent over the price of the generic. Lakeland claims Astellas insisted that generic adenosine not be used in its stress test procedure and enforced the alleged tie through litigation threats and visits from Astellas representatives. The patent on Adenoscan expired on May 18, 2009. Astellas also holds the patents

for a method of continuous infusion of adenosine which is allegedly the "only medically recognized process to administer adenosine" in the stress test. According to Lakeland's complaint, the majority of all stress tests are now administered using the patented continuous infusion process and no other medically recognized process for inducing stress for a stress test is available.

Lakeland plans to pursue its case individually, alleging state tort law violations and seeking injunctive relief to overcome *Illinois Brick* limitations.

STATE COURT CASES

Out-of-State Health Care System Accuses Rhode Island Insurer of Monopolization

Steward Health Care System LLC v. Blue Cross Blue Shield of Rhode Island, No. PC-2013-2051 (Sup. Ct. RI, filed May 1, 2013)

On May 1, 2013, Steward Health Care System LLC sued Blue Cross Blue Shield of Rhode Island (BCBSRI or Blue Cross) alleging violations of the Rhode Island Antitrust Act and tortious interference with Steward's actual and prospective contractual relations.

Steward is a for-profit, community-based accountable care organization, which owns and operates hospitals in southeast Massachusetts. Steward also offers limited network health insurance plans in Massachusetts.

Steward alleges that it had planned to enter the Rhode Island market by acquiring the financially-distressed, 214-bed general acute care community hospital Landmark Medical Center and its subsidiary, the Rehabilitation Hospital of Rhode Island (RHRI). Landmark is located near the Massachusetts border. According to the complaint, Steward would have purchased and rehabilitated Landmark and offered lower-cost commercial health insurance to Rhode Island subscribers, but for BCBSRI's actions.

Steward defines the relevant markets as a sale of commercial health insurance in Rhode Island and a commercial purchase of hospital services in Rhode Island. Blue Cross commands monopoly power in the former market and monopsony power in the latter, according to Steward, as its "share of both relevant markets has exceeded 70 percent for years" and entry barriers exist. Steward assigns significant blame for Landmark's poor financial condition to BCBSRI by asserting that the insurer paid too-low reimbursement rates to the hospital for years. Furthermore, Steward claims that BCBSRI frustrated its plans to acquire the Landmark entities in several ways, including:

- Lobbying the state legislature (unsuccessfully) to prevent for-profit multi-hospital networks, such as the one Steward planned to create from negotiating collectively with commercial health insurers on behalf of its entire network of hospitals;
- Terminating its reimbursement contracts with Landmark and RHRI and ceasing to make payments to Landmark for services BCBSRI's subscribers received there;
- Attempting to dissuade other health care providers with whom Steward wanted to collaborate in building its Rhode Island network from dealing with Steward; and
- Ceasing relations with a Steward-owned hospital on the Massachusetts/Rhode Island border that serviced Rhode Island residents.

On September 27, 2012, Steward did in fact terminate its efforts to acquire Landmark and RHRI. It claims that BCBSRI's actions were motivated by fear that Steward's entry into Rhode Island—both as a provider of health care services and as a prospective low-cost insurance supplier—would threaten BCBSRI's dominant position in both markets. Steward seeks treble damages and other relief in its suit.

Landmark has been negotiating to be acquired by another for-profit system, Prime Healthcare Services, since the Steward transaction collapsed.

Antitrust Suit Filed Against Blue Cross in California State Court Mirroring Allegations in Alabama MDL

Sheridan v. Blue Cross of California, No. BC504431 (Cal. Sup. Ct. filed Apr. 1, 2013)

On March 29, 2013, a class action complaint was filed against Blue Cross Blue Shield Association (BCBSA), Blue Cross of California, and thirteen other Blue Cross members in California state court, Los Angeles County. The complaint alleges that for the past ten years, defendants engaged in a horizontal conspiracy to restrict competition and allocate markets in violation of California's Cartwright Act. The action is brought on behalf of all persons and entities that paid health insurance premiums to the defendants and seeks to recover damages in the form of a refund of the inflated premiums charged by defendants to California subscribers.

