ABA Section of Antitrust Law
Health Care and Pharmaceuticals Committee Presents

Recent Developments Series
July – September 2014
September 15, 2014
12:00 – 1:30 p.m. ET
Agenda

- Litigation Updates
- Pay-for-Delay Developments
- European Updates
- Merger Updates
Litigation Updates

Peter Alfano
Schuylkill Health System v. Cardinal Health Inc.
No. 2:12-cv-07065 (E.D. Pa.)

- **December 18, 2012**: Schuylkill Health System filed a class action Complaint against Cardinal Health and Owens Minor alleging that their distribution contracts, which required the bundling of purchases to receive discounts, made it prohibitively expensive to purchase sutures and endo related products from Defendants' rivals.

- **December 13, 2013**: 12(b)(6) MTD

- **July 30, 2014**: The judge dismissed monopolization claims but upheld Section 1 claims alleging unlawful bundling, tying, and exclusive dealing.

- **August 13, 2014**: Answer to Complaint filed
Monopolization Claims Proceeding

  - Retrophin claimed Questcor illegally monopolized medical treatment for infantile spasm drug Acthar when it prevented Retrophin’s entry by blocking Retrophin from acquiring the rights to a competing treatment.
  - August 8, 2014, judge denied Questcor’s MTD claims

  - Bone mill manufacturer Lenox MacLaren Surgical Corp.’s brought a monopolization suit against competitor, and distributor of Lenox’s product, Medtronic, arguing that Medtronic’s recall of Lenox’s bone mills allowed Medtronic to maintain market share.
  - August 5, 2014, the Tenth Circuit reversed summary judgment granted to Medtronic, finding that material factual disputes remained.
In re Nexium Antitrust Litig.
Pending 1st Cir. Appeal on Class Cert. Issue

The case focuses on reverse-payment settlements for AstraZeneca’s heartburn medication Nexium (discussed later)

• **May 15, 2014**: Appeal certification of end-payor damages class where some members potentially did not suffer injury.

  District Court acknowledged that “certain class members were not actually injured, including more than a *de minimis* number of [third-party payors] and consumers who—through rebates, contracts, and brand-loyal purchasing—suffered no damages from the foreclosure of a generic version of Nexium to the market.” (1:12-md-02409, D. Mass., Mem. & Order, Nov. 14, 2013, ECF No. 519)

• **July 31, 2014**: Oral arguments
  – Whether cases could be certified as a class action if the class included uninjured buyers.
  – Whether Plaintiffs could ensure that only the injured members receive damages.

• **Awaiting Decision**
Mylan Pharmaceuticals v. Warner Chilcott
Settlement

- **July 6, 2012:** Complaint alleged that Warner Chilcott maintained a monopoly in the market for its antibacterial drug Doryx by suppressing generic competition through insignificant reformulations of the drug.
- **October 1, 2012:** Warner Chilcott filed a MTD, asserting that the product reformulations were *per se* legal.
- **November 21, 2012:** FTC filed an amicus brief asserting that a strategy known as "product-switching" or "product hopping" can violate antitrust law.

On **July 15, 2014**, a class of indirect purchases settled with Warner Chilcott for $8 million.
New Antitrust Actions

• **July 3, 2014:** *UniStrip Technologies LLC v. LifeScan Inc.* (C.D. Cal. No. 2:14cv5189).
  - UniStrip alleged LifeScan attempted to monopolize the market for blood glucose test strips used with LifeScan's OneTouch Ultra blood glucose meters.
  - July 29, 2014: Voluntarily dismissed and re-filed in the E.D. of Penn (No. 2:14cv4518).

• **July 9, 2014:** *Rivera-Nazario v. Corporación del Fondo del Seguro del Estato (CFSE)* (D.P.R. No. 14-cv-01533)
  - A Group of Chiropractors brought an action against CFSE, an organization that provides compensation to workers injured in occupational accidents, for issuing guidance to its members in that allegedly encouraged a boycott chiropractors.
• **July 14, 2014: ** *Signature MD Inc. v. MDVIP Inc.*, No. 14-cv-05453 (C.D. Cal. 2014)
  
  – Signature MD Inc., a California-based concierge medicine provider, filed suit against Florida-based concierge medicine provider MDVIP Inc., alleging claims under Sherman Act §§ 1 & 2, and state law.
  
