Health and Pharmaceuticals Committee: Recent Developments Series November – December 2013

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King & Spalding
Agenda

- Recent Transactions in the Healthcare and Pharma Industries
  - Jeffrey S. Spigel
- Reverse Payment Update
  - John D. Carroll
- Pharma Litigation Update
  - Wendy Huang Waszmer
- Healthcare Litigation Update
  - Carolyn M. Sweeney
- Questions
Transactions Update

- FTC Finalizes Amendments to HSR Rules on Transfers of Exclusive Pharmaceutical Patent Rights


- Changes the paradigm of whether the licensing of IP triggers an HSR filing such that the licensing is the acquisition of an “asset.”
- Prior to the new rule, granting of a license only triggered HSR if the license was exclusive, even against the licensor.
- Prior rule was not pharma specific.
**Transactions Update**

- **HSR Amendments (continued)**
  - Now the granting of a license will be deemed to be exclusive if “all commercially significant rights” are conveyed, even if limited manufacturing rights or co-rights are retained by the licensor.
  - HSR now triggered if the licensee has the right to commercially use the patent as a whole or in part in a certain therapeutic area or for a specific indication within a therapeutic area.
  - Unlike the “make, use, and sell,” approach, under the new rules a transaction in which a licensor retains limited manufacturing rights is potentially reportable.
Transactions Update

Overall, antitrust activity has been relatively quiet on the mergers and acquisitions front

- **FTC issues closing letter in Tenet/Emanuel Medical Center**
  

  - FTC’s Western Region investigated acquisition of Emanuel Medical Center by Tenet.
  - Tenet’s Doctors Medical Center and Emanuel Medical Center both located in Modesto, California area.
  - Investigation lasted several months; November 18 closing letter did not describe in detail why the FTC closed its investigation.
Transactions Update

  - FTC and Idaho challenging St. Luke’s Health System’s acquisition of Saltzer Medical Group (adult primary care physician services sold to commercial health plans in Nampa, Idaho).
  - Arguments concluded in early November; decision not yet reached.
Pennsylvania AG Settles Hospital Merger Challenge (Geisinger Health Services acquisition of Lewistown Hospital)

- Alleges harm in the markets for primary care physician services and primary and secondary inpatient acute care hospital services in Mifflin and Juaniata Counties, Pennsylvania.

- High market shares alleged to result from the acquisition: almost 70% of the primary care physicians; over 74% of the discharges for primary and secondary inpatient acute care hospital services.

- While physician overlap in Mifflin and Juaniata Counties, no actual overlap in the Counties. The hospital overlap allegation is based on the 11% outmigration to Geisinger Medical Center, which notably is 60 miles from Lewistown Hospital (63% of the discharges stay within the Counties to Lewiston, which is the only hospital in the Counties).
Pennsylvania AG Settles Hospital Merger Challenge (continued)

- Settlement requires Geisinger:
  - not to arbitrarily increase prices for hospital or primary care services in Lewistown;
  - to continue to operate Lewistown Hospital as an acute care hospital for at least eight years;
  - to waive any restrictions on the ability of Lewistown's physicians to practice at competing hospitals;
  - to maintain Lewistown's contracts with health plans and its physician group;
  - and to continue allowing health plans to offer products to consumers with different tiers of providers based on cost and quality.

- No FTC enforcement action.
Reverse Payment

US Developments: FTC

- Overall, FTC continues to move forward on reverse payment cases post-Actavis.
- Commissioner Wright urged additional study on so-called “Pay-for-Delay” Cases.
- FTC sought to add Teva as a Defendant in Provigil Pay-For-Delay Suit.
- FTC opposes Cephalon’s motion to dismiss in Provigil Pay-For-Delay Suit.
Reverse Payment

