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.

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FEDERAL COURT CASES

Mylan Jury Award Appealed by GSK in Paxil Case
_Mylan Inc. v. SmithKline Beecham Corp., No. 3:10-cv-04809 (D. N.J.)_

A jury found that GlaxoSmithKline PLC (GSK) breached its licensing agreement with generic manufacturer Mylan—an agreement that granted Mylan an exclusive license to market a generic version of GSK’s Paxil CR. The jury awarded Mylan $106.7 million in damages. Following the adverse jury verdict and an order affirming the verdict from the federal district court in New Jersey, GSK filed a notice of appeal to the Third Circuit on August 15, 2014.

Under the terms of the GSK-Mylan licensing agreement, GSK (or its affiliate) could market and sell its own authorized generic (AG) of Paxil CR two years after Mylan launched its own generic version of the drug. The issue before the jury was whether GSK breached this covenant in late 2010 when it entered into a supply and distribution agreement with Apotex that allows Apotex to launch an AG of Paxil CR as part of a settlement to resolve a patent litigation over Paxil CR. After the jury returned a verdict finding that GSK breached the covenant, GSK filed motions for judgment as a matter of law, new trial, and/or remittitur. Mylan filed a cross-motion for a permanent injunction against GSK, accounting, and prejudgment interest.

The court also found that an accounting and prejudgment interest were appropriate under the circumstances: the former to compensate Mylan for GSK’s ongoing breach after trial, and the latter to compensate Mylan for interest on the profits it was owed since 2010. The court denied Mylan’s request for prejudgment interest to the extent that it sought a two percent increase above the interest rate typically awarded, and interest during the pendency of an earlier appeal before the Third Circuit.

The court denied GSK’s motions for judgment as a matter of law, new trial, or remittitur, finding that Mylan presented sufficient evidence at trial to sustain the jury’s verdict that GSK breached its agreement with Mylan. Similarly, the court found remittitur improper because: (1) Mylan rebutted GSK’s efforts to show that factors other than Apotex’s entry caused Mylan to lose profits; (2) Mylan alleged supply issues would not have prevented it from filling orders for generic Paxil CR; and (3) Mylan produced sufficient evidence that its decision not to lower prices in the face of Apotex’s entry was a “responsible business decision.”

Illinois Suit Alleges Pay-For-Delay Scheme against Endo Pharmaceuticals and Impax Laboratories
_Penn. Employees Benefit Trust Fund v. Endo Health Solutions Inc., No. 14-cv-06171 (N.D. Ill.)_

Endo Pharmaceuticals and Impax Laboratories are facing a second proposed antitrust class action lawsuit over an alleged pay-for-delay scheme that postponed the launch of a generic version of Endo’s pain medication Opana ER (oxymorphone hydrochloride). The most recent suit was filed in the U.S. District Court for the Northern District of Illinois by the Pennsylvania Employees Benefit...
Trust Fund (Fund). In its complaint, the Fund alleges that Endo paid Impax at least $112 million to delay its release of generic oxymorphone hydrochloride for more than two years, forcing the Fund to pay supra-competitive prices for Endo’s brand version of the drug for its members. The complaint states that “Endo essentially bribed Impax to stay out of the market for two-and-a-half years to protect Endo’s stream of monopoly profits,” and that “Endo literally bought itself freedom from generic competition.”

The Illinois lawsuit is substantially similar to a suit brought in June by Wisconsin Masons’ Health Care Fund and Rochester Drug Cooperative Inc.

The Illinois complaint alleges that in 2010, Endo settled patent infringement litigation against Impax related to Opana ER with a deal to keep Impax’s generic version off the market for three additional years in exchange for at least $112 million. The Fund argues that Endo also promised not to compete with Impax by launching its own generic drug. Rather, Endo allegedly was able to use its deal as a bottleneck against generic manufacturers Roxane Laboratories, Actavis and Sandoz. According to the complaint, Endo used this delay to switch the market for Opana ER to a new, more crush-resistant formulation of the drug, called Opana ER CRF. The switch to the new formulation, the complaint continues, blunted generic competition because the generic versions of the old product are not automatically substitutable for the new crush-resistant formulation.