  – Signature MD alleged MDVIP systematically tied up markets for concierge medicine membership programs by entering into exclusive dealing agreements with physicians in violation of the Sherman Act.
  
  – MDVIP has until October 17, 2014 to respond to the complaint.
Pay-for-Delay Developments

Jessica Hoke
Pay-for-Delay
FTC Developments

• Lamictal Direct Purchaser Antitrust Litigation
  – Background – Multiple amicus briefs submitted to court by FTC over the course of the litigation
    • October 5, 2012
    • April 28, 2014
Pay-for-Delay
FTC Developments

• Lamictal Direct Purchaser Antitrust Litigation
  – In July, FTC sought permission to take part in oral arguments
    • To shed light on why Actavis applies to no-authorized-generic settlements
  – GlaxoSmithKline and Teva Pharmaceuticals have urged the Third Circuit to reject request because FTC is not “independent” observer.
Pay-for-Delay
Recently Filed Private Litigation

• Class action lawsuits filed against Endo Pharmaceuticals and Impax Laboratories
  – Filed in E.D. Pa. and N.D. Ill.
  – Claim – Endo paid Impax more than $112 million to delay the generic version of Endo’s Opana ER (a painkiller) from coming to market.
Pay-for-Delay
Recently Filed Private Litigation

• Class action lawsuits filed against Pfizer
  – Five class action lawsuits all filed in E.D. Va.
  – Claim – Pfizer improperly obtained a patent for the U.S. PTO for Celebrex and used that patent to induce generic manufacturers into settlements to delay entering the market.
Pay-for-Delay  
Ongoing Private Litigation

• **Pfizer Skelaxin Litigation**
  - Pfizer filed a motion for judgment on the pleadings arguing that the claims were precluded by a previous federal antitrust suit.
  - Motion has been denied and litigation continues.
  - But note, several federal multidistrict lawsuits have seen recent movement towards settlement.
Pay-for-Delay
Ongoing Private Litigation

• Mutual Pharma Settlement in Skelaxin Multidistrict Litigation
  – $9 million settlement to end-payors to settle claims (settlement awaiting final approval)
  – Previously settled with indirect purchasers for $2 million
  – Previously settled with direct purchasers for $73 million
Pay-for-Delay
Ongoing Private Litigation

- **Teva, AstraZeneca Nexium Litigation**
  - Teva and AstraZeneca filed a motion for judgment on the pleadings arguing that there are no scenarios in which Teva could have entered the market early.
  - No ruling on that motion at this time, but...
  - In September 4th Opinion explaining earlier orders, Judge Young concludes that plaintiffs can only sustain their arguments as to the agreement between AstraZeneca and Teva.
Pay-for-Delay
Things to Watch

• FTC filed suit against AbbVie for filing baseless lawsuits to delay introduction of generic versions of AndroGel.

• *Loestrin* ruling – *Actavis* requires cash payments
  – Judge expressed concern for future cases

• Teva, AstraZeneca Nexium trial set for October
European Updates

Katie French
European Commission: Pay for Delay Investigation

- European Commission investigation
- Prevention/delay of generic version of Perindopril
- Case opened July 2009
- Statement of obligations issued in July 2012
- Infringement decision issued in July 2014
Servier Infringement Decision

- Articles 101 and 102 TFEU (anti-competitive agreements and abuse of dominance)
- Fines amounting to €427.7 million (9 July 2014)
- Les Laboratories Servier
- Niche/Unichem
- Matrix (now part of Mylar)
- Teva
- Krka
- Lupin
Servier History

- Servier had significant market power in the market for the Perindopril molecule, according to the Commission
- Servier settled numerous cases where generic companies challenged the perindopril patent
- Generics agreed not to compete in exchange for a share of Servier’s market rents as part of the settlements
Commission’s Findings

- Commission found an infringement by object (per se) different to the position adopted by the Courts in FTC v Actavis
- Fines based on European Commission’s 2006 Guidelines
- Companies have until 22 September 2014 to appeal
• On 9 July 2014 Joaquin Alumina, European Commission VP said:

