ABA Health Care and Pharmaceuticals Committee
Recent Developments

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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

GSK Settles Suit Alleging Monopolization Conspiracy

Am. Sales Co., Inc. v. SmithKline Beecham Corp., No. 2:08-cv-03149-AB (E.D. Penn. 2008)

SmithKline Beecham Corporation, which does business under the name GlaxoSmithKline (GSK), entered into a $150 million settlement agreement with a proposed class of direct purchasers of the well-known prescription drug Flonase. American Sales Company, the class representative, alleged that GSK used sham citizen petitions to delay the entrance of generic rivals and maintain monopoly power, in violation of Section 2 of the Sherman Act.

The unopposed settlement agreement was filed with the Eastern District of Pennsylvania on December 11, 2012, and was ordered and signed by Justice Anita B. Brody on January 14, 2013.

GSK manufactures and sells Flonase, a brand name prescription nasal spray that contains fluticasone propionate, to treat seasonal allergies. The class action complaint, which was filed on July 3, 2008, alleged that, after GSK's period of exclusivity expired, the company filed an "objectively baseless" citizen petition that asked the Food and Drug Administration (FDA) to delay approving Abbreviated New Drug Applications (ANDA) for fluticasone propionate until the FDA issued final guidance related to determining the bioequivalency for nasal sprays. GSK filed the petition "five days after its exclusivity period expired . . . but more than a year and a half after Roxane [a generic equivalent] filed its ANDA for a generic version of the drug." GSK thereafter filed supplemental petitions, which the plaintiff alleges were designed to maintain market exclusivity beyond the statutory period.

Citizen petitions, according to the complaint, "allow individual to express genuine concerns about safety, scientific, or legal issues regarding a product." The plaintiff alleged that GSK's petition and supplemental petitions were "shams" that did not raise issues about the safety or efficacy of generic equivalents.

Indirect purchasers also alleged antitrust violations, and that GSK's practices led to overcharges for purchases in *In re: Flonase Antitrust Litigation*, Case No. 08-CV-3301 (E.D. Penn.), filed on July 14, 2008. GSK reached an agreement with the indirect purchasers—an unopposed motion for a class action settlement was filed on December 14, 2012 and approved by Justice Anita B. Brody on January 14, 2013.

U.S. Medical Supply Companies Accused of Exclusionary Tactics in Two Lawsuits

Suture Express, Inc. v. Cardinal Health, Inc. and Owens & Minor, Inc., No. 2:12-cv-02760 (D. Kan. filed Dec. 5, 2012)
Schuylkill Health Sys. v. Cardinal Health, Inc. and Owens & Minor, Inc., No. 2:12-cv-07065 (E.D. Pa. filed Dec. 18, 2012)

Cardinal Health, Inc. (Cardinal) and Owens & Minor, Inc. (O&M) have been named in two related lawsuits—one filed by a competing medical product supplier and the other by an acute care hospital customer—that challenge the companies' pricing and distribution practices.

On December 5, 2012, Suture Express, Inc. (Suture) filed a complaint against the companies in U.S. District Court in Kansas alleging violations of Sections 1 and 2 of the Sherman Act, Section 3 of the Clayton Act, Kansas state law, and common law. Suture seeks injunctive relief

and $200 million in treble damages. According to the complaint, Cardinal and O&M collectively control more than 70 percent of the $22 billion acute care medical and surgical supply market. Suture is a self-described specialized distributor that primarily supplies goods in two medical/surgical product categories: sutures and endomechanical products.

Suture claims that in 2008, Cardinal and O&M began exploiting their combined dominance in the broader medical/surgical product distribution market by coercing acute care providers not to purchase sutures and endomechanical products from Suture. Specifically, Suture alleges that the defendants impose prohibitive price penalties on customers who wish to purchase sutures and endomechanical products elsewhere (effectively creating an unlawful tie-in and exclusive dealing arrangement) and that they also bundle medical/surgical products in such a way as to effectively engage in predatory pricing for the competitive products. Further, Suture alleges that Cardinal and O&M have conspired with each other to implement this exclusionary conduct because their practices are "strikingly similar," in "lock-step," and would be against each of their independent economic interests but for the alleged conspiracy.

Two weeks after Suture filed its complaint, on December 18, 2012, Schuylkill Health System (Schuylkill) filed a putative direct purchaser class action lawsuit against Cardinal and O&M in the U.S. District Court for the Eastern District of Pennsylvania, alleging violations of Sections 1 and 2 of the Sherman Act. Schuylkill operates multiple acute care hospitals, purchases sutures and endomechanical products directly from the defendants, and alleges that it has been forced to pay supracompetitive prices for these products because of the defendants' exclusionary practices. Schuylkill asserts the same operative facts as alleged in the Suture lawsuit. According to its complaint, Cardinal and O&M "have entered into exclusionary contracts with a majority of acute care providers, covering a majority of private sector purchasers." Schuylkill thus seeks to represent a proposed nationwide class of entities that purchased sutures and endomechanical products from Cardinal and/or O&M beginning from December 18, 2008, and requests treble damages based on the defendants' alleged overcharges.