The allegations are based on the claim that the license agreements between BCBSA—an association allegedly owned and controlled by the 37 Blue Cross Blue Shield plans—and each individual Blue Cross Blue Shield licensee, unlawfully divide the geographic market for health insurance coverage by restricting the areas in which Blue plans are permitted to compete. In addition to the territorial restrictions, the complaint alleges that certain provisions of BCBSA's rules and regulations illegally limit competition including, "Most Favored Nation" clauses, acquisition restrictions, and general prohibitions on the plans' ability to generate revenue from non-Blue branded business. Plaintiffs assert that these allegedly anticompetitive practices have increased healthcare costs in California and resulted in artificially inflated and supra-competitive premiums for individuals and small groups purchasing defendants' full-service commercial health insurance in California.

The California complaint is similar to the allegations made in the class action complaints filed by providers and subscribers against BCBSA and the other Blue Cross entities throughout the country last year. In January 2013, the U.S. Judicial Panel on Multidistrict Litigation consolidated and transferred those Blue Cross Blue Shield suits to the Northern District of Alabama where they are currently pending before Judge R. David Proctor. *See In re Blue Cross Blue Shield Antitrust Litig.*, MDL No. 2406, Master Case No. 2:13-cv-20000-RDP (N.D. Ala.).

AGENCY DECISIONS

FTC Staff Files Comment with Illinois Legislature Regarding Pain Management Services

See http://www.ftc.gov/opa/2013/04/bosch- illcrna .shtm

The FTC has responded to a request from Illinois State Senator Heather Steans for comments on a proposed state law that would allow only physicians to provide chronic interventional pain treatments. The law would also bar certified registered nurse anesthetists (CRNAs) from providing pain management services, such as epidural injections, that they currently provide.

According to the FTC staff comment, the proposed law "threatens to raise costs, limit access, and reduce choices for Illinois patients. We therefore recommend that the Illinois Senate carefully investigate patient safety issues and ensure that any statutory limits on CRNAs are no stricter than patient safety requires."

The FTC staff comment notes that the Institute of Medicine has identified a key role for advanced practice nurses, a group that includes CRNAs, in improving health care delivery and access. It also notes that many Illinois counties face shortages of anesthesiologists and board-certified physician pain specialists. The Commission voted to approve the comment was 4-0.

FTC Describes Its Success Challenging Health Care Consolidation and Reverse Payments before Senate Subcommittee

See http://www.ftc.gov/opa/2013/04/antitrust.shtm

The rising cost of health care is behind the FTC recent focus on consolidation among health care providers and reverse payment agreements in the pharmaceutical industry. In testimony before the Senate Judiciary Subcommittee on Antitrust, Competition Policy and Consumer Rights, Chairwoman Edith Ramirez described the agency's successes in both areas and its recent state action victory before the Supreme Court in *Phoebe Putney*.

The FTC first reviewed its string of hospital merger victories in Toledo, Ohio, Rockford, Illinois, and Reading, Pennsylvania as well as its current challenge to St. Luke's Health System's acquisition of a large multi-specialty physician group in Boise, Idaho. The FTC also noted its success challenging mergers of psychiatric providers and long-term care pharmacies. The FTC clarified, however, that the agency "will not stand in the way of legitimate provider collaboration that will reduce costs and improve the quality of care."

Another "top priority" for the FTC is the agency's decade old crusade against "pay-for-delay" agreements. In a typical pay-for delay or "reverse payment" agreement, branded drug manufacturers settle patent litigation by paying generic manufacturers to delay entry of competing equivalents to their products. These agreements are a problem, according to the FTC, because they "enable branded manufacturers to buy more protection from competition than the assertion of their patent rights alone provide." The FTC says this costs consumers billions of dollars each year.

The Eleventh Circuit, along with the Second and Federal Circuits, currently apply the so-called "scope of the patent test" under which pay-for-delay settlements do not violate the antitrust laws so long as their anticompetitive effects do not exceed the scope of the patent. The Third Circuit takes a dimmer view, finding the agreements presumptively unlawful. The Supreme Court is poised to resolve the propriety of these

agreements—having heard oral arguments in the seminal Eleventh Circuit case, *FTC v. Actavis, Inc.*, on March 25, 2013. Chairwoman Ramirez expressed hope for "a favorable decision from the Supreme Court that stops these anticompetitive settlements."