The Illinois suit seeks treble damages arising out of the defendants’ alleged unlawful scheme to allocate the market for extended release oxymorphone hydrochloride, and alleges violations of state and federal antitrust laws, including the Sherman Act.

Infantile Spasm Drug Antitrust Suit Survives Motion to Dismiss

_Retrophin, Inc., v. Questcor Pharma., Inc., No. 14-cv-00026 (C.D. Cal.)_

On August 8, 2014, the United States District Court for the Central District of California denied Questcor Pharmaceuticals, Inc.’s motion to dismiss Retrophin, Inc.’s antitrust suit, which accuses Questcor of monopolizing various markets related to adrenocorticotropic hormone (ACTH) therapeutic drugs used to treat infantile spasms.

Questcor is the only U.S. provider of approved therapeutic preparations of ACTH. Retrophin alleged that since Questcor acquired the rights to the ACTH drug Acthar in 2001, Questcor has increased the price of Acthar from $50-or-less per vial, to $28,000 per vial. Retrophin also alleged that Questcor blocked Retrophin’s entry into the relevant ACTH drug market by thwarting Retrophin’s acquisition of the rights to sell Synacthen, a synthetic ACTH drug approved in Europe.

In its motion to dismiss, Questcor argued that Retrophin lacks antitrust injury and antitrust standing and that Retrophin failed to allege market power. Judge Josephine L. Staton denied Questcor’s motion to dismiss, finding that Retrophin’s injury of exclusion from the relevant markets is inseparable from the alleged harm to competition and is sufficient to allege antitrust injury. Judge Staton also found that while Retrophin failed to allege facts that could constitute direct evidence of market power, it sufficiently alleged facts that could constitute circumstantial evidence of market power.
Ninth Circuit Briefing in St. Luke’s Appeal
St. Alphonsus Medical Center-Nampa et al. v. St. Luke’s Health System Ltd., No. 14-35173 (9th Cir.)

As discussed in prior issues of Recent Developments, St. Luke’s Health System is appealing, in the U.S. Court of Appeals for the Ninth Circuit, a 2014 decision by the U.S. District Court in Idaho that St. Luke’s acquisition of the Saltzer Medical Group violated Section 7 of the Clayton Act and Idaho state antitrust law by virtue of the transaction’s likely anticompetitive effects in the local market for adult primary care physician services. The court ordered St. Luke’s to “divest itself of Saltzer’s physicians and assets and take any further action needed to unwind the Acquisition,” holding that the acquisition would enable the combined entity to “(1) negotiate higher reimbursement rates from health insurance plans that will be passed on to the consumer … and (2) raise rates for ancillary services (like x-rays) to the higher hospital billing rates.”

Recent Developments previously reported that, in its appeal brief, St. Luke’s argued that the district court did not properly define the relevant markets and did not appropriately take into account the pro-competitive benefits of the transaction. In their opposition brief filed August 13, 2014, the FTC and State of Idaho argued that St. Luke’s failed to show efficiencies that are concrete, merger-specific, and sufficient to offset the acquisition’s likely anticompetitive effects. The government plaintiffs also asserted that the district court correctly applied Clayton Act Section 7 principles and rejected arguments by St. Luke’s in support of the transaction based on policies underlying the Affordable Care Act. The FTC and Idaho argued that St. Luke’s acquisition of Saltzer lessens competition and would result in higher prices for insurers, which will in turn lead to higher premiums, deductibles and copayments borne by the commercially insured. Sixteen state attorneys general filed an amicus brief supporting the rejection of the appeal.