US Developments: Private Litigation

- There continues to be significant development in reverse payment litigation.
- Effexor suit stalled until Supreme Court decides K-Dur cert petition.
- Federal Judge granted Daiichi Sankyo’s motion to dismiss in Lipitor pay-for-delay suit.
- California Judge approved Bayer’s $74M class action settlement in Cipro pay-for-delay suit.
- Federal Judge granted class certification motion in Nexium antitrust suit.
- Union Health and Welfare Fund filed Lidoderm pay-for-delay suit against Endo and Actavis.
Reverse Payment

International Developments

- EC Fines Johnson & Johnson and Novartis for delaying market entry of generic painkiller.
  - Fines totaled about €16 million on Johnson & Johnson and Novartis for entering into an anticompetitive agreement to delay the introduction of fentanyl, a generic painkiller, in the Netherlands.
  - According to the EC, the agreement delayed the entry of a cheaper generic medicine for seventeen months and kept prices for fentanyl in the Netherlands artificially high to the detriment of Dutch patients and taxpayers.
Pharma Litigation

- CSL to Settle Blood Plasma Antitrust Suit for $64 million
  
  *In re: Plasma-Derivative Protein Therapies Antitrust Litigation, 09-cv-7666 (N.D. Ill.)*
  
  • In 2009, plaintiff hospital groups filed a claim alleging that CSL conspired to artificially increase the price of plasma-derivative therapies.
  
  • Plaintiffs alleged that CSL and co-defendant Plasma Protein Therapeutics Association (“PPTA”) met with competitors and colluded to limit the supply of plasma products, even as demand grew.
  
  • CSL and Baxter International Inc. alleged to hold 60% share of the market and met through PPTA to discuss pricing.
  
  • Settlement pending court approval.

- There is antitrust exposure where the market is perceived as a “tight oligopoly” that is ripe for collusion. Independent pricing theory may not prevail as a defense.
Becton Dickinson Urges Judge to Overturn Jury Verdict and Order New Trial

Retractable Tech., Inc. v. Becton Dickinson & Co., No. 08-cv-16 (E.D. Tex.)

• In September 2013, a jury issued a verdict for $114 million in favor of Retractable Technologies, finding that Becton violated the Sherman Act by attempting to monopolize the safety syringe market with deceptive advertising.
• Becton filed a renewed motion for JMOL, or alternatively a new trial or remittitur.
• Becton argued that deceptive practices cannot be basis of Sherman Act violation because misleading ads are a byproduct of highly competitive markets and challenged sufficiency of the evidence.

• The jury rejected other claims based on bundling, exclusive dealing, and loyalty discounts, but conduct perceived as exclusionary or fraudulent by an alleged monopolist is appealing.
• This case presents an interesting nexus of consumer protection and competitive issues.
Pharma Litigation

- Impax Laboratories, Inc. and Purdue Pharma LP Settle IP Claims in OxyContin Antitrust MDL

  *Purdue Pharma L.P. et al. v. IMPAX Labs., Inc., No. 13-cv-763 (S.D.N.Y.)*

  - Consent judgment was filed December 6 for case by Purdue and Grunenthal against Impax alleging that its ANDA for generic oxycodone extended-release tablets infringed on patents.

  - Settlement conditions include:
    - Impax will not to market or sell product or challenge the validity of Purdue’s patents until a future, unspecified date.
    - Impax is enjoined from infringing Purdue’s patents.
    - Impax agreed drop potential antitrust or other claims against Purdue from the MDL.

- Fast litigation schedules encourage settlement where costs of litigation are high; relief in this case means a generic product cannot be marketed prior to Jan. 1, 2016.
Healthcare Litigation

- Chiropractor Files Suit against Virginia Medical Board alleging Anticompetitive conduct

*Dr. Yvoune Kara Petrie, DC v. Virginia Board of Medicine, No. 13-cv-01486 (E.D. Va.)*

- Complaint filed December 3, alleging that the Virginia Medical Board engaged in anticompetitive conduct: colluding to exclude chiropractors and non-medical doctor personnel from competing with medical doctors in Virginia.
Healthcare Litigation

- Nurses Oppose Appeal in Class Certification
  
  
  - In 2006, 20,000 Detroit-area nurses filed suit accusing VHS of Michigan, among other hospitals, of exchanging nurses’ wage information to keep wages low in violation of the Sherman Act.
  