The defendants are expected to answer the complaint in the *Suture* matter by February 15, 2013. The plaintiff in the *Schuylkill* case will be filing an amended complaint naming the proper Cardinal and O&M entities, which will supersede the December 18, 2012 complaint.

U.S. Supreme Court Grants Cert in Pay-For-Delay Case

Fed. Trade Comm'n v. Watson Pharm. Inc., No. 12-416 (filed Oct. 12, 2012)

The U.S. Supreme Court granted certiorari on the Federal Trade Commission's (FTC) petition for review of the Eleventh Circuit's decision that Hatch-Waxman Act settlements (or "pay-for-delay" settlements) are legal under certain circumstances. Justice Samuel Alito did not take part in making this decision. The case involves a patent settlement agreement between Solvay Pharmaceuticals Inc. and generic drug makers to protect Solvay's testosterone-replacement therapy drug AndroGel.

The case is noteworthy as it will give the Supreme Court the chance to clarify the standard for "pay-for-delay" settlement agreements. The Eleventh Circuit has stated that these agreements are legal so long as they do not exceed the scope of the patent. The Second and Federal Circuits have also endorsed this "scope of the patent" test. However, the Third Circuit refused to apply the "scope of the patent" test in a case involving a

challenge to settlements into which Schering-Plough Corp. (now part of Merck) entered to protect its patents for its potassium-release drug K-Dur. Instead, the Third Circuit instructed the district court to consider any payment from a patent-holding drug company to a generic maker in exchange for that maker's agreement to postpone its entry into the market for a particular drug to be prima facie evidence of an antitrust violation.

Oral argument in the case is scheduled for March 25, 2013.

New Jersey Judge Rules that K-Dur Does Not Apply to Authorized Generic Deals

La. Wholesale Drug Co. Inc. v. SmithKline Beecham Corp. et al., No. 2:12-cv-00995 (D.N.J. 2012)

In December 2012, U.S. District Judge William H. Walls of New Jersey held that the Third Circuit's decision in *In re K-Dur Antitrust Litig.* only applied to cash payments, and did not extend to promises to forego launching authorized generics. The Federal Trade Commission (FTC) had tried to persuade district courts through an amicus brief that the *K-Dur* decision should encompass other settlements between patent holders and generic companies that result in delayed competition. In this case, the agency argued that GlaxoSmithKline's (GSK) agreement to withhold its own authorized generic during Teva's exclusivity period should be considered as compensation alongside monetary payments, and that such an arrangement should also be considered presumptively anticompetitive. Judge Walls declined to follow this argument, writing that the *K-Dur* decision only contemplated cash payments.

Judge Walls's ruling explained that the settlement between GSK and Teva represented the type of agreement that should not be prohibited by the holding in *K-Dur*. While the FTC contended that the distinction between cash payments and other types of compensation was "artificial," Judge Walls stated that the Third Circuit was not considering these types of arrangements when it made its decision. He agreed that authorized generic delay was a form of consideration as part of the settlement, but ruled it was necessary for the settlement to occur. He explained that the *K-Dur* decision specifically sought to prevent companies from paying generic challengers to delay market entry, and that the present matter was not such a case. Judge Walls also pointed out that the parties' settlement would still bring generic drugs to market before the patent expired, which was a benefit from a policy perspective.

Judge Denies Request to Preliminarily Enjoin Health System Acquisition of Provider Group

Saint Alphonsus Med. Ctr. v. St. Luke's Health Sys., Ltd, No. 1:12-cv-560-BLW (D. Idaho, filed Nov. 12, 2012)

On December 20, 2012, a Federal District Court Judge in Idaho denied the request by Saint Alphonsus Health System, part of the Michigan based Trinity Health System, and Treasure Valley Hospital, a surgical hospital co-owned and operated by Surgical Care Affiliates, to block the acquisition of Saltzer Medical Group, by St. Luke's Health System. Saltzer Medical Group, is a forty-physician practice based in Nampa, Idaho while St. Luke's operates a number of medical facilities in Idaho, including hospitals in Boise and Meridian, and competes directly with Saint Alphonsus's Nampa and Boise hospitals, as well as Treasure Valley Hospital in Boise.

In the complaint, the plaintiffs alleged the acquisition would violate Section 7 of the Clayton Act and Section 1 of the Sherman Act by giving St. Luke's a dominant market share in the primary care physician services market in Nampa thereby allowing it to raise prices and block referrals to the plaintiffs' facilities in that community. Further, the plaintiffs alleged that the acquisition would result in anticompetitive effects in the general acute care inpatient services market in the Boise-Nampa Metropolitan Statistical Area.

Saint Alphonsus argued that St. Luke's would pressure the ex-Saltzer physicians to steer their patients away from Saint Alphonsus and to St. Luke's for procedures such as CT scans and MRIs, among other things. The original complaint also alleges that over the last four years St. Luke's has purchased over 20 physician practices in the Boise area, describes a history of such post-purchase steering, and suggests purported monopoly abuses by St. Luke in other areas of Idaho where it has acquired large market shares. The plaintiffs sought a preliminary injunction to block the acquisition.