On September 2, 2014, filed its reply brief. St. Luke’s reiterated that its acquisition of Saltzer does not violate federal and state antitrust laws and advances the public policy embedded in the Affordable Care Act (ACA) to promote clinically integrated care delivered through value-based arrangements that expand coverage to the poor and uninsured. St. Luke’s emphasized that the transaction with Saltzer is an example of vertical integration, which, St. Luke’s asserted, advances the goals of the Affordable Care Act to improve patient care and reduce costs. The brief states that the transaction: (1) “was intended . . . primarily to improve patient outcomes” and “if left intact” would accomplish that objective; (2) will promote movement toward integrated, value-based healthcare, which is a “consensus … solution to the cost and quality concerns” about healthcare delivery; and (3) will “increase access to medical care for the significant population of Medicaid and Medicare patients.”

The Ninth Circuit has stayed the divestiture of Saltzer until the appeal is decided.

Federal Judge Denies Apotex Summary Judgment in Provigil Suit

Apotex Inc. v. Cephalon Inc., No. 2:06-cv-02768 (E.D. Pa.)

In August, U.S. District Judge Mitchell S. Goldberg denied Apotex Inc.’s motion for summary judgment of its claims that Cephalon’s patents for its branded modafinil product Provigil were invalid and unenforceable and that Cephalon violated antitrust laws by improperly delaying generic competitors to Provigil.
Apotex had argued that it was entitled to summary judgment because it presented what Apotex asserted to be undisputed direct evidence of Cephalon’s monopoly power in a modafinil market: Cephalon’s history of price increases without lost sales and 95 percent profit margin, and certain statements by Cephalon’s executives. Judge Goldberg found that factual disputes between the parties still existed, and that Apotex did not establish the relevant product market or cite cases to support the position that direct evidence of monopoly power was sufficient for summary judgment without establishing a relevant product market.

Judge Bars Cephalon’s Patent Experts in Pay-for-Delay Suit

FTC v. Cephalon, No. 2:08-cv-214 (E.D. Pa.)

A Pennsylvania federal judge barred Cephalon from having ten patent experts testify on the risks of its Provigil patent litigation in the FTC lawsuit against the Cephalon.

The court concluded that Cephalon is not permitted to revive claims about the validity of its patents in the litigation because a previous decision had already found the patents invalid and unenforceable. The court will allow Cephalon to present evidence about whether the types of settlements were reasonable, considering the risk it faced in litigation.

Additionally, Judge Mitchell S. Goldberg did not definitively rule on whether the experts could testify in the parallel private antitrust claims against Cephalon. The court had previously determined that Cephalon could argue the validity of its underlying patent in private antitrust claims because the company had a right to a jury trial in those proceedings, and the previous decision on the validity of the patents had been made in a bench trial.

Shareholder Sues Lannett Over Price-Fixing Scheme


On August 27, 2014, David Schaefer, a shareholder who seeks to certify a class of others in a similar situation, filed a securities class action against Lannett Company Inc., accusing the generic manufacturer of purposely and repeatedly making “false and misleading statements regarding the Company’s business, operational and compliance policies,” and failing to disclose a scheme to fix the price of its drug digoxin.

According to the complaint, digoxin is a drug used for the treatment of congestive heart disorder. Sales of the drug account for approximately 23 percent of Lannett’s total sales. The plaintiff alleges that Lannett executives fixed the price of digoxin, causing the company’s sales to inflate and making shareholders believe that the company was achieving record sales during the period between Sept. 10, 2013 and July 16, 2014. As part of the alleged scheme, the plaintiff also alleges that the company allocated and divided customers and territories with other competitors.

