About Recent Developments

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Please contact the editors, Kari Wallace (kwallace@ftc.gov), Imran Ahmad (iahmad@casselsbrock.com), or Christopher D. Cazenave (ccazenave@joneswalker.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:


To get involved with any other activities of the Committee, please contact the Committee Chairs, Philip Nelson (nelson.p@ei.com) and Jeffrey Brennan (jbrennan@mwe.com).

Recent Developments Contributors

Yolanda Gutierrez-Almazan
Wilson Sonsini Goodrich & Rosati
Washington, DC

Matthew Berkle
Kedrion Biopharma Inc.
Fort Lee, NJ

Ryan P. Blaney
Cozen O’Connor
Washington, DC

Kate Byers
Cassels Brock
Toronto, ON

Ausra O. Deluard
Jones Day
San Francisco, CA

William Huynh
Fed. Trade Comm’n
Washington, DC

Brian Miller, MD
Johns Hopkins University
Baltimore, MD

Daniel Dukki Moon
Linklaters
New York, NY

Amy D. Paul
Ropes & Gray LLP
Washington, DC

Matthew J. Perez
Labaton Sucharow LLP
New York, NY

Matthew J. Piehl
Faegre Baker Daniels LLP
Minneapolis, MN

William A. Roach Jr.
Winston & Strawn LLP
Washington, DC
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FEDERAL COURT CASES

ProMedica Seeks Supreme Court Review of FTC Challenge to Merger


ProMedica Health Systems Inc. has filed a petition for a writ of certiorari with the U.S. Supreme Court, seeking to have it overturn a Sixth Circuit ruling affirming the Federal Trade Commission’s (FTC) order requiring ProMedica to divest St. Luke’s Hospital, a non-profit hospital in Toledo, Ohio, that ProMedica acquired in 2010.

In early 2011, the FTC filed an administrative complaint, challenging ProMedica’s acquisition of St. Luke’s and alleging that the transaction would reduce competition and allow ProMedica to increase prices for general acute-care and inpatient obstetrical services. Shortly thereafter, The FTC and Ohio Attorney General filed a separate complaint in the U.S. District Court for the Northern District of Ohio, asking that the court order ProMedica to preserve St. Luke’s as a separate, independent competitor while the administrative proceeding was underway. The district court granted the injunction and, in March 2011, Chief Administrative Law Judge D. Michael Chappell found that ProMedica’s acquisition violated the antitrust law and ordered ProMedica to divest St Luke’s. ProMedica appealed the decision to the FTC and the FTC upheld Judge Chappell’s decision. ProMedica appealed the decision to the Sixth Circuit and the Sixth Circuit agreed with the FTC.

ProMedica’s petition argues that this case is “a rare and uniquely apt vehicle for consideration of the [antitrust] issues based on a fully-developed record.” Hospital merger antitrust cases rarely are litigated on the merits through appeal, and this case is an opportunity for the Court to address competition aspects of a merger for the first time since United States v. General Dynamics Corp., 415 U.S. 486 (1974).

ProMedica’s petition focuses on three issues on which ProMedica says the lower courts are divided:

1. In defining the relevant product market for a merger analysis, is the FTC permitted to ignore the group of services that market participants actually negotiate for and purchase as a package, and instead define the product market based on supply-side considerations, thus allowing the FTC to gerrymander the product market to artificially inflate market shares?

2. Where the FTC relies exclusively on a unilateral effects theory in challenging a merger—a theory that turns on substitutability, not on market share—may a court nonetheless adopt a strong presumption of anticompetitive harm based solely on market-share statistics?

3. Assuming that the FTC can rely on a strong presumption of harm based on market-share statistics in unilateral-effects cases, can it then separately rely on market-share statistics to preclude consideration of the merger target’s financial weakness to rebut that presumption?

ProMedica Petition for Cert. at i–ii.

Unilateral effects analysis attempts to determine the degree to which customers view merging parties as close substitutes for each other. The greater the closeness of competition, other things equal, the greater the risk of anticompetitive
effects from the merger. ProMedica contends that a different competitor, Mercy Hospital, not St. Luke’s, is ProMedica’s closest substitute in the Toledo area.

The American Hospital Association (AHA) filed an amicus brief in support of ProMedica’s petition, focusing on the “weakened competitor” doctrine. Pointing to the Sixth Circuit’s characterization of the “weakened competitor” defense as a “Hail Mary” that deserves credence only in rare situations, AHA argues that the Sixth Circuit decision leaves the “viability of many small and stand-alone hospitals in jeopardy.” AHA also argues that there are conflicting interpretations by the lower courts of the General Dynamics decision, and that clarity is needed from the Court, especially in the context of health care mergers. According to the AHA, hospitals should not have to wait until they are on the edge of bankruptcy to merge, and that the Sixth Circuit erred by not correctly applying the General Dynamics analysis to the ProMedica acquisition.

Injunction against Actavis Upheld in Namenda Product Hopping Case

On January 6, 2015, the U.S. Court of Appeals for the Second Circuit, while granting defendant Actavis’ application for an expedited appeal in a “product-hopping” challenge brought by the Attorney General of New York, denied Actavis’ request to stay the district court’s injunction regarding the conduct at issue. The injunction requires Actavis to continue selling Namenda IR without the need for a doctor to deem the treatment a “medical necessity,” and to inform healthcare professionals, patients, and others of the injunction.