  - District Court certified the class, and VHS appealed the certification.
  
  - Nurses oppose appeal, arguing that it is meritless and an effort of VHS to rescue its litigation strategy after it missed its opportunity to settle.
Class Certification in Evanston

In re: Evanston Northwestern Healthcare Corp. Antitrust Litigation, No. 07-cv-04446 (N.D. Ill.)

• On December 10, Illinois U.S. District Court granted class certification to customers who allege that the merger of two Chicago-area hospital groups resulted in increased prices for patients.
• Action arises from Evanston Northwestern Healthcare Corp.’s acquisition of rival Highland Park Hospital in 2000. Acquisition created four-hospital NorthShore University Health System.
• Case filed in 2007 on behalf of a proposed class that purchased inpatient hospital services and hospital-based outpatient services from NorthShore Hospitals.

• This is a case to follow closely, as private litigation regarding transactions is rarely successful.
Healthcare Litigation

- North Carolina Board of Dental Examiners filed Petition for Certiorari in Antitrust Immunity Case
  
  *North Carolina Board of Dental Examiners v. Federal Trade Commission, No. 13-534 (U.S.)*
  
  • In 2011, FTC determined that the North Carolina Board of Dental Examiners violated the FTC Act, Section 5 by prohibiting non-dentists from performing teeth-whitening services.
  
  • FTC alleged that Board members have a financial interest in the industry being tightly regulated and should not be permitted to exclude members from the market.
  
  • Board argued that they are protected by the state-action doctrine; FTC disagreed.
  
  • Fourth Circuit upheld FTC’s findings in May 2013.
  
  • Board filed a petition for certiorari.
  
  • Amicus Briefs in support of the Board have been filed by Attorneys General of 10 states, the American Dental Association, and the North Carolina State Bar.
  
  • The FTC continues to express confidence in its state action position after *Phoebe Putney*. 
Presenters

Jeffrey S. Spigel
Mr. Spigel is a partner in King & Spalding’s Washington, D.C. office and head of the antitrust group. Mr. Spigel represents healthcare and pharmaceutical clients in civil and criminal government antitrust and investigations and in antitrust litigation disputes. He also routinely advises these clients on a variety of antitrust issues, including mergers & acquisitions, licensing, pricing, and distribution, and competitor collaborations, including integrated networks.

John D. Carroll
Mr. Carroll is a senior associate in King & Spalding’s antitrust group. Mr. Carroll is a former FTC staff attorney in the Mergers I Division, which investigates pharmaceutical mergers and acquisitions, and is a recipient of FTC’s Award for Meritorious service. Mr. Carroll also has substantial healthcare antitrust experience and regularly provides a broad range of antitrust advice to healthcare systems and hospitals.

Wendy Huang Waszmer
Ms. Waszmer is a partner in King & Spalding’s antitrust group and former Assistant Chief of the New York field office of the U.S. Department of Justice Antitrust Division. She also served as counsel to the Assistant Attorney General of the Antitrust Division of the Justice Department. Ms. Waszmer’s focus is criminal and civil antitrust, including government investigations and counseling and compliance, as well as complex civil litigation.

Carolyn M. Sweeney
Ms. Sweeney is an associate in King & Spalding’s Business Litigation group. Ms. Sweeney has focused on antitrust counselling and criminal antitrust investigations, in addition to complex civil litigation and appellate litigation. Ms. Sweeney has represented clients in various industries, including the pharmaceutical and healthcare industries. Ms. Sweeney clerked on the United States Court of Appeals for the Eleventh Circuit prior to joining King & Spalding.