On July 16, 2014, Lannett filed a Form 8-K with the Securities and Exchange Commission and issued a press release, acknowledging in both that it had received a subpoena and interrogatories from the Connecticut Office of the Attorney General and under investigation for the pricing and the territorial and customer division of digoxin.
Federal Circuit Revives Long-Running Antitrust Suit against Tyco Healthcare Group  

On August 6, 2014, in a 2-1 decision, the U.S. Court of Appeals for the Federal Circuit reversed a district court decision and reinstate antitrust case against Tyco Healthcare Group LP regarding its insomnia medication Restoril. The U.S. District Court in New Jersey had previously rejected claims by Mutual Pharmaceutical Company that Tyco violated antitrust laws by filing an allegedly sham infringement suit against Mutual and sham citizens petition with the FDA. Tyco owns patents related to temazepam, marketed as Restoril. In 2006, Mutual filed an Abbreviated New Drug Application (ANDA) with the FDA to sell a generic version of temazepam. Tyco brought a patent infringement suit against Mutual, and Mutual subsequently filed an amended answer with the antitrust counterclaims. On August 4, 2009, the district court ruled that Mutual did not infringe Tyco’s patent. Tyco thereafter filed a citizen petition with the FDA, requesting a change in the bioequivalence criteria for Restoril. The FDA later approved Mutual’s ANDA and denied Tyco’s petition.

The district court granted summary judgment in favor of Tyco on four claims, holding that Tyco: did not file a sham lawsuit; reasonably believed that its patents could withstand a validity challenge; did not file a sham citizen petition; and did not engage in fraud. The Federal Circuit reversed on two claims: that holding that Tyco did not file a sham lawsuit and that Tyco’s citizen petition to the FDA was not a sham; and directed the district court to conduct a factual inquiry into whether Mutual’s generic product would infringe on the patents covering Tyco’s branded product. It further directed the district court to determine whether the citizen petition caused Mutual antitrust injury in the form of a delay to its ANDA approval. In a dissent, Judge Newman stated that the majority’s decision creates new grounds for antitrust liability and “inserts a strong antitrust presence into routine patent litigation, adding the potential of antitrust penalties for patent enforcement.”

Judge dismisses Loestrin Pay-for-Delay Case, Says Cash Payment Necessary to Meet *Actavis* Standard  
*In re: Loestrin 24 Fe Antitrust Litig., No. 1:13-md-02472 (D. R.I.)*

Last month, a federal judge in Rhode Island dismissed all claims in a pay-for-delay suit against Warner Chilcott, finding that the Supreme Court’s holding in *FTC v. Actavis* was inapplicable because the deals at issue did not include a cash payment.

The plaintiffs in the case, both direct and indirect purchasers of Warner Chilcott’s oral contraceptive Loestrin 24 Fe, had alleged that Warner Chilcott made reverse payments to two generic manufacturers, Watson Pharmaceuticals Inc. and Lupin Pharmaceuticals Inc., in exchange for their agreement not to launch a generic version of Warner Chilcott’s product.

U.S. District Court Judge William E. Smith said that the plaintiffs presented no evidence that the agreements between the three defendants included any sort of cash payment. Instead, the agreements included non-cash consideration: a license to market the product at a later date and access to generic versions of other Warner Chilcott products. According to Judge Smith, because the monetary value of the settlement is unclear, it is almost impossible to apply the *Actavis* rule of reason factors to analyze the legality of the settlement.
Judge Smith acknowledged that if other courts also apply the Actavis standard literally, pharmaceutical companies can evade antitrust scrutiny in future pay-for-delay cases by simply structuring the settlement to avoid a cash payment.

Security Precautions may Mitigate Liability in Hospital Patient Data Breach

In August 2014, Tennessee-based Community Health Systems Inc. (CHS) disclosed that hackers had stolen non-medical personal data of approximately 4.5 million patients. The data breach included information about patients who received services over the past five years from CHS-affiliated physicians. CHS reports that the breach was due to highly sophisticated hackers that bypassed its security measures to infiltrate its data servers. Information that was breached included patient names, addresses, birth dates, telephone numbers, and social security numbers but did not include medical information.