The judge noted that post-acquisition, St. Luke's would account for 90 percent of pediatric physicians and 67 percent of the adult primary care physicians in Nampa and that over 40 percent of the total adult primary care admissions and 100 percent of the pediatric admissions at Saint Alphonsus's Nampa hospital were referred by Saltzer Medical Group physicians. Nevertheless, the court denied the plaintiffs' motion, stressing that a preliminary injunction is an extraordinary remedy requiring a clear showing of irreparable injury absent preliminary injunctive relief.

The judge determined that, since trial is scheduled for late July 2013, little harm could befall the plaintiffs before the trial is concluded. St. Luke's has already entered into a two-year agreement with Idaho's largest insurer, Blue Cross of Idaho, so that even if the transaction were to give St. Luke's anticompetitive leverage, it could not be exercised until well after the trial on the merits. The court also recognized that the integration of the Saltzer physicians into St. Luke's would only take place over time, and that the agreement between St. Luke's and Saltzer Medical Group contained a provision for an orderly and non-disruptive unwinding of the transaction if one is ordered by the Courts or federal or state officials.

Texas AG, Feds and Whistleblower Settle Medicaid Fraud Cases with Pharma Companies

See *https://www.oag.state.tx.us/oagnews/release.php?id=4262*

On January 4, 2013, Texas Attorney General Greg Abbott announced that Pfizer, Inc. (Pfizer) and Endo Pharmaceuticals, Inc. (Endo) agreed to settle the state's civil Medicaid fraud investigation against the companies. Under the settlement, Pfizer and Endo have each agreed to pay $25 million, of which approximately $18 million from each company will go the State of Texas. The federal government will share in the remainder of the settlement payment, because it jointly funds Medicaid with the states.

Texas charged Pfizer and Endo with defrauding the state's Medicaid program by reporting inflated market prices for their drugs to the state's Vendor Drug Program. Drug manufacturers are required by law to report the prices they charge pharmacies, wholesalers, and distributors for their products. By reporting deceptively high prices, claims the Attorney General's Office, Pfizer and Endo caused the state to reimburse pharmacies at vastly inflated rates. The state alleges that the companies used this over-reimbursement scheme to improperly induce pharmacies to purchase their products. Neither Pfizer nor Endo have admitted

guilt, and both companies' settlements contain mutual releases for civil claims related to the challenged conduct.

The Texas investigation was the result of a whistleblower lawsuit filed by Florida-based pharmacy Ven-A-Care, which will also receive a portion of the $50 million overall recovery from both settlements.

Texas has for years been among the leading states involved in investigating alleged Medicaid abuses and extracting hefty payments. A 2012 study by Public Citizen shows Texas leading all states in settlements made possible by private whistleblowers. The same study reports that Ven-A-Care has played a significant role in uncovering alleged Medicaid fraud, and may be responsible for initiating nearly half of the federal settlements in recent years by filing False Claims Act lawsuits.

MDL Panel Orders Consolidation of Nine Actions against Blue Cross

In re: Blue Cross Blue Shield Antitrust Litig., No. MDL-2406 (N.D. Ala. 2012)

On December 12, 2012, the United States Judicial Panel on Multidistrict Litigation ordered nine actions to be consolidated in the Northern District of Alabama. Each case alleges that Blue Cross and Blue Shield Association (Blue Cross) entered into improper arrangements with independent health insurance companies to inflate insurance premiums and eliminate competition.

The litigation against Blue Cross originally encompassed alleged anticompetitive behavior in Alabama, North Carolina, and Tennessee; however, similar allegations have surfaced in other districts, increasing the number of allegations against Blue Cross to at least fourteen districts across the country. Three Notices of Potential Tag-Along suits were filed in January 2013 alone, representing district courts in Florida, Minnesota, and South Carolina.

The pending multidistrict litigation stems from Blue Cross's licensing of its thirty-eight member plans, known as "Blue Plans." Blue Cross has an arrangement with members of the Blue Plans to use Blue Cross' name, but only in specified areas. The plaintiffs allege that these arrangements conflict with the Sherman Act and state antitrust laws by reducing or eliminating competition and inflating health-insurance premiums. Blue Cross maintains that its licensing agreements represent an attempt to unify separate companies into a national brand, as opposed to conspiring to divide the health-insurance market.

In *Richards v. Blue Cross and Blue Shield of Alabama*, the First Amended Class Action Complaint (Complaint) noted that Blue Cross and Blue Shield of Alabama have a 90 percent market share, whereas the second largest provider in the state enjoys only a 5 percent share. The Complaint underscored Blue Cross's "near-complete dominance of the commercial health insurance market in Alabama." Similar concerns were raised in other complaints, including the North Carolina case, *Cerven v. Blue Cross and Blue Shield of North Carolina*.