In September 2014, the New York Attorney General (NYAG) sued Actavis to enjoin it from pursuing a “hard switch” from Namenda IR to a next-generation Alzheimer’s drug called Namenda XR. According to the complaint, under the hard switch, Actavis sought to restrict the supply of Namenda IR to a single distributor, which would only sell Namenda IR if a physician deemed the drug to be medically necessary for a patient. By doing this, Actavis allegedly sought to move patients from Namenda IR to Namenda XR. The NYAG alleged that this conduct unlawfully sought to reduce competition to Namenda XR from generic versions of Namenda IR, which were scheduled to launch in mid-2015.

After a five-day hearing in November 2014, a federal judge found that the NYAG had met its burden for a preliminary injunction because it had shown that Actavis’ actions were unreasonably exclusionary and done for the purpose of reducing competition from Namenda generics. The court further found that Actavis’ business justification for the hard switch—which would allow Actavis to better “focus” on Namenda XR sales—was pretextual and inconsistent with earlier statements by Actavis’ CEO to shareholders, to whom he said: “if we do the hard switch and we’ve converted patients and caregivers to [Namenda XR] from [Namenda IR], it’s very difficult for generics then to reverse-commute back, at least with existing [prescriptions]. They don’t have the sales force, they don’t have the capabilities to go do that.” New York v. Actavis PLC, No. 14-7473, slip op. at 50 (S.D.N.Y.).

In granting the preliminary injunction, the district court ordered the following conduct through July 11, 2015: (1) Actavis shall continue to make Namenda IR tablets available on the same terms as before the imposition of the hard switch; (2) Actavis is required to inform healthcare providers, pharmacists, patients, caregivers, and others of the
Actavis appealed and moved to stay the injunction. On December 22, 2014, the district court partially granted the motion to stay, but only to the extent that the injunction required Actavis to notify healthcare professionals, patients and others about the injunction. It further ruled that this portion of the injunction was only stayed until the Second Circuit ruled on Actavis’ parallel “Emergency Motion a Stay Pending Appeal and for an Expedited Appeal.” This was followed by the Second Circuit ruling described above.

Jury Finds for Defendant in First Pay-For-Delay Trial since Actavis

In re Nexium (Esomeprazole Magnesium) Antitrust Litig., No. 12-2409 (D. Mass.)

In December 2014, after a six-week trial, an eleven-member jury in Massachusetts federal court rejected claims that a branded drug manufacturer’s patent settlement agreement with a generic drug manufacturer violated the Sherman Act. The plaintiffs—purchasers of the branded drug Nexium—alleged that branded and generic drug manufacturers violated antitrust laws when they entered into a “pay-for-delay” settlement agreement that ended a patent infringement lawsuit.

In 2008, branded drug manufacturer AstraZeneca, the manufacturer and marketer of patent-protected Nexium, sued generic manufacturer Ranbaxy, which had filed an Abbreviated New Drug Application with the Food and Drug Administration (FDA) to sell a generic version of Nexium before all of AstraZeneca’s patents covering Nexium expired. AstraZeneca and Ranbaxy settled their patent infringement suit in 2008 and as part of the settlement, AstraZeneca agreed that Ranbaxy would become the exclusive distributor of generic Nexium for the first six months starting in May 2014.

At trial, the plaintiffs argued that AstraZeneca’s settlement with Ranbaxy and two other generic drug manufacturers (Dr. Reddy’s Laboratories and Teva Pharmaceuticals) were anticompetitive “reverse payment” settlements, as clarified by the Supreme Court in FTC v. Actavis, 133 S. Ct. 2223 (2013). The plaintiffs argued that the value of the settlement agreement was hundreds of millions of dollars. Plaintiffs contended that, had AstraZeneca and Ranbaxy not included a reverse payment as part of their settlement, other generic manufacturers of Nexium could have entered the market sooner. As a result, the plaintiffs continued, a cheaper version of generic Nexium would have been available to consumers.

AstraZeneca and Ranbaxy argued that the plaintiffs’ theory was based entirely on speculation. They told the jury that no other generic drug manufacturer could have sold a generic version of Nexium any sooner, since no one had received FDA approval to sell such a product. Moreover, the defendants argued that AstraZeneca’s other patents would have protected Nexium until 2018, whereby the settlement allowed Ranbaxy to enter the market before the patents expired. According to the defendants, their settlement did not—and could not have—caused any delay in the availability of a generic version of Nexium. They argued that there was no evidence of harm to competition, an essential element in the plaintiffs’ antitrust theory.

The jury found that AstraZeneca had market power and that its settlement with Ranbaxy involved a “large and unjustified payment,” consistent with the analysis set forth by the
Supreme Court’s decision is Actavis. The jury also found that, under the rule of reason, the anti-competitive effects of the settlement outweighed any pro-competitive justifications.

Nevertheless, the jury also found that the plaintiffs’ theory was implausible, because there was no evidence that AstraZeneca would have granted Ranbaxy an earlier launch date under any circumstances—even in the absence of the settlement. Therefore, the jury found that there could not have been any harm to competition or consumers caused by the settlement. Thus, the plaintiffs failed to meet each element of their burden of proof, and the jury’s verdict was in favor of the defendants.

About a month after the verdict, the plaintiffs moved for a new trial based on the jury instructions, arguing that the instructions confused the jury. According to the plaintiffs, the judge initially instructed the jury to focus on a settlement agreement between AstraZeneca and Teva (another generic manufacturer), and then, towards the end of trial, changed course and instructed the jury to focus on the settlement between AstraZeneca and Ranbaxy. The plaintiffs’ motion is pending.