This data breach will be assessed under the Security Rule of the Health Insurance Portability and Accountability Act of 1996, as amended (HIPAA). The Security Rule provides that covered health care entities must: (i) ensure the confidentiality, integrity and availability of all electronic protected health information that the covered entity or business associate creates, receives, maintains, or transmits; (ii) protect against any reasonably anticipated threats or hazards to the security or integrity of such information; (iii) protect against any reasonably anticipated uses or disclosures of such information not permitted or required under HIPAA; and (iv) ensure compliance with the Security Rule.

Generic Lipitor Lawsuit Alleging Pay-for-Delay Dismissed with Prejudice

U.S. District Judge Peter G. Sheridan dismissed with prejudice a proposed direct purchaser class action lawsuit against Pfizer and Ranbaxy Laboratories. Wholesalers and retailers alleged that the drug manufacturers conspired to delay the entry of generic Lipitor into the cholesterol drug marketplace. Plaintiffs alleged that Pfizer and Ranbaxy entered into a non-monetary “reverse payment” in 2008, absolving Ranbaxy from damages but preventing Ranbaxy’s generic challenge to Lipitor from entering the market until November 2011. Plaintiffs argued that the deal-in-dispute was a form of a reverse-payment and caused wholesalers and retailers to overpay for the cholesterol drug. Pfizer argued that Ranbaxy received no cash payment as part of the settlement, but was granted permission to launch its generic Lipitor prior to the expiration of Pfizer’s related patents.

Rejecting the claims, Judge Sheridan said that “where Plaintiffs rely on a non-monetary reverse payment of an inchoate claim, they must plead plausible facts including an estimate the monetary value of same so the Actavis rationale can be applied.” The court determined the plaintiffs “failed to delineate any type of methodology to connect the claim to its monetary value.” Judge Sheridan noted that “[a] reliable foundation need not yield a precise amount of the alleged non-monetary payment, but one that fits within the ballpark like using the loss of profit standard.”
Federal Antitrust Claims Survive Motion to Dismiss against AbbVie and Teva
In re: Niaspan Antitrust Litigation, MDL No. 2460 (E.D. Pa.)

US District Judge Jan E. DuBois has dismissed several claims from a multidistrict litigation against AbbVie Inc. and Teva Pharmaceuticals Industries Ltd over alleged “pay-for-delay” settlements regarding generics of the cholesterol drug Niaspan. However, the plaintiffs’ federal antitrust claims were kept intact.

Both federal antitrust claims originally arose out of patent litigation settlement agreement in 2005 between Kos Pharmaceuticals Inc., acquired by AbbVie’s predecessor in 2006, and Barr Pharmaceuticals Inc., a generic manufacturer acquired by Teva in 2008. The agreement settled Kos’s allegation that Barr’s generic version of Niaspan violated Kos’s patents. As part of the settlement, Barr agreed not to launch a generic version of Niaspan until September 20, 2013.

Class actions against AbbVie and Teva arising out of deal began in April 2013, but only the federal antitrust claims survived the motions to dismiss. Both claims overcame allegations that they were time-barred because the ongoing sales of Niaspan at “supracompetitive price” constituted a continuing violation in the judge’s view. Furthermore, Judge DuBois held that the plaintiffs had sufficiently alleged the existence of a reverse payment to delay generic entry into the market.

In addition, the judge held the plaintiffs pled plausible grounds that, but for the allegedly anti-competitive settlements, Barr would have succeeded in the underlying patent litigation against Kos.
FEDERAL AGENCY DECISIONS

FTC Requires Divestiture in Prestige/Insight Deal
See [link]

The FTC has placed certain conditions on the approval of a proposed acquisition by Prestige Brands Holdings, Inc. of Insight Pharmaceuticals Corporation. Specifically, the FTC ordered Insight to divest its interests in over-the-counter (OTC) drug Bonine, a drug that is used to treat motion sickness, within ten days after the acquisition.

On April 25, 2014, Prestige, through its subsidiary Medtech Products Inc., entered into a $750 million stock purchase agreement with Insight, through which Prestige would acquire all of Insight’s outstanding shares.