FTC/DOJ Working Group Releases Summary of Activities since ACO Antitrust Enforcement Policy Introduced

See http://www.ftc.gov/opa/2013/04/aco.shtm

The Department of Justice (DOJ) and the FTC recently issued a joint summary of the activities that the Accountable Care Organization (ACO) Working Group (Working Group) has undertaken between October 2011 and March 31, 2013. Since its emergence in 2011, the working group has been closely monitoring and discussing matters regarding ACOs, integrated entities of physicians, hospitals and health care providers created under the Affordable Care Act of 2010 (the "Act"). The DOJ and FTC issued a Policy Statement in October 2011 intended to assure health care providers that they would receive guidance from the agencies on how to avoid antitrust risks and create pro-competitive ACO entities in the Medicare and commercial markets. The working group released a summary of its activities through March 31, 2013 as part of its effort to provide this guidance. From October 2011 through March 2013, the working group addressed thirty-three questions chiefly relating to primary service area (PSA) share calculations. It also received two requests from ACO candidates for expedited review, though they were subsequently withdrawn.

Under the Policy Statement, the PSA shares of an ACO may fall within an antitrust safety zone where the agencies consider it unlikely that its formation will raise significant competitive concerns. If an ACO hits a certain PSA share or level of market power, the Policy Statement also provides advice on what conduct an ACO should avoid to evade increased antitrust scrutiny. The DOJ and FTC provided responses to all thirty-three questions, the majority of which received answers within five business days.

The working group found that the largest number of questions covered how to secure and analyze data in order to calculate PSA shares. Another series of questions related to the steps for how PSA shares are calculated. Three questions dealt with the protocol for obtaining voluntary review and the final five addressed miscellaneous issues related to ACOs.

Between October 2011 and March 31, 2013, two entities requested that the working group provide expedited review of their ACO. Under the Policy Statement, newly formed ACOs may seek and receive guidance on their program from the agencies. The agencies must then advise the ACO whether it sees any competitive concerns with the operation or formation of the entity within 90 days of receiving the request. Both companies who requested expedited review eventually withdrew their request, however. One applicant rescinded its request after the reviewing antitrust agency informed them that they were not eligible for review because they did not have plans to operate commercially. The other applicant withdrew its application for undisclosed reasons. Both companies applied for expedited review of their ASO in March 2012. The reviewing agency offered informal guidance to the first applicant, which was eventually accepted to participate in the Medicare Shared Savings Program (MSSP). To date, the other applicant has not entered into the MSSP.

According to press releases, the Working Group will continue responding to ACO questions and requests, including the PSA share questions and

requests for voluntary expedited review discussed above.

FTC Issues 2013 Overviews of Enforcement in Health Care and Pharmaceutical Industries

See http://www.ftc.gov/bc/healthcare/antitrust/index.htm

In March, the FTC released its 2013 Overview of FTC Antitrust Actions in Health Care Services and 2013 Overview of FTC Actions in Pharmaceutical Services. The Overviews contain information about more than 200 public antitrust actions involving the FTC's antitrust enforcement efforts in the health care sector. They also discuss a wide range of documents, including complaints and settlement orders, amicus briefs, and industry guidance statements. Topics covered include FTC involvement in hospital mergers, mergers in the pharmaceutical industry, and mergers in the medical equipment industry.

Highmark Completes $1.1B Acquisition of West Penn amid Antitrust Suit

https://www.highmark.com/hmk2/newsroom/pressreleases/2013/pr042913.shtml

On April 29, 2013, Insurer Highmark Inc. announced that it had completed its acquisition of the West Penn Allegheny Health System. The Pennsylvania Insurance Commission (the "Commission") approved the $1.1 billion transaction, first announced in June 2011. Highmark and West Penn will together form the Allegheny Health Network, an integrated health care system serving western Pennsylvania.

Highmark publicized its intent to acquire West Penn in June 2011 and the parties signed an official agreement in November of that year. Merger talks stalled in October of 2012 and West Penn decided not to pursue the transaction. This prompted Highmark to sue West Penn to enforce an exclusivity clause in their affiliation agreement and stop the health system from entering into merger or acquisition agreements with other potential buyers. In January 2013, the parties negotiated a deal to resume the transaction.

During that time, West Penn rival University of Pittsburgh Medical Center (UPMC) filed a suit against the parties claiming that they had conspired to restrain competition in the Pittsburgh health care market. UPMC and Highmark agreed in May 2012, however, that UPMC would drop all of its claims and counterclaims if Highmark and West Penn successfully consummated the proposed merger. The Commission's decision was the final regulatory approval required to complete the transaction. Given that West Penn anticipated that the Commission would approve the deal, the company had requested a 90-day uncontested stay of the UPMC suit, stating that an imminent approval from the Commission would end the litigation.