**Court holds that FTC’s Challenge to Patent Settlements Meets Actavis Standard**
*Fed. Trade Comm’n v. Cephalon, No. 08-2141 (E.D. Pa.)*

In a ruling issued January 28, 2015, Pennsylvania federal Judge Mitchell S. Goldberg ruled that the FTC’s suit against Cephalon Inc. over alleged “pay-for-delay” patent settlement agreements met the standard set forth by the Supreme Court in Actavis for antitrust challenges to settlements that allegedly delay entry of generic alternatives to branded drugs. The suit involves settlement agreements between Cephalon and four generic companies involving Cephalon’s narcolepsy drug Provigil, all of which allegedly contained “reverse payment” features that the FTC says cause delayed entry of generic competition.

Cephalon’s motion argued that Actavis requires a plaintiff challenging a pay-for-delay settlement to meet a “threshold burden” for triggering a rule of reason analysis by establishing that the payment is both large and unjustified. Judge Goldberg rejected Cephalon’s interpretation, concluding instead “that Actavis primarily instructs that the familiar antitrust rule-of-reason analysis be applied to cases challenging reverse-payment settlements.” The court further held that the FTC, along with generic manufacturer Apotex Inc. and other private party plaintiffs, met their burden under the rule of reason to present evidence of anticompetitive effects. The burden shifted to defendants Cephalon and four generic companies to justify that the reverse payment is procompetitive.

**Federal Judge Allows “Product-Hopping” Claims to Proceed against Reckitt**
*In re Suboxone Antitrust Litig., No. 13-02445 (E.D. Pa.)*

On December 3, 2014, United States District Judge Mitchell Goldberg of the Eastern District of Pennsylvania dismissed some claims in a multidistrict class action against Reckitt Benckiser Inc. but allowed direct purchasers of Reckitt’s drug Suboxone to move forward with claims under the Sherman Act.

The plaintiffs allege that Reckitt engaged in an anticompetitive “product-hopping” scheme to keep generic rivals of Suboxone off the market. Suboxone is the only medication for the maintenance treatment of opioid dependence that
can be prescribed for home use. The FDA approved Reckitt’s new drug application for Suboxone tablets in 2002. Although Reckitt does not have a patent for Suboxone tablets, Reckitt obtained a seven-year exclusivity period since the drug was determined to be an “orphan drug.” The plaintiffs contended that, as the exclusivity period expired, Reckitt engaged in an anticompetitive “product-hopping” scheme by obtaining a patent for Suboxone film—a dissolvable-strip derivative of the tablet—designed to maintain Reckitt’s monopoly on the drug.

Since the introduction of new products is typically procompetitive, the court required that the plaintiffs demonstrate that the launch of Suboxone coincided with some other wrongful conduct to create an effect likely to lessen competition and prevent consumer choice. The court found that plaintiffs met this standard by alleging that Reckitt switched from Suboxone tablets to Suboxone film while publicly disparaging the tablet formulation with fabricated safety concerns. According to the plaintiffs, this public marketing campaign was designed to divert sales from the tablet, which would soon face generic competition, to the patent-protected film, by delaying FDA approval of the generic tablet for safety reasons and by discouraging physicians and consumers from using the tablet.

Judge Goldberg held that such allegations were enough to overcome Reckitt’s motion to dismiss, stating that the threatened removal of tablets from the market in conjunction with alleged safety concerns could plausibly coerce physicians and patients to switch from Suboxone tablets to film. It was therefore possible, according to the court, that generic manufacturers would face increased costs when entering the market and so would raise prices to direct purchasers, as the plaintiffs allege.

Reckitt requested that the court reconsider its decision. Reckitt argues that Judge Goldberg did not consider the strong presumption that competitor statements have little effect on competition, especially when the audience consists of medical professionals. Further, Reckitt has requested that the court consider the FDA’s recent statement indicating that Reckitt’s citizen petition and public campaign did not delay approval of generic Suboxone. Judge Goldberg has not yet ruled on Reckitt’s petition.

Astellas Settles Prograf Antitrust MDL for $98 Million

In re Prograf Antitrust Litig., No. 11-02242 (D. Mass.)

Astellas Pharma US LLC will pay $98 million to settle certain multidistrict antitrust litigation, in which Astellas was accused of unlawfully delaying entry of a generic form of its immunosuppressant Prograf—a branded drug prescribed to prevent rejection of transplanted organs. Class plaintiffs allege that, in September 2007, Astellas violated the Sherman Act by filing a sham citizen petition with the FDA that delayed entry of a generic version of Prograf. According to the complaint, Astellas filed the citizen petition less than a year after Sandoz sought approval to sell a generic form of Prograf. The FDA denied Astellas’ petition and approved Sandoz’s application. The class, composed of retail pharmacies and other direct purchasers of Prograf, sought preliminary approval of the settlement from the court.

Astellas said in a statement that it believes it acted in the best interest of patients by filing the petition, and that subsequent FDA activities and research corroborate the petition’s merit. However, the company said it decided to “resolve this matter expeditiously” due to the uncertain and expensive nature of litigation, so as to move...
forward with “providing quality products to the transplant patients who need them.”

It is alleged that counsel for a class of indirect purchasers of Prograf said on January 20, 2015 that there was no settlement with his clients.

First Written Opinion Issued in REMS Antitrust Case
Mylan Pharm., Inc. v. Celgene Corp., No. 14-2094 (D.N.J.)