Prestige holds the rights to Dramamine, the best-selling OTC branded motion sickness drug. Insight’s Bonine is, according to the FTC’s complaint, the only significant competitor, and through the proposed acquisition, Prestige would have obtained the rights to the only two OTC motion sickness medications with significant sales. Further, according to the complaint, private label OTC motion sickness medications have only a limited competitive impact because they usually price at a fixed discount to the OTC versions, and entry is unlikely because limited sales opportunities in the market mean that few companies would absorb the large start-up costs associated with launching and successfully marketing a competing medication.

The FTC alleged that should Prestige’s acquisition proceed as proposed, competition between Dramamine and Bonine would substantially decrease and result in higher prices for consumers.

In a consent agreement, Prestige and Insight agreed to divest the Bonine assets to another pharmaceutical company, Wellspring Pharmaceutical Corporation, within ten days of completing of Prestige’s acquisition of Insight. The assets include Insight’s manufacturing and contract packaging agreements for Bonine, as well as confidential business information, customer accounts, and intellectual property rights relating to Bonine. The FTC said that the divestiture would allow Wellspring to step into Insight’s existing contract manufacturing relationship for the production of Bonine and begin competing immediately.

In addition, Prestige and Insight agreed to an FTC-appointed an interim monitor charged with ensuring compliance with the consent agreement, as well as a divestiture trustee to oversee the divestiture in the event that Insight fails to divest its interests in Bonine within the timeframe set forth in the consent agreement.

Should the FTC find that the divestiture of Bonine to Wellspring is unacceptable, Prestige and Insight are required to unwind the sale within six months of the date when the Consent Order becomes final.

Green Light, with Conditions, for Akorn’s Acquisition of VersaPharm Inc.
See [link]

The FTC and Akorn, Inc. have entered into a consent agreement allowing Akorn to acquire VersaPharm Inc. on the condition that Akorn
divest its rights to develop, manufacture and market the generic injectable tuberculosis drug, rifampin, to Watson Laboratories, Inc.

The FTC alleged that: the acquisition, absent the divestiture, would have lessened competition or created a monopoly in the market for generic rifampin; only VersaPharm and two other companies have FDA approval to sell generic injectable rifampin, and there are no viable substitutes for rifampin in treating tuberculosis; and, but for Akorn’s acquisition of VersaPharm, Akorn likely would have entered the market for generic injectable rifampin in the near future, which would have reduced the price of the drug. The FTC also alleged that the newly combined firms would likely have waited to enter the market or forgone doing so altogether. According to the FTC, this would have caused significant harm to consumers by eliminating future competition in the market for generic rifampin.

In addition to requiring the divestiture of Akorn’s rights to develop, manufacture, and market rifampin, the consent order also appoints an interim monitor to ensure that Akorn complies with its obligations.

On September 19, 2014, the FTC approved a final order on the Akorn consent agreement.

FTC reverses its Decision on Phoebe’s Merger with Palmyra

On September 5, 2014, the FTC withdrew its acceptance of a proposed consent order that would have permitted Phoebe Putney Health System Inc. to keep Palmyra Park Hospital Inc., and returned the matter to administrative litigation. In its statement, the FTC explained that its understanding that Georgia’s requirements governing the issuance of a Certificate of Need (CON) would likely have prevented an effective divestiture of Palmyra’s assets had changed. The Commission noted that public comments it received and a recent decision by Georgia’s Department of Community Health had left open the possibility that structural relief—a divestiture of Palmyra—was still available.

In 2011, the FTC challenged Phoebe’s plans to acquire Palmyra, stating that the acquisition would create a monopoly in Albany, Georgia and leave only one other independently-owned hospital within the six-county area. Phoebe argued that since the Hospital Authority of Albany-Dougherty County technically carried out the acquisition, the transaction was exempt from federal antitrust liability by the state action doctrine. The Eleventh Circuit agreed with Phoebe and the transaction was consummated in December 2011.