On October 1, 2012, a number of Blue Cross entities jointly filed a Motion to Transfer and Consolidate the various lawsuits, arguing that the cases have the same factual underpinnings and that consolidation would be more just and efficient. The Judicial Panel agreed, finding that the "actions involve substantial common questions of fact" and consolidation would help "ensure streamlined resolution of this litigation to the overall benefit of the parties and the judiciary."

The outcome of the lawsuit may have a significant effect on Blue Cross, which has noted that its

licensing agreements have permitted it to compete with other powerhouse insurance providers like Aetna and Cigna.

More Direct Purchasers Jump into the Pay-For-Delay MDL Involving Skelaxin

Rite Aid Corp. v. King Pharm., Inc., No. 1:13-cv-0005 (E.D. Tenn. filed Jan. 4, 2013); lead case In re Skelaxin (Metaxalone) Antitrust Litig., No. 1:12-cv-2343 (E.D. Tenn. filed May 16, 2012)

On January 9, 2013, Rite Aid, Brooks Pharmacy, and Eckerd joined the pending MDL against King Pharmaceuticals and Mutual Pharmaceutical involving the muscle relaxant Skelaxin. The suit alleges, among other things, that King and Mutual settled their patent dispute by entering into an illegal license agreement in which Mutual agreed not to launch a generic version of Skelaxin in exchange for payments from King exceeding $200 million. The complaint also alleges that King pursued an anticompetitive scheme to exclude and delay generic competition by filing sham patent litigation against prospective generic competitors, and that King and Mutual submitted baseless petitions to the Food and Drug Administration (FDA) to thwart and delay other generic companies' efforts to obtain FDA approval for generic versions of Skelaxin.

This direct purchaser complaint is similar to the allegations made in the class action complaints previously filed by direct and indirect purchasers against King and Mutual. In April 2012, the U.S. Judicial Panel on Multidistrict Litigation consolidated and transferred those Skelaxin suits to the Eastern District of Tennessee before Chief Judge Curtis L. Collier. King and Mutual filed a motion to dismiss on January 4, 2013, arguing, among other things, that their patent licensing arrangement did not prevent generics from coming to market. King also denies the allegations that it lodged sham infringement suits and that it joined with Mutual to file sham FDA petitions.

Pharmaceutical Giant GlaxoSmithKline to Pay $21.5 Million to Settle Wellbutrin Antitrust Suit

Sheet Metal Workers Local 441 v. GlaxoSmithKline PLC et al., No. 2:04-cv-05898 (E.D. Penn. filed Dec. 17 ,2004)

GlaxoSmithKline PLC (GSK) has agreed to pay $21.5 million to settle with employee benefit plans in a class action lawsuit alleging that GSK filed sham patent suits to delay its generic competitors from entering the market to compete with GSK's antidepressant Wellbutrin SR and related drug Zyban. Judge Lawrence F. Stengel of the Eastern District of Pennsylvania recently decided in favor of the proposed agreement, which was submitted to the Court in late December 2012.

The initial suit was brought back in 2004 by a class of third-party payors that, beginning in 2002, paid for or reimbursed members for their purchase of Wellbutrin or Zyban. The plaintiffs alleged that GSK employed several delay tactics including filing frivolous patent infringement lawsuits to keep generic competition out of the market, and as a result, forced consumers to pay monopoly prices for the drugs. The complaint further alleged that GSK's anticompetitive conduct restrained and eliminated competition in the market for antidepressants with similar characteristics as Wellbutrin and Zyban and thus, GSK was liable for illegally maintaining a monopoly in those markets.

Judge Stengel commented that the proposed settlement comes after arm's length negotiations by practiced counsel following years of protracted litigation and is within the range of acceptable settlements. The plaintiffs' class counsel stated

that the settlement ensures that class members receive payments now while avoiding the uncertainties of litigation and further that the $21.5 million dollar figure is "fair, reasonable, and adequate" under the facts and circumstances. For GSK, the agreement settles allegations that the company violated antitrust, consumer fraud, consumer protection laws in connection with its sale of Wellbutrin and Zyban.

Third Circuit Dismisses Ethypharma's Suit for Lack of Standing

Ethypharm SA France v. Abbott Labs., No. 11-3602 (3rd Cir. 2012)

On January 23, 2013, a three-judge panel of the Third Circuit Court of Appeals held that Ethypharma SA France lacks standing to bring an antitrust suit against Abbott Laboratories because Ethypharma licensed its drug Antara for distribution in the United States to Reliant Pharmaceuticals, Inc., rather than entering the market on its own.

In its complaint, Ethypharm alleged that a patent settlement agreement between Abbott and Reliant violated Section 1 and Section 2 of the Clayton Act because it ensured that the Antara assets would only be transferred to a company that would not be able to compete effectively against Abbott.

Ethypharma developed Antara, a fenofibrate product used for the treatment of high cholesterol. In 2001, Ethypharm entered into a license and distribution agreement for Antara with Reliant whereby Reliant would be responsible for selling Antara in the United States, including seeking Food and Drug Administration (FDA) approval. Reliant received FDA approval to sell Antara in the United States in 2004 and began marketing the product in early 2005.