Commissioner Michael Consedine approved the transaction with conditions designed to promote continued competition in the region, foster transparency, and decrease any financial risks to Highmark and its policyholders due to financial commitments to West Penn. The new entity will also be required to make charitable and community contributions across western Pennsylvania.

INTERNATIONAL

U.K. Charges Pharma Companies with "Pay-for-Delay"

See *http://www.oft.gov.uk/news-and-updates/press/2013/36-13*

On April 19, 2013, the U.K. Office of Fair Trading (OFT) issued a Statement of Objections to GlaxoSmithKline (GSK) alleging that it had made substantial payments to generic drug makers Alpharma Ltd., Generics Ltd. and Norton Healthcare Limited (collectively, the "Generics") to delay generic entry of its Seroxat antidepressant. The OFT's complaint alleges that GSK abused its dominant position in the market for paroxetine and that the patent settlements infringed competition law.

The payments in question were part of patent settlements entered into between GSK and the Generics between 2001 and 2004. GSK had sued the Generics for patent infringement when they had attempted to market generic versions of GSK's blockbuster antidepressant Seroxat (or Paxil in the United States) prior to patent expiry. The settlement arrangements allowed generic paroxetine to enter the market before GSK's patents expired. Although the European Commission had investigated the same deals in 2005 and again in 2009, neither investigation had resulted in any sanctions against GSK.

A Statement of Objections gives notice of a proposed infringement decision to the parties involved. However, before the decision is finalized, the parties have the opportunity to make written and oral representations in response to the allegations. The OFT will carefully consider the drug makers' response to the Statement of Objections before deciding whether the Competition Act 1998 has been infringed. The Competition Act 1998 is the UK counterpart to Article 101 of the Treaty on the Functioning of the European Union (TFEU). Any business found to have infringed the Competition Act 1998 or TFEU could be fined up to 10 percent of its worldwide turnover.

Mexico Clears Nestlé's Acquisition of Pfizer's Infant Formula Business after Divestiture

See *http://www.cfc.gob.mx/images/stories/Noticias/Comunicados2013/CFC-05-2013.pdf*

On April 15, 2013, Mexico's Federal Competition Commission (CFC) announced that it had accepted a proposal by Nestlé to sell Pfizer's infant formula business in Mexico to a third party in order to maintain competitive conditions in the infant formula market. The assets to be sold include Pfizer's formula plant, sales force, and exclusive brand licenses. This agreement ends Mexico's opposition to Nestlé's $11.85 billion global acquisition of Pfizer's infant nutrition business, Pfizer Nutrition.

The CFC originally raised concerns in connection with the Mexican portion of the global transaction in November 2012, saying that proposals submitted in support of Nestlé's acquisition did not sufficiently address the potential harm to the infant formula market that could result from Nestlé's concentrated market power following the acquisition. According to the CFC, without a divestiture, the acquisition would have given Nestlé a 71 percent Mexican market share for stage 1 and stage 2 infant formulas, and an 88 percent market share for stage 3 formulas. In addition, the acquisition would have allowed Nestlé to increase its prices up to 11.5 percent and paved the way for competitors to also raise prices.

Although Nestlé and Pfizer completed their deal in December 2012, the parties have yet to secure approval for the deal from regulators in Chile, Columbia, Ecuador, and Nicaragua. Nestlé has resolved its antitrust issues in Australia, South Africa, and now, Mexico.

The CFC did not specify a precise timeframe for the divestiture, but said the sale would be made soon subject to its approval.

France Imposes $53M Fine on Sanofi

See http://www.autoritedelaconcurrence.fr/user/standard.php?id_rub=483&id_article=2091

On May 14, 2013, the French Competition Authority (FCA) issued a $53M fine against Sanofi-Aventis for "disparaging" generic versions of the blood thinner Plavix.

In 2010, Teva Pharmaceutical Industries' French unit filed a complaint with the FCA that Sanofi sales representatives were spreading criticism about the quality and safety of its generic version of Plavix. According to the FCA, Sanofi's strategy was directed at healthcare professionals and aimed to limit the entry of generic versions in the market and favor Sanofi's own products, namely the originator Plavix and its generic version, Clopidogrel Whinthrop.

As a result of Sanofi's practice, there was uncertainty in the healthcare sector regarding the quality and safety of the generic versions of Plavix, without any evidentiary basis for Sanofi's claims. The FCA found that Sanofi's strategy had succeeded to the extent that there was an abnormally low substitution rate for Plavix, a drug that generates over $2 billion in revenues for Sanofi.