“Servier had a strategy to buy out any competitive threats to make sure that they stayed out of the market. Such behaviour is clearly anti-competitive and abusive. Competitors cannot agree to share markets or market rents instead of competition, even when these agreements are in the form of patent settlements. Such practices directly harm patients, national health systems and taxpayers. Pharmaceutical companies should focus their efforts on innovating and competing rather than attempting to extract extra rents from patients”. 
Appeals and Follow-on Action

- Commission imposed fines on Lundbeck and generic companies in 2013. This decision is being appealed in the General Court.
- UK health authorities have brought a follow-on damages claim against Servier
- Valued at €260M
- High Court ordered cases to proceed in parallel (31 July 2014)
- Appeals may succeed as the Commission’s decisions are extreme and muddled
The European Commission launched a public exchange of views to strengthen the competitiveness of the EU’s pharmaceutical industry on 27 June 2014.

- Published staff working document on 1 August 2014
- Pharmaceutical sector is of significant importance in Europe
  - €220 billion output
  - 800,000 (approx.) employed
Commission staff document published on 1 August 2014 identifies the main challenges for the European pharmaceutical industry, including:

- Health threats
- R&D costs
- IP issues
- Increased global competition
- Public budgets
- Ethical behaviour
- Demographic changes
Next steps

- The Commission intends to organise an event in Autumn 2014 to prepare future policy decisions which will include decision makers from Member States, healthcare professionals, trade union representatives and industry representatives.

- Pharmaceutical companies will argue that the Commission’s use of competition law to limit IP rights will discourage R&D
M&A in Health Care & Pharmaceuticals

Christopher H. Gordon
Recent Views From the FTC on Merger Enforcement in Health Care

• In August, the Federal Trade Commission's Bureau of Competition Director Deborah Feinstein explained the FTC’s current approach to antitrust enforcement in health care at ACO summit.

• Although no enforcement actions have been taken against ACOs, Feinstein reiterated areas of concern with ACOs:
  – preventing payers from steering patients to certain providers
  – tying sales of the ACO’s services to services from providers outside the ACO
  – Exclusivity
  – restricting a payer’s ability to inform enrollees about key cost and quality information
Recent Views From the FTC on Enforcement in Health Care (cont’d.)

- FTC has challenged less than 1 percent of hospital deals and brought only three challenges to physician acquisitions in the last decade.

- Two examples where mergers were not challenged:
  - Merger of a large medical center and a community hospital located 40 miles away.
  - Merger of a health care system with a large teaching hospital that was less than 10 miles from the nearest system hospital, but where there were numerous other hospitals nearby.

- Vertical provider transactions in the FTC sights?

- Hospital management agreements problematic?
In the Matter of Phoebe Putney Health System, Inc.

- April 2011: Administrative complaint filed by FTC.
- December 2011: 11th Circuit holds that transaction protected by state action doctrine.
- February 2013: Supreme Court largely reaffirms its previous decisions on so-called state action immunity, ruling that the Georgia law had not "clearly articulated and affirmatively expressed" a plan to replace competition with regulation.
• **August 2013**: FTC decides not to unwind merger due to Georgia certificate of need law and enters into proposed settlement with the parties.

• **March 2014**: North Albany Medical Center LLC petitions Georgia's Department of Community Health in March for a determination as to whether Georgia’s certificate of need requirements would in fact block it from acquiring the former Palmyra assets.
• June 2014: DCH sided with North Albany, concluding that Phoebe had never actually given up or invalidated Palmyra's original authorizations. As a result, divesting those assets wouldn't require a new certificate of need review.

• Based on this information, as well as public comments received during public comment period, FTC concluded that the Georgia CON laws might not bar a structural remedy. The FTC therefore rejected the proposed settlement with Phoebe Putney, returning the matter to administrative court.
FTC v. St. Luke’s Health System


- **January 2014**: District court holds that acquisition was anticompetitive and requires that Saltzer Medical Group be divested.

- **June 2014**: St. Luke’s appeals district court decision to Ninth Circuit but is denied request to keep Saltzer pending appeal.


- **August 2014**: FTC briefs Ninth Circuit.
• Massachusetts AG began antitrust investigation in 2009 into contracting activities of Partners Healthcare System.