While the Antara approval was pending at the FDA, Reliant brought a declaratory judgment action seeking a declaration of non-infringement with respect to four of Abbott's patents covering TriCor, Abbott's fenofibrate product indicated for the treatment of high cholesterol. Abbott subsequently filed a counterclaim. In 2006, Abbott and Reliant reached a settlement, granting Reliant a license to the Abbott patents for Antara, but restricting Reliant from entering into a partnership with or assigning its rights to a so-called "Restricted Entity". The Restricted Entities included thirty-six pharmaceutical companies. Ultimately, according to Ethyphram, Reliant sold Antara to Oscient Pharmaceuticals Corp, a company that subsequently went bankrupt.

The Third Circuit panel held that Ethypharma was not permitted to transfer the expense and risk of competing in the United States to a third party, but then also avail itself of laws protecting fair competition when the arrangement is not successful.

New Jersey District Court Strikes Sanofi Pasteur's Antitrust Counter-Claim in Vaccine Class Action Suit

Castro v. Sanofi Pasteur, Inc., No. 11-7178, (D.N.J. Dec. 20, 2012)

On December 2012, the U.S. District Court for the District of New Jersey granted the plaintiffs' motion to strike Sanofi Pasteur Inc.'s antitrust counterclaim in a class action suit filed against the company by vaccine customers. In the suit, the plaintiffs alleged that Sanofi imposed anticompetitive contract restrictions on vaccine customers. Sanofi's counterclaim alleged that the plaintiff vaccine customers had colluded to demand discounts that lowered vaccine prices to noncompetitive levels for physician buying groups.

According to Sanofi's counterclaim, the plaintiffs had market power because of collective action and unlawful agreements, and controlled the price and availability of certain vaccines. Sanofi asserted that the plaintiffs, through physician buying groups employing aggressive negotiation tactics, have increased concentration and reduced competition in the relevant markets by coordinating and aggregating member purchases in the physician buying groups, resulting in depressed price levels.

In its decision, the court rejected Sanofi's allegations that vaccine buyers, through physician buying groups, had created per se illegal horizontal purchasing agreements. The court determined that there could be no inference that the vaccine buyers' purchases, through the physician buying groups, were based on preset fixed prices or fixed purchases. Given that Sanofi did not allege facts that set forth a plausible inference that the physician buying groups fixed prices or restricted purchases, the court concluded that any price reductions by vaccine purchasers were the result of negotiation and not a preset price.

The court also determined that Sanofi failed to allege that physician buying groups unreasonably restrained trade under a rule of reason analysis. According to the court, Sanofi's allegations failed to assert a plausible inference that the physician buying groups were prima facie anticompetitive, as the facts did not allege any fixed prices or restricted purchases if a supplier did not agree to a demand.

Moreover, the court concluded that Sanofi did not allege market power, as the facts did not support direct evidence that the buying groups could control or depress prices. Although Sanofi asserted that indirect evidence could demonstrate market power, the court found that the alleged facts failed to show dominant market share in the relevant market, or the existence of entry barriers to the market. Accordingly, the court struck Sanofi's antitrust counterclaim because it failed on both the per se and rule of reason analyses.

AGENCY DECISIONS

Iovate Health Settles Deceptive Advertising Charge

See
http://www.ftc.gov/opa/2013/01/iovaterefund.shtm

Iovate Health Sciences U.S.A. has agreed to pay $5.5 million for consumer refunds to settle claims by the Federal Trade Commission (FTC) that the company engaged in deceptive advertising. In 2010, the FTC charged Iovate and two Canadian affiliates with misleadingly informing consumers that the supplements Accelis, nanoSLIM, Cold MD, Germ MD, and Allergy MD could help them to lose weight or could treat and prevent colds and other ailments.

Consumers who purchased these supplements between January 2006 and July 2010 might be eligible to receive one of these refunds. To apply, consumers must file a claim online or in paper form by April 1, 2013. Certain limitations apply. For example, consumers who have received a refund from a class action settlement related to Cold MD in California may not receive a second refund. Further, consumers may only submit claims for up to five of a single type of product and for a maximum of ten individual products. The amount of each refund will depend on the number of products purchased or the number of claims submitted.

FTC Staff Approve Methodist Hospital System Request to Sell Discounted Drugs to Baytown EMS as an Emergency Humanitarian Gesture

See *http://www.ftc.gov/opa/2012/11/uhs.shtm*

On November 30, 2012, the Federal Trade Commission (FTC) staff issued a letter to the Methodist Hospital System of Houston, Texas, stating that it would be permissible to sell discounted pharmaceuticals to Baytown EMS, the exclusive transport provider for 9-1-1 services in Baytown, Texas, because a nationwide drug shortage made the transactions an emergency humanitarian gesture. The letter came in response to a July 25, 2012 request from Methodist proposing that the hospital sell drugs at cost to Baytown EMS because the latter's operations were unable to sustain safe inventory of certain critical drugs during the shortage. Methodist requested that the FTC staff comment on how the Robinson-Patman Act, which prohibits anti-competitive price discrimination, would apply to its unique circumstances.