On December 22, 2014, Judge Esther Salas of the U.S. District Court for the District of New Jersey, in the first written decision involving a Risk Evaluation and Mitigati on Strategies (REMS) antitrust litigation case, granted in part and denied in part Celgene’s Motion to Dismiss.

In April 2014, Mylan sued Celgene, alleging that Celgene would not provide Mylan with samples of its Thalomid and Revlimid products to allow Mylan to perform the bioequivalence tests required by the FDA to file an ANDA submission for the generic versions of the products. Mylan was not able to obtain samples of the products from third-party wholesalers without Celgene’s permission because the distribution of Thalomid and Revlimid is subject to restrictions imposed by two different programs: the REMS and the Elements to Assure Safe Use (ETASU). In its complaint, Mylan claims Celgene has used the programs as a means to refuse the sale to Mylan of the product quantities necessary to test bioequivalence, and to ultimately prevent generic competition to its products.

Judge Salas denied Celgene’s motion to dismiss the complaint’s Sherman Act Section 2 and state antitrust and unfair competition claims. She granted Celgene’s motion to dismiss Mylan’s allegations that “Celgene entered into unlawful agreements with wholesale distributors and pharmacies to unduly restrain trade,” in violation of Section 1 of the Sherman Act and Section 56:9-3 of the New Jersey Antitrust Act.

Celgene argued that Section 2 of the Sherman Act does not impose a “duty to deal with competitors” except under very limited circumstances. Mylan asserted that Celgene’s conduct is within the parameters of those limited cases where a duty to deal applies. Judge Salas determined that a “prior course of dealing” between Celgene and Mylan was not required under the established precedent. Further, she rejected Celgene’s argument that the patents on its products prevent a finding of antitrust injury.

The FTC filed an amicus brief arguing that Celgene’s refusal to sell samples to an ANDA filer can constitute exclusionary conduct. Legislation is also under consideration by Congress (H.R. 5657 Fair Access for Safe and Timely Generics Acts of 2014) to address the availability of products subject to distribution-restricting programs. The FDA has also prepared draft guidance to formalize a process by which an ANDA applicant could obtain a letter from the FDA stating that the agency will not consider the provision by the RLD sponsor of drug samples in enough quantity to perform bioequivalence tests to constitute a violation of REMS.

State Medical Board’s Motion for Summary Judgment Granted against Plaintiff Chiropractor

The Virginia Board of Medicine (Board) was granted summary judgment on Section 1 of the Sherman Act claims filed by a chiropractor, who alleged that the Board had entered into an agreement to allocate the relevant service markets of medical professionals and to exclude chiropractors from competing in those markets.
Given what the court said is a “general reluctance to employ the per se unreasonable analysis when dealing with a professional association,” Eastern District of Virginia Judge Claude M. Hilton applied a rule of reason analysis, and weighed the procompetitive benefits of the Board’s actions of monitoring and regulating the practice of medicine for the benefit of consumers against the alleged anticompetitive effects, which were found lacking.

The Board, which regulates all forms of medicine in Virginia, suspended Yvonne Petrie’s chiropractic license for six months after a formal hearing concluded that Petrie’s practice exceeded the scope of chiropractic practice under Virginia law. Petrie appealed the Board’s decision to the Virginia Court of Appeals, which upheld the sanction. She also brought suit in district court alleging the Board entered an agreement to allocate the relevant service markets to medical doctors and to exclude chiropractors from competing in those markets, in violation of Section 1 of the Sherman Act.

The court found that while the plaintiff’s claims alleged individual harm, the claims failed to allege harm to overall competition, which was required to establish an antitrust injury. Without evidence of altered market pricing or exclusion of other chiropractors, the plaintiff failed to demonstrate the necessary anticompetitive effects for a Sherman Act antitrust claim. Likewise, by not showing any anticompetitive effects, the court found that the plaintiff failed to show the antitrust injury necessary to have standing to bring suit.

**FTC Files Brief in Response to PhRMA’s Challenge to FTC Rule on HSR Reportability of Exclusive Patent Licenses**


On December 10, 2014, the FTC filed a brief in response to an appeal by Pharmaceutical Research and Manufacturers of America (PhRMA) challenging an FTC rule that established that the exclusive transfer of “all commercially significant rights” to a pharmaceutical patent constituted the “acquisition” of an “asset” under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (the “HSR Act”). PhRMA had appealed a ruling from the district court that rejected its argument that the HSR Act prohibited the FTC from making a rule that applied only to the pharmaceutical industry.

Prior to the rule, such patent license arrangements would potentially not be HSR reportable under the traditional “make, use, or sell” approach to exclusive patent licenses. With the rule change, however, situations where the patent holder retained “limited manufacturing rights” or “co-rights” (defined as “shared rights retained by the patent holder to assist the recipient of the exclusive patent rights in developing and commercializing the product covered by the patent”) are potentially reportable. The FTC argued that the HSR Act granted it the authority to adopt rules that define terms targeting specific industries. Further, the FTC said that it intended with its rule to address licensing arrangements it found almost exclusively occurring in the pharmaceutical industry. It argued that even if the Commission inappropriately applied a rule too narrowly targeted at the pharmaceutical industry, the more appropriate remedy would be to extend the rule to other industries rather than eliminate the rule.
Texas Court Held that Becton Dickinson Lacked Monopoly Power
Retractable Tech. Inc. v. Becton Dickinson and Co., No. 08-16 (E.D. Tex.)