In 2013, however, the Supreme Court unanimously held that the state action doctrine did not immunize the transaction. In August 2013, the FTC announced that it had entered into a consent agreement with Phoebe that did not include a divestiture of Palmyra because the CON requirements would prohibit an effective divestiture.

FTC Sues AbbVie, Besins Healthcare, and Teva for Monopolization and Illegal Restraint of Trade in Sale of AndroGel

On September 8, 2014, the Federal Trade Commission filed suit in the U.S. District Court for the Eastern District of Pennsylvania, charging (1) AbbVie Inc. and Besins Healthcare Inc. with monopolization and (2) AbbVie and Teva
Pharmaceuticals USA, Inc. with illegal restraint of trade in the sale of the over-$1 billion testosterone replacement drug, AndroGel.

The FTC monopolization count alleges that AbbVie and Besins Healthcare filed sham patent infringement litigation against Teva and Perrigo Company to delay entry of generic versions of AndroGel. The AbbVie and Besins Healthcare suits focus on an AndroGel ingredient called isopropyl myristate (IPM), used as a “penetration enhancer” to speed delivery of testosterone through the skin and into the bloodstream. Teva and Perrigo’s products did not contain IPM and used different penetration enhancers. Thus, according to the FTC complaint, AbbVie and Besins Healthcare had no reasonable basis to believe that Teva’s and Perrigo’s drugs infringed on the AndroGel formulation patent and their litigation was instead motivated by the desire to extend their monopoly profits from AndroGel sales.

Teva countersued AbbVie and Besins Healthcare, claiming their suit constituted sham litigation. The FTC alleges that AbbVie and Teva then engaged in illegal restraint of trade when Teva agreed to (1) withdraw its countersuit and (2) delay launching its AndroGel alternative, in exchange for an authorized generic deal for AbbVie’s TriCor, a cholesterol drug with over $1 billion in U.S. sales in 2011. The deal was highly profitable for Teva, but made no independent business sense for AbbVie, according to the FTC.

The FTC complaint seeks (1) judgment that the defendants’ conduct violates the FTC Act, (2) disgorgement of the defendants’ ill-gotten gains, and (3) a permanent bar on defendants’ engaging in similar anticompetitive conduct in the future. The Commission vote to sue was 3-2, with Commissioners Maureen K. Ohlhausen and Joshua D. Wright dissenting.
NY AG Sued Actavis for Allegedly Forcing Patients to Switch Alzheimer Drugs

New York v. Actavis PLC et al., No. 14-cv-07473 (S.D.N.Y)

On September 15, 2014, New York Attorney General Eric T. Schneiderman sued Actavis and its New York-based subsidiary Forest Laboratories LLC, alleging the companies improperly maintained and extended their monopoly in the market for Alzheimer drugs by halting sales of its twice-daily Namenda IR (immediate release) and switching patients to its once-daily extended release version, Namenda XR.

Patents for Namenda IR expire July 2015; Namenda XR is protected by patents for many more years. The New York AG’s complaint argues Actavis “is using the ‘forced switch’ to reap several more years of monopoly profits” because “[u]nder generic substitution laws, a pharmacist will not be able to substitute lower-priced generic Namenda IR (known as memantine) for Namenda XR.”
FEDERAL AND STATE LEGISLATIVE TOPICS

Proposed Legislation Would Amend FDC Act to Address Abuse of REMS

A bill introduced in the House of Representatives by Congressmen Steve Stivers (R-OH) and Peter Welch (D-VT) would amend the FDC Act to address accusations that brand-name drug manufacturers exploit an FDA program known as Risk Evaluation and Mitigation Strategies (REMS). The FDA requires brand-name drug manufacturers to develop REMS plans when a medicine is in the market place but poses a safety risk. REMS plans typically require monitoring of distribution.