In its letter to the FTC, Methodist argued that Baytown EMS was exempt from the Robinson-Patman Act under the Non-Profits Institutions Act (NPIA) because Baytown was an eligible entity and was purchasing supplies for its "own use." Baytown EMS was a government entity providing important health-related services to the Baytown community, did not compete with private parties, and did not generate a profit. Furthermore, the provider needed the drugs in order to carry out its only purpose: to provide emergency medical services to patients en route to an acute medical facility. Methodist argued that Baytown EMS satisfied these two requirements of the NPIA and thus could receive the drugs at cost without violating the Robinson-Patman Act.

The FTC staff approved Methodist's request to sell the necessary drugs during the shortages, but stated that it need not weigh in on whether the NPIA applied because the proposal represented an emergency humanitarian gesture as discussed in *Abbott Labs. v. Portland Retail Druggists Ass'n, Inc.*, 425 U.S. I (1976) and *St. Peter's Hospital of the City of Albany* 92 F.T.C. 1037 (1978) (Commission advisory opinion). In both cases, the Commission concluded that hospitals could

supply critical drugs as a humanitarian gesture during emergencies when the drugs were not available elsewhere, or were difficult to obtain. Staff's letter stated that the circumstances of Methodist and Baytown were similar to both of these cases.

DOJ Gives Green Light for Cost and Performance Data Sharing Plan among Hospitals

See
http://www.justice.gov/atr/public/busreview/291451.pdf

The Department of Justice (DOJ) allowed the Greater New York Hospital Association (GNYHA), a trade association of 250 hospitals and continuing care facilities in New York and several nearby states, to proceed with a voluntary gainsharing program for its New York hospital members. The gainsharing program provides incentives for physicians to reduce costs while meeting hospital-specific quality standards by compensating physicians with a share of the savings realized by the participating hospital. The DOJ found that GNYHA's proposed program is unlikely to cause anticompetitive effects as it does not involve any horizontal agreements among competing hospitals about compensation levels for physicians and the information exchanged would not facilitate such anticompetitive coordination.

Modeled after Medicare gainsharing programs, the GNYHA proposal allows hospitals to replicate Medicare gainsharing programs for a broader spectrum of health care, including commercial health insurance as well as Medicaid and Medicare managed care products. Under GNYHA's proposed program, hospitals would submit publicly available, historical cost data and patient discharge statistics to GNYHA, who in turn would share the data with Applied Medical Software, Inc. (AMS) to compute the costs associated with specific inpatient services performed by specific physicians. AMS will also use the data to calculate "Best Practice Norms" for specific treatments and procedures. These "Best Practice Norms" will be common across all 100 participating hospitals in New York. To calculate these "Best Practice Norms," AMS will only use data that is at least three months old and supplied by at least five providers with no individual provider's data representing more than 25 percent. This complies with the antitrust safety-zone requirements of Statement 6 of the Department of Justice's and Federal Trade Commission's *Statement of Antitrust Enforcement Policy in Health Care* (1996).

The specific physician performance results would not be shared with anyone other than the particular hospital and participating hospitals would not share the data or results with each other. The specific physician performance results would allow the hospital to reward physicians that improved their own cost performance over time as well as physicians that are more cost-efficient vis-à-vis their peers based on "Best Practice Norms" calculated by AMS. The hospitals would each independently determine the level of incentives appropriate for its physicians. The incentives will also be conditioned on the satisfaction of quality metrics that are also independently established by each hospital. The hospitals will not share their incentive plans, or any other competitively sensitive information, with each other.

However, GNYHA reserves the right to exclude any hospital from the program, if, in GNYHA's unilateral opinion, the hospital's proposed incentive cap does not comply with applicable laws and regulations. GNYHA will also conduct a fair market value analysis to ensure that the hospital and its physicians have actually taken concrete steps to justify the award of incentive payments. These provisions are designed to

prevent fraud and abuse and are consistent with various Medicare hospital gainsharing programs.

According to the DOJ, the provisions appear reasonably necessary and ancillary to the overall legitimate purpose of the program. They also appear to be the least restrictive means possible to achieve the program's purposes.

FTC Report Shows Increasing Number of "Pay-for-Delay" Agreements

See *http://www.ftc.gov/opa/2013/01/mmarpt.shtm*

The Federal Trade Commission's (FTC) annual report on "pay-for-delay" settlements indicates that not only has the number of potentially unlawful pharmaceutical patent settlements been increasing, but that the promise by a brand drug company to not market an authorized generic has dramatically increased from 6 percent of relevant settlements in 2009 to 44 percent in 2012.

Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), pharmaceutical companies involved in Paragraph IV patent litigation must file all agreements between a branded drug manufacturer and a generic drug manufacturer if the agreement concerns either: "the manufacture, marketing or sale" of the branded or generic drug at issue in the litigation, or the Hatch-Waxman 180-day exclusivity period. The FTC publishes reports summarizing the agreements filed each year.