On December 17, 2014, Judge Leonard Davis of the United States District Court for the Eastern District of Texas denied Retractable Technologies Inc.’s attempt to add a charge of monopoly power to a 2013 verdict against Becton Dickinson and Co. (Becton). Judge Davis found that Becton did not hold a monopoly on the grounds that (1) Becton’s declining 50 percent market share constituted a proper basis justifying the jury’s conclusion that it lacked monopoly power; (2) Retractable provided no reason why the jury was obligated to prioritize barriers to entry over market share evidence; and (3) the ability to charge a pricing premium or high prices over competitors is not inconsistent with a finding of no monopoly power.

In September 2013, a jury awarded Retractable $113.5 million in antitrust damages, finding that Becton violated the Sherman Act by attempting to monopolize the safety syringe market with deceptive advertising. On September 30, 2014, Judge Davis issued an order denying Becton a Renewed Motion for Judgment as a Matter of Law or a new trial, finding that there was sufficient evidence for the jury to find that Becton had attempted to monopolize the safety syringe market. On November 10, 2014, Becton was ordered to pay Retractable $340 million for making false claims about its safety syringe. Judge Davis found that disgorgement of a portion of Becton’s profits was appropriate, and that a trebled jury award permitted by federal statute was sufficient.

Suit Alleges Pfizer Fraudulently Kept Generic Celebrex off the Market

Allied Services Division Welfare Fund filed suit on January 21, 2015 against Pfizer, Inc., alleging that the pharmaceutical company fraudulently obtained an extension for its method-of-use patent for Celebrex, a leading arthritis drug. The complaint alleges that after the Federal Circuit ruled that Pfizer’s patent for administering Celebrex was invalid, Pfizer submitted false information to the U.S. Patent and Trademark Office in order to obtain the extension and protect itself from generic entry.

The complaint alleges that, in addition to initiating lawsuits to prevent generic entry, Pfizer also entered into an exclusive contact with Teva Pharmaceuticals to manufacture and market an authorized generic of the drug. Watson and Mylan, two of five generic drug manufacturers who had filed ANDAs with the FDA to market generic Celebrex, sued to invalidate the exclusive arrangement between Teva and Pfizer.

Allied Services, which aims to represent all persons or entities that paid for the drug, argues that as a result of Pfizer’s actions, Celebrex purchasers were forced to pay “hundreds of millions of dollars” more for the drug since May 2014. It also contends that given the exclusive relationship between Pfizer and Teva, generic Celebrex will be further delayed.

Specialty Pharmacy Sues PBM Alleging Monopoly
Sorkin’s Rx Ltd. v. Express Scripts Inc., No. 15-114 (E.D. Mo.)

On January 14, 2015, CareMed Pharmaceutical Services, a New York-based specialty pharmacy
that provides products to approximately 8,000 patients, filed suit in Missouri federal court against Express Scripts Inc. (ESI), a pharmacy benefit manager. CareMed alleges that (1) ESI illegitimately used CareMed’s recent False Claims Act settlement with the United States and the State of New York to terminate its pharmacy provider agreement with CareMed; (2) the agreement was terminated by ESI to divert CareMed’s approximately 8,000 patients to ESI’s own specialty pharmacy, which equates to approximately $100 million in annual revenue; (3) ESI would monopolize the Eastern United States specialty pharmacy market if CareMed’s patient network was diverted to ESI; (4) CareMed would be put out of business as a result of the diversion, which was not the intent of the settlement with the United States or State of New York; and (5) ESI did not terminate the pharmacy provider agreement in a manner prescribed under the agreement.

In 2007, CareMed entered into a pharmacy provider agreement with ESI (formerly Medco) to become a participant in ESI’s pharmacy network. The agreement provided four possible circumstances for termination: notice of nonrenewal; termination without cause on thirty days’ notice; termination for breach with a thirty-day cure period; and CareMed’s failure to maintain proper licensure. For the latter three criteria, CareMed would be entitled to a right to review, including the right to a hearing panel. On or about October 6, 2014, CareMed entered into a Stipulation and Order of Settlement and Dismissal related to allegations of false claims. In consideration of the Settlement and corresponding corporate integrity agreement, the Office of Inspector General agreed not to exclude CareMed from Medicare, Medicaid, and all other federal healthcare programs. On October 24, ESI notified CureMed that it was terminating the pharmacy provider agreement the following week because CareMed pleaded guilty to fraud, the basis and accuracy of which was contested by CareMed. ESI subsequently sent a second termination letter that offered new justifications for terminating the agreement, which is being disputed by CareMed.

Mylan Awarded another $13.7 Million from GSK in Paxil Damages
*Mylan Inc. v. SmithKline Beecham Corp., No. 10-4809 (D.N.J.)*

In late January, a New Jersey federal judge granted Mylan, Inc. $13.7 million in supplemental damages in its suit against GlaxoSmithKline. The additional damages brings the total award to Mylan to $120.6 million arising from this case.

The damages are a result of a breach of contract claim by Mylan against GSK. Last year, Judge Joel A. Pisano found that GSK breached its contract with Mylan by allowing Apotex to sell a generic version of GSK’s antidepressant Paxil as part of an antitrust settlement. To settle claims by Apotex that GSK improperly kept generic versions of Paxil from the market, GSK agreed to provide generic Paxil to Apotex for it to sell as an authorized generic product in the United States.