• Expanded to include investigation of Partners' proposed acquisitions of two hospitals — South Shore Hospital in 2012 and Hallmark Health System in 2013.

• June 2014: After considering a lawsuit to block the acquisitions, AG entered into settlement with Partners intended to “fundamentally alter the negotiating power of Partners HealthCare for 10 years and control health costs across its entire network…..”
Partners Healthcare System (cont’d.)

- Under the terms of the final agreement, Partners would be allowed to complete its acquisition of South Shore and Hallmark, but insurers would be able to contract with Partners providers on component basis for up to 10 years.

- Agreement also would cap both health costs at the rate of inflation across the entire network through 2020 and its physician growth for five years.

- July 2014: Health Policy Commission issues preliminary report calling into question purported benefits of settlement.
• In light of the HPC report’s findings that the proposed acquisitions could drive up health care costs, AG requested postponement of an August 5th hearing on the proposed settlement, which the court rescheduled for September 29th.

• In seeking postponement, AG noted that it “always retained the option to seek to renegotiate portions of this agreement as it relates to Hallmark following a final report by the Health Policy Commission,” thereby signaling a possible intention to strengthen the terms of the settlement.

• HPC final report was issued in early September.
• Prestige Brands Holdings
  – FTC requires divestiture of assets connected with the motion sickness drug Bonine to resolve competition concerns over proposed $750 million acquisition of Insight Pharmaceuticals LLC.

  – FTC argued that Prestige’s potential ownership of both Dramamine and Bonine, which are the only two branded OTC motion sickness drugs with “significant sales,” would raise competition concerns.
Pharma Mergers (cont’d.)

• Akorn, Inc.
  – Required to divest assets related to the generic injectable tuberculosis drug, rifamprin, in order to settle FTC concerns regarding proposed acquisition of VersaPharm Inc.

  – VersaPharm was one of 3 firms with FDA approval to sell generic rifamprin, however Akorn was expected to receive FDA approval in the near future.

• The FTC concluded that absent the acquisition, Akorn would have entered the market to sell generic rifamprin, resulting in a significant price reduction.
Squire Patton Boggs
Key Contacts

Peter Alfano
Associate, Washington DC
T: +1 202 626 6263
Peter.alfano@squirepb.com

Peter Alfano is a member of the Squire Patton Boggs global Antitrust & Competition Practice Group. His practice covers all aspects of antitrust matters affecting the health care industry, including representing insurers and providers in merger reviews before the Federal Trade Commission; counseling on hospital affiliations, joint ventures and other collaborations; and representing companies and individuals in both civil antitrust actions and during government antitrust investigations at both the state and federal levels.

Christopher Gordon
Principal, Washington DC
T: +1 202 626 6284
Christopher.gordon@squirepb.com

Christopher Gordon is a member of the Squire Patton Boggs global Antitrust & Competition Practice Group. His practice includes representing clients in mergers and acquisitions; counseling clients on a variety of joint venture and marketing and distribution practices; and advising clients on consumer protection issues. Christopher has advised clients in a variety of industries, with a particular emphasis on antitrust-related hospital and healthcare issues. He has represented healthcare clients before both federal and state competition agencies, and has counseled clients on antitrust issues related to managed care contracting, clinical integration, mergers and affiliations, and provider collaborations.

Jessica Hoke
Associate, Washington DC
T: +1 202 626 6609
Jessica.hoke@squirepb.com

Jessica Hoke is a member of the Squire Patton Boggs Antitrust & Competition Practice Group. Her antitrust practice focuses on client counseling on a variety of business practices and competitor collaborations, merger review representation before the Federal Trade Commission and the US Department of Justice, as well as civil and criminal antitrust litigation and other government investigations.

Katie French
Associate, London, UK
T: +44 20 7655 1184
Katie.french@squirepb.com

Katie French is a member of the Squire Patton Boggs’ global Antitrust & Competition Practice Group based in London. She advises on all aspects of European and UK competition law including litigation in the High Court, Competition Appeal Tribunal and European Courts, cartel investigations and transactional and behavioral issues. Prior to qualifying as a solicitor, Katie worked in risk management. She graduated from the University of Essex and BPP Law School.
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