In 2012, companies filed 140 patent settlements. Approximately 28 percent of those settlements contained some form of payment to a generic manufacturer and also restricted the generic's ability to market its product before patent expiry. While this is an increase from 2011, when only 18 percent of the reported settlements contained a payment and restriction on entry, the 2012 ratio is in line with percentages from 2009 and 2010, when 28 percent and 27 percent, respectively, of reported settlements contained a payment and a restriction.

The notable trend is the increasing prevalence of a promise by a brand manufacturer not to market an authorized generic ("AG") in competition with the generic manufacturer's product for some period of time (a "no-AG commitment"). The FTC regards the "no-AG commitment" as a form of compensation to the generic. The promise delivers the most value for a generic manufacture that filed first and therefore holds a 180-day exclusivity right under the Hatch-Waxman Act. That exclusivity right only prevents other generic manufacturers from marketing during the 180-day period, but does not prevent the branded company's authorized generic from competing with the "first-filer's" generic drug. Thus, the "no-AG commitment" allows the first-filer to enjoy a generic monopoly for six months.

Assuming that only settlements with a first filer would contain a "no-AG commitment" (as non-first filers do not have a 180-day exclusivity right and presumably would already face generic competition), the proportion of "no-AG commitments" in settlements involving first-filers has increased significantly over the past few years from 6 percent in 2009 to 44 percent in 2012.

DOJ Halts Price-Fixing Scheme by Oklahoma Chiropractors

See *http://www.justice.gov/atr/cases/oscipa.html*

On January 10, 2013, the Department of Justice (DOJ) filed a price-fixing complaint, against the Oklahoma State Chiropractic Independent Physicians Association (OSCIPA) and its executive director. The suit was brought in federal court in the Northern District of Oklahoma and was filed along with a settlement and proposed final judgment.

The complaint alleges that OSCIPA violated Section 1 of the Sherman Act by negotiating contracts with insurers and other payers on behalf of OSCIPA-member chiropractors. The association's membership includes approximately 45 percent of Oklahoma's practicing chiropractors. Between 2004 and 2011, OSCIPA negotiated at least seven contracts with payers to fix prices. The association also banned its members from offering their patients discounts such as waiving insurance deductibles. Further, since at least 1997, and at the same time it negotiated contracts, OSCIPA disallowed its members the ability to create their own payment agreements with providers or payers and even required members to cancel any existing contracts with payers made before implementation of the 1997 policy. The DOJ asserted that OSCIPA's anticompetitive conduct increased prices for chiropractic services in Oklahoma and further decreased availability for such services.

Under the proposed final judgment, OSCIPA is prohibited from contracting with payers on behalf of its members and cannot facilitate or coordinate any joint contracting among chiropractors. Further, the decree does not affect the right of consumers to bring private antitrust actions against OSCIPA. To date no such actions have been filed.

LEGISLATIVE TOPICS

Congress Again Considers Repeal of McCarran-Ferguson Act's Exemption for Insurers

See *http://thomas.loc.gov/cgi-bin/query/z?r113:E03JA3-0010:/*

In early January 2013, Michigan Representative John Conyers, Jr. introduced the Health Insurance Industry Antitrust Enforcement Act of 2013, a bill to eliminate the antitrust immunity provided by the McCarran-Ferguson Act for price-fixing, bid-rigging, and market allocation by health insurance issuers or medical malpractice insurers. Eliminating, or at least greatly curtailing McCarran-Ferguson Act antitrust immunity for insurers has long been the subject of Congressional action, and while such measures have passed the U.S. House of Representatives before, they have been blocked in the Senate.

Representative Conyers stressed that the Act is intended to level the playing field between health care professionals and insurance companies in the health care industry and improve the quality of patient care." It will extend antitrust enforcement over health insurers, and by removing the antitrust exemption the Act, "will restore competition to the health insurance marketplace."

Given the history of failure of similar bills in the past the chances of passage of the Act are reported to be slim. However, major changes underway in the health care industry as a result of the Affordable Care Act, and new relationships and paradigms which are developing between and among providers, patients and insurers, suggest a closer scrutiny of antitrust issues in the health insurance industry. Key provisions of the health care reform law, such as creation of Accountable Care Organizations and insurance exchanges, may offer new opportunities for anticompetitive activity in the health care industry. Representative Conyers noted: "The bill I introduce today is intended to root out unlawful activity in an industry that has grown complacent by decades of protection from antitrust oversight."

A similar bill passed the House of Representatives by a wide margin during the health care reform debates in early 2010, but neither the bill nor amendments to other related bills survived a vote in the Senate. Another attempt made in 2012 also passed the House but died in the Senate. However, an increased focus on the price and availability of health care may force a closer look at attempts to affect at least a limited repeal of the McCarran-Ferguson Act's exemption for health industry insurers.

INTERNATIONAL

The European Court of Justice Upholds the Commission's Decision that AstraZeneca Misused the Patent System to Delay Generic Competition for Losec

AstraZeneca AB and AstraZeneca plc v. European Commission, Case No. C-457/10 P.