The contract between GSK and Mylan permitted GSK to sell its own generic version of Paxil, but did not allow GSK to supply another company with generic Paxil to sell in competition with Mylan. As a result, in March 2014, GSK was found in breach of that contract and Mylan was awarded $106.7 million. Mylan requested an accounting of sales, and the additional damages awarded to Mylan reflect that accounting. GSK has an appeal pending in the Third Circuit. The new accounting does not affect GSK’s appeal.
FEDERAL AGENCY ACTIVITIES

Editorial Outlines Concerns Regarding Harms to Competition in Recent Flurry of Hospital Mergers

On December 11, 2014, the New England Journal of Medicine published a special editorial by FTC Chairwoman Edith Ramirez. Commissioner Ramirez who highlighted the FTC’s concerns regarding increasing concentration and reduced competition in markets for health care services, and described recent actions taken by the Commission.

In her editorial, Chairwoman Ramirez described the role of the FTC in maintaining competition between health care providers and raised the question of whether hospital mergers result in price increases for consumers, while acknowledging that the mergers can achieve meaningful increases in healthcare quality.

Ramirez described legislation that has been proposed in certain states to exempt healthcare joint ventures and mergers from antitrust review based upon argument that antitrust enforcement undermines the efforts to costs through provider collaboration and is at odds with the Affordable Care Act (ACA). Ramirez argued that the ACA and robust antitrust enforcement can coexist because the Commission’s assessment of potential hospital mergers weighs potential harms to competition (such as potential price increases) against the opportunities for increases in healthcare quality: medical quality from scaled delivery systems for routine care, an increased scope or intensity of complex care from the combined entity, and also quality as defined by the clinician and patient experiences of care.

FDA Issues New Guidance to Promote Competition for REMS Drugs

In December 2014, the FDA issued draft guidance concerning the sale of drugs covered by REMS to generic drug manufacturers that wish to conduct bioequivalence testing. According to the draft guidance, generic manufacturers wishing to submit an ANDA for REMS drugs can obtain a letter from the FDA stating that:

1. the prospective applicant’s bioequivalence study protocol contains safety protections comparable to those in the REMS with elements to assure safe use; and

2. the FDA will not consider it a violation of the REMS for a brand manufacturer to provide a sufficient quantity of the REMS drug to the generic manufacturer to allow the firm to perform the bioequivalence testing necessary to support its ANDA.

To obtain a letter from the FDA stating that a prospective applicant’s bioequivalence protocol meets the protections in a brand drug’s REMS, the FDA provides the following guidance to generics:

- Develop a protocol for the bioequivalence study that incorporates elements of the REMS of the brand drug;
- Submit to the FDA the draft bioequivalence protocol draft, as well as all informed consent and informational materials;

- After FDA review, make any recommended changes and resubmit them; and

- If accepted, the ANDA applicant must submit a disclosure form to FDA requesting them to send the letter to the brand manufacturer of the REMS drug.

Upon completion of these steps, the FDA will send a letter to the manufacturer of the REMS drug stating that the ANDA applicant’s bioequivalence study is comparable to the drug’s REMS protocol and that the FDA will not consider it a violation of REMS for the brand manufacturer to sell a sufficient quantity of the REMS drug to the generic for bioequivalence testing.

The FTC’s report found that in 2013, a total of 145 patent settlements were reached, of which 29 created potential “pay-for-delay” agreements between branded and generic drug manufacturers. This figure is down from 2012 (40 potential pay-for-delay settlements) and more in line with the figures from 2010 (31 potential pay-for-delay settlements) and 2011 (28).

The FTC stated that “[t]hose 29 settlements potentially involve pay-for-delay because the brand manufacturer compensated the generic manufacturer and the generic manufacturer was restricted from marketing its product in competition with the branded product for some period of time.”

Of these 29 potentially anticompetitive settlements, fourteen included compensation solely in the form of a cash payment from the brand to the generic that purported to reimburse the generic’s litigation fees, and eleven included compensation in the form of a business deal between the brand and generic. Four of the agreements included compensation in the form of a brand manufacturer’s promise not to market an authorized generic that would compete with the generic manufacturer’s product for a period of time.

Moreover, thirteen of the agreements involved “first-filer” generics, that is companies that were the first to seek approval from the FDA to market a generic version of the branded drug and, at the time of the settlement, were eligible to market the generic version of the drug for 180 days without competition from other manufacturers that were not first-filers.

According to FDA regulations, no generic manufacturers other than the first-filer can enter the market during this 180-day exclusivity period. The FTC’s position has been that settlements between first-filer generic manufacturers and branded manufacturers (i.e., the patent holders)
are potentially anticompetitive because they may harm consumers.

In its report, the FTC stated that, “despite the existence of a substantial number of potential pay-for-delay settlements in FY 2013, the vast majority (at least 73%, and up to 80%) of patent disputes were resolved without compensation to the generic manufacturer and/or without restrictions on generic competition.”

The FTC has been compiling data and other information on reverse-payment settlements since the passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

**FTC Approves Eli Lilly-Novartis Deal with Conditions**

The FTC cleared Eli Lilly & Company’s $5.4 billion acquisition of Novartis Animal Health on the condition that Eli Lilly divest Novartis’s canine heartworm medication line to the French pharmaceutical company, Virbac S.A.

The Commission alleged that the proposed acquisition would be anticompetitive and lead to higher prices. According to the FTC’s complaint, Eli Lilly’s Trifexis and Novartis’s Sentinel products are particularly close substitutes: they are the only two products given orally once per month; they contain the same active ingredient; and they both can be used to treat fleas and other internal parasites in canines. The Commission concluded that Trifexis and Sentinel are each other’s closest competitors.