When a generic manufacturer wants to introduce a generic version of a branded product to the market, the FDA requires that the generic manufacturer demonstrate that its drug is equivalent to the branded product. Normally, generic manufacturers can easily access samples to conduct these tests through wholesalers, but REMS-restricted products often must be obtained directly from manufacturers. Over the past few years, generic manufacturers have claimed they have been denied access to samples of branded drugs needed to conduct equivalency testing necessary to win FDA approval, not because of public safety concerns, but because of alleged efforts by their branded counterparts to thwart generic entry.

The Fair Access for Safe and Timely Generics Act, or FAST Generics Act, would prevent branded manufacturers from taking steps to prevent generic manufacturers from obtaining needed samples of REMS-restricted drugs. The bill creates a formal process for generic manufacturers to obtain authorization from the FDA to access REMS-restricted products. And if branded drug manufacturers continued to deny access, generic manufacturers would be authorized to sue for an injunction and treble damages.
INTERNATIONAL

Merck Fined $1.8 Million over Plot to Block Generics in Brazil

On August 6, 2014, Merck KGaA was fined $1.8 million by Brazil’s antitrust enforcer for conspiring with other pharmaceutical companies in the country to keep distributors from working with generic drug makers.

An investigation by the Administrative Council for Economic Defense (CADE) found that Merck had attended a meeting with some of Brazil’s most relevant pharmaceutical companies. Allegedly, during that meeting, the pharmaceutical companies planned to limit the sale of generic drugs in Brazilian territory, a plot that would keep the country’s consumers from accessing more affordable medications. The CADE found that Merck did not voice its disagreement with the plan during this meeting, which amounted to the tacit acceptance of the plan to keep generic competition from the markets, in order to protect brand makers from the loss of profits.

Competition Commission of India Invites Public Comments on Sun Pharmaceuticals’ Proposed Merger with Ranbaxy

On September 4, 2014, the Competition Commission of India (CCI) formed a prima facie opinion that the proposed merger between Sun Pharmaceuticals Limited and Ranbaxy Laboratories Limited is likely to have an adverse effect on competition and directed the parties to publish details of combination for public comment. The public inquiry period ended on September 27, and the CCI will make a decision on the deal within 45 days of that date.

On April 6, 2014, Sun Pharma announced that it would acquire Ranbaxy from Daiichi Sankyo in an all-share deal for approximately $4 billion, potentially making Sun Pharma India’s largest drug maker by sales and the world’s fifth largest generic manufacturer. The CCI had received notice from Sun Pharma and Ranbaxy of the proposed merger on May 6, and in August, it ordered a second-stage investigation into the merger citing the risk of harm to the “national interest.” This is the first time that the CCI has ordered a second-stage inquiry and raised this type of objection.

Canadian Commissioner of Competition Discusses Patent Litigation Settlement in the Pharma Industry
See www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03816.html

On September 23, 2014, Canada’s Commissioner of Competition gave a speech at the Global Antitrust Challenges conference where he outlined the Competition Bureau’s enforcement approach to potentially anticompetitive patent litigation settlement agreements.

He recognized that patent litigation settlement agreements may be an effective way to avoid litigation, but that their implementation could potentially prevent or delay the entry of generic drugs into the pharmaceutical industry. The
Commissioner noted that “the Bureau has taken a keen interest in reverse-payment settlements and product hopping issues, given the possibility that they may delay generic entry.”

He also noted that the Bureau’s enforcement approach for these types of potentially anti-competitive agreements will be decided on a case–by-case basis and could be reviewed under the criminal conspiracy, civil agreements, or abuse of dominance provisions under the Competition Act.

The Commissioner also announced the release of a white paper on the issue titled “Patent Litigation Settlement Agreements: A Canadian Perspective”. The paper provides an overview of the entry of generic drugs in Canada, the role of competition legislation, and the Bureau’s preliminary views on how Canadian competition law may apply in the context of patent litigation settlement agreements.