On December 6, 2012, the highest court in the European Union dismissed AstraZeneca's appeal of the General Court's judgment upholding the European Commission's (Commission) 2005 decision that AstraZeneca abused its dominant position relating to its anti-ulcer medication Losec. This is the first time the Court of Justice has ruled on a Commission decision on the abuse of a dominant market position in the pharmaceutical sector.

In June 2005, the Commission adopted a decision fining AstraZeneca €60 million ($80 million) for abusing its dominant position and violating EU antitrust laws in two ways. The first abuse involved AstraZeneca's pattern of making misleading representations to various EU-member patent offices with the aim of preventing or delaying market entry of competing generic products. The second abuse involved AstraZeneca's deregistration of the marketing authorizations for Losec capsules in selected EU countries combined with AstraZeneca's withdrawal from the market of Losec capsules and the launch of a new version of that product in those countries. Notably, the Commission found that these two courses of conduct constituted abuses of regulatory procedures, not the abuse of patents or intellectual property rights.

In reviewing the first abuse, the Court of Justice explained that the assessment of whether representations made to public authorities for the purpose of improperly obtaining exclusive rights are misleading must be made from an objective perspective and involve concrete actions. The Court found it significant that AstraZeneca's misrepresentations to the patent offices did not involve merely a lack of disclosure, but rather affirmative "highly misleading representations." On the second abuse, the Court stated that a company holding a dominant position has a special responsibility under the EU antitrust laws, and that it cannot use regulatory procedures in a way that prevents or encumbers the entry of generic competitors, unless there is an objective and legitimate basis for the challenged conduct.

The Court of Justice's decision is significant because it confirms that the misuse of regulatory procedures, including the patent system, may constitute a violation of EU competition laws, and it clarifies issues relating to market definition, dominance, and the concept of an abuse within the meaning of Article 102 of the Treaty on the Functioning of the European Union. The decision also confirms the Commission's method defining a relevant product market and the existence of a dominant position within the pharmaceutical sector.

U.K.'s OFT Refers Hospital Merger to Competition Commission

See *http://www.oft.gov.uk/news-and-updates/press/2013/01-13#.UPQTWBjNkxE*

On January 8, 2013, the United Kingdom's Office of Fair Trading (OFT) announced that it had referred the proposed merger of Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust and Poole Hospital NHS Foundation Trust to the Competition Commission for further investigation. Both hospitals provide services to patients in England's southwestern county of Dorset. The OFT's initial review

concluded that the hospitals compete both for patients and for funding.

This marks the first investigation of foundation mergers. Prior to the enactment of the Health and Social Care Act 2012, it was unclear whether the OFT had the power to conduct antitrust investigations of foundation mergers given that foundation trusts are non-profit corporations that are insulated with greater government protection. The Dorset investigation also follows an April 2013 referral by the OFT to the Competition Commission of the U.K.'s private health care market citing high barriers to entry, high concentration, and limited access to information, all of which allegedly distorts competition.

The Competition Commission published its statement of issues as part of the investigation on January 28, 2013. It is expected to publish its full report on June 24, 2013.

ACCC Demands Improvement in Transparency of Pharmaceutical Companies' Payments to Healthcare Professions

See
http://www.accc.gov.au/content/index.phtml/itemId/1094788/fromItemId/142

The Australian Competition and Consumer Commission (ACCC) granted a two-year authorization for the Medicines Australia's Code of Conduct (Code). The Code regulates interactions between pharmaceutical companies and healthcare professions such as doctors and pharmacists. Authorization by the ACCC provides statutory protection from court action for conduct that might otherwise raise concerns under Australian competition law.

The Code requires member companies to report: (1) all payments made to healthcare professionals for advisory board and consulting arrangements; (2) all sponsorship of healthcare professionals to attend medical conferences and educational events; (3) all payments made to speakers at educational events; and (4) all sponsorships of all individual organizations for each financial year, including the value of non-monetary support. Pharmaceutical companies in the United States already publish such information. In granting the authorization, the ACCC is seeking to improve transparency around payments to individual healthcare professionals by pharmaceutical companies and promote integrity and confidence in the medical profession.

The new Code took effect on January 11, 2013.

Spain's Competition Authority Investigates Pfizer for Patent Abuse

See
http://www.cncompetencia.es/Inicio/Noticias/tabid/105/Default.aspx?Contentid=564908&Pag=1

Spain's competition authority, Comisión Nacional de la Competencia (CNC), opened a preliminary investigation in December 2012 into whether Pfizer Health AC and Pfizer S.L.U. has unjustifiably caused the delay products that would compete with Xalatan, Pfizer's glaucoma product. The CNC is investigating whether Pfizer artificially prolonged its Xalatan patent in Spain and prevented entry of other products containing the active ingredient latanoprost, which would compete with Xalatan, in violation of Spain's competition law and Article 102 of Treaty of the Functioning of the European Union.

Spain's investigation follows a finding by the Italian competition authority that Pfizer artificially extended patent protection of the active ingredient latanoprost in Italy to prevent or delay generics from entering the market in 2012, and fined Pfizer $10.6 million dollars for abuse of dominant position.