Without the required divestiture, the FTC asserted that the transaction would have eliminated the close competition between Eli Lilly’s Trifexis and Novartis’s Sentinel, thereby decreasing competition in the market for canine heartworm parasiticides. The FTC further asserted that new entrants to the market face high barriers, because developing new animal health medications is difficult and time-consuming.

The Commission voted unanimously to accept the proposed consent order. The acquisition makes Eli Lilly’s Elanco unit the world’s second-largest animal health company based on revenue behind Zoetis Inc.

**FTC Puts Conditions on Sun Pharmaceutical’s Proposed Acquisition of Ranbaxy**

Sun Pharmaceutical Industries Ltd.’s and Ranbaxy Laboratories Ltd. have agreed to divest Ranbaxy’s generic minocycline tablets assets in order to secure FTC approval of their proposed $4 billion transaction. The proposed merger was also investigated by the Competition Commission of India, which likewise found that the proposed merger would be likely to have an appreciable adverse effect on the relevant market in India, and that divestiture of the relevant products was the proper solution. The divested assets will be acquired by Torrent Pharmaceuticals, a global drug company based in India that markets generic drugs in the United States.

The FTC alleged that the proposed merger likely would harm future competition by reducing the number of suppliers in the US markets for three dosage strengths of generic minocycline, which are used to treat a wide array of bacterial infections. Ranbaxy is currently one of three suppliers of the product, and Sun is one of a limited number of firms likely to sell the tablets in the United States in the near future, which would have resulted in significantly lower prices for those drugs.
Under the proposed settlement, Sun and Ranbaxy must also sell Ranbaxy’s generic minocycline capsule assets to Torrent, to facilitate Torrent’s ability to obtain regulatory approvals as quickly as Ranbaxy would have been able to in the absence of the merger, and must also supply tablets and capsules to Torrent until the company establishes its own manufacturing infrastructure. An FTC-appointed interim monitor will oversee the divestiture.

FTC Staff Urge Dental Commission to Adopt National Accreditation Standards for Dental Therapists


The FTC staff submitted comments to the Commission on Dental Accreditation (CODA), urging CODA to adopt dental therapy accreditation standards that could facilitate the expansion of supply of dental therapists, a relatively new type of provider that offers basic dental services. National accreditation standards could aid the creation of new dental therapy programs and state legislation for the licensure of dental therapists that would enable state-to-state mobility, increase the output of basic dental services, enhance competition, reduce costs and expand access to dental care, especially in underserved populations.

The Accreditation Standards for Dental Therapy Education Programs (2014) proposed by CODA reflect revisions that have addressed many of the FTC’s prior concerns on earlier versions of the accreditation standards, voiced in December 2013, that some of the provisions could have been interpreted to impede competition. Specifically, the 2014 standards have deleted statements that required supervision of dental therapists for diagnosis and treatment planning that could have discouraged educational programs that would train dental therapists, and state level legislation that would allow dental therapists to conduct evaluations and formulate treatments plans without a supervising dentist.

The proposed standards were also revised to provide advanced standing and career laddering for students licensed in other dental professions such as dental hygiene and dental assisting, which could enhance competition by increasing the number of dental therapists entering the field.
**INTERNATIONAL**

**Brazilian Antitrust Regulator Recommends Commendation of Companies in Antiretroviral Cartel**

CADE, Brazil’s Antitrust Regulator, issued an opinion on December 31, 2014 in which it recommended the conviction of AB Farmo Quimica Ltda., Aurobindo Farmaceutica do Brasil Ltda., Brasvit Industria e Comecio Ltda, and four individuals for participating in a cartel. The regulator alleged that the companies agreed to fix prices on antiretroviral drugs sold to Brazilian hospitals between 2003 and 2005.

CADE’s investigation into the companies stemmed from an administrative proceeding opened in 2008 to investigate bid rigging in the procurement of laundry services to public hospitals. During the laundry investigation, Brazil’s Federal Police found evidence of price fixing in the drug manufacturing market as well.

The case will be tried before CADE’s Tribunal and if convicted, the companies will pay fines of up to 20 percent of gross revenue in the market sector in which the conduct occurred.

**Paris Appeals Court Upholds Antitrust Fine against Sanofi**

Sanofi SA v. L’Autorite de la Concurrence, No. 2013/12370 (Cour d’Appel de Paris)

On December 22, 2014, a Paris Appeals court upheld a €40.6 million ($49.7 million) fine against Sanofi SA for abuse of dominance in violation of the antitrust laws. France’s antitrust regulator had previously ruled that the Sanofi had engaged in a campaign against generic competitors by discouraging doctors and pharmacists from prescribing generic versions of its blood-thinning drug Plavix.

According to the French Competition Authority, Sanofi had encouraging doctors to list generic Plavix as “nonsubstitutable” and—if not marked nonsubstitutable—encouraged pharmacists only to substitute the Sanofi-manufactured Winthrop generic. It found that through its representatives, Sanofi led a campaign of misinformation that non-Winthrop generics presented a health risk to patients. These actions led to a slower-than-expected growth rate in the generic market.

In upholding the fine, the court ruled that Sanofi had abused its dominance through the aforementioned practices. Although noting that there were differences between the Sanofi products and those of its generic competitors, the differences did not affect the efficacy of the generic versions.

**Canadian Competition Bureau Issues Decisions to Support Quebec Pharmacists**

http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03863.html

On December 12, 2014, the Canadian Competition Bureau reached an agreement to address the competition issues raised by stakeholders about the effects that the proposed non-notifiable acquisition of XD3 Solutions by TELUS Health would have in the Quebec pharmacist community. Both companies offer pharmacy management solutions, including technical support to pharmacists in Quebec. TELUS Health offers, among other services, electronic medical and health records, benefits management, and pharmacy management products across Canada. XD3 Solutions
provides dispensary management software, currently serving one hundred and fifty pharmacies in Quebec.

Some of the main concerns raised by the Bureau focused on the contractual term limits imposed by XD3 Solutions and TELUS Health, by which they restrained the pharmacist’s ability to switch providers. The terms required a pharmacist to use TELUS Health’s data transfer tool, obtain TELUS Health consent prior to transferring data to a different supplier’s platform, and pay a fee for that transfer of data.

TELUS Health, working in cooperation with the Bureau, has agreed to amend some of its contracting practices under review for limiting competition. As part of this cooperation and for a period of five years, all of its contracts in Quebec will have their terms amended as follows: Pharmacists will not need the consent of TELUS Health prior to transferring data, nor they will be obligated to use their data transfer tool. Additionally, TELUS Health will either provide the pharmacist with a copy of its data, or facilitate access to the pharmacist’s data by a new service provider for data transferring purposes. Lastly, a fee of up to $2,500 may only be charged if the pharmacist requests TELUS Health’s help with the data transferring process.

The agreement, reached on the terms mentioned above, will facilitate competition among existing pharmacy management solution providers in Quebec, as well as eliminate the restrictions that previously limited the pharmacists’ ability to switch providers. As Lisa Campbell, a Senior Deputy Commissioner of Competition stated “[t]his agreement will allow pharmacists in Quebec to benefit from competition when it comes to buying pharmacy management solutions.”

**IMS-Cegedim Deal Cleared By European Commission**


The European Commission cleared IMS Health’s, a healthcare industry global information and technology services company, acquisition of rival Cegedim S.A., a French information solutions and customer relationship management (CRM) business. IMS Health announced the Commission’s approval on December 19, 2014 and confirmed that the U.S. Antitrust review under the Hart-Scott-Rodino Antitrust Improvements Act (HSR) expired on December 5, 2014. The €385 million ($470.1 million) cash acquisition is scheduled to close in early 2015.

As a condition to the Commission’s approval, IMS Health agreed to divest part of its market research business and to grant third-party access for ten years to the “brick structure,” a sales tracking database for tracking the sales of prescription drugs in the European Economic Area (EEA) by which pharmaceutical companies measure their performance. The market research business had revenue of approximately $2 million in 2013. Absent the divestiture and the third-party access, the Commission was concerned that the proposed transaction could lead to less choice and higher prices for customers of standardized primary market research services and prevent IMS Health’s competitors from competing in the market.

The Commission analyzed both Cegedim and IMS Health’s businesses. Cegedim provides companies in the pharmaceutical, biotech, life sciences, and healthcare sectors with solutions to measure and improve their performance. The Commission found that Cegedim offers one of the largest databases of doctors’ contact
information in Europe on which most pharmaceutical companies rely. Cegedim is also a leading European provider of CRM software.

IMS Health uses information and technology services to analyze complex healthcare data on diseases, treatments, costs and outcomes to help its clients operate more efficiently. IMS Health draws on information from 100,000 suppliers and from more than 45 billion healthcare transactions processed annually.

In addition to analyzing Cegedim and IMS Health’s businesses and impact on competition in Europe, the Commission also examined the competitive effects of the proposed acquisition on the broader markets for CRM, business intelligence solutions, consulting services and “Real World Evidence.” Real World Evidence is information provided to pharmaceutical companies regarding the “real life” performance of their drugs. The Commission concluded that the transaction would not raise anti-competitive concerns on these markets.

Generic Drug Maker Lupin Appeals European Commission’s €40 Million Pay-For-Delay Decision

*Lupin v Commission, No. T-680/14 (General Court of the European Union)*

On December 9, 2014, Lupin Ltd., an India-based generic pharmaceutical company, appealed the European Commission’s (EC) pay-for-delay decision that resulted in a €40 million ($49 million). The fine comes from the EC’s finding that Lupin had violated the European Union’s (EU) prohibition on agreements that would delay generic versions of branded drugs.

The initial decision in July 2014 imposed fines on Servier, a French pharmaceutical company, and five generic drug makers, including Lupin, for entering into agreements to delay generic entry of perindopril, Servier’s leading blood pressure drug. The fines imposed totaled €427.7 million. Servier’s primary patents for perindopril expired in 2003 and several generic manufacturers challenged the patents’ validity in court, at which point Servier entered into settlements with the challengers that prevented generic entry.

In its appeal, Lupin contends that the EC applied a “wholly novel and incorrect legal test” in finding that it violated antitrust law. It argued that by grounding its finding that the drug companies entered into restrictive agreements upon the payment of a “significant inducement,” the EC ignores the objectives of competition law, as well as civil procedure and patent law. Instead, Lupin suggests that the EC should have assessed the restriction question by referencing the “ancillary restraints doctrine” and/or by referencing the principles outlined in the *Wouters* case, which held that rules that restrict competition may nevertheless be legal if the anticompetitive effects of such rules are “inherent” in the pursuit of a professional body’s valid objectives.