ABA SECTION OF ANTITRUST LAW

Promoting Competition Protecting Consumers

Health and Pharmaceuticals Committee: Recent Developments Series April – May 2012

June 13, 2012

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Morgan Lewis
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Agenda

- Welcome / Overview
- Pay for delay
- Hospital Merger Activity
- ACOs
- Express Scripts / Medco
- Questions?

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FTC v. Watson Pharms, et al., No. 10-12729 (11th Cir. Apr. 25, 2012)

- Another "pay for delay" setback for the FTC
- 11th Circuit reaffirmed its *Schering Plough* and *Valley Drug* holdings
- 11th Circuit rejected FTC invitation to assess the strength of the patents

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FTC v. Watson Pharms, et al., No. 10-12729 (11th Cir. Apr. 25, 2012)

- Product: Androgel (topical testosterone treatment)
- Formulation patent: expiration 2020
- Two paragraph iv certifications in 2003
- Patent litigation 2003-2006
- Settlement in 2006, while motions for summary judgment pending (invalidity + non-infringement)

FTC v. Watson

- Settlement terms:
  - Entry on August 31, 2015
  - Defendants agree to promote branded Androgel for payment
  - Back-up manufacturer for product
  - Payments from patentee to defendants of roughly $30 million per year

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FTC v. Watson

- FTC challenged settlement in court
- Case originally filed in CD Cal, but transferred to ND GA
- FTC alleged that the agreement was a naked restraint of trade
- Defendants' motion to dismiss granted
- Appeal to 11th Circuit

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FTC v. Watson

- "The key allegation in the FTC's complaint is that the patent holder was not likely to prevail in the infringement actions that it brought against generic manufacturers and settled."
- 11th Circuit refuses to consider the "likely outcome" of the patent litigation
  - "The FTC's position equates a likely result (failure of an infringement claim) with an actual result, but it is simply not true that an infringement claim that is 'likely' to fail actually will fail."
  - FTC's position would require essentially full patent trial within antitrust trial

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FTC v. Watson

- 11th Circuit re-confirmed previous holding: patent settlements "immune" if within the exclusionary scope of the patent
- FTC looking for opportunity to get Supreme Court review
- What next?

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Hospital Mergers

- Several recent challenges provide intriguing defenses:
  1. Phoebe Putney – state action doctrine
  2. Promedica – bargaining leverage, weakened firm defense
  3. OSA – changing health care landscape

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Phoebe Putney

- Tests the limits of intermingling of state and private action
- Phoebe Putney acquired rival Palmyra through use of Hospital Authority, resulting in virtual monopoly in Albany, GA
- FTC: Hospital Authority was merely a "straw man" that rubber stamped deal and used solely to circumvent antitrust laws.
- 11th Circuit: Transaction immune from antitrust scrutiny under state action doctrine
  - State authorized Authority's acquisition and contemplated anticompetitive effects
- FTC petitioned for writ of certiorari
  - In petition, argued that grant of general corporate powers to political subdivision does not imply foreseeability of anticompetitive effects

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Promedica

- FTC challenged merger between Promedica and St. Luke's in Lucas County, OH
- Focus on bargaining leverage
  - For health insurers, leverage stems from volume of in-network members; hospitals compete for access
  - For hospitals, leverage stems from inability of a health insurer to offer plans to their exclusion
    - FTC alleged pro-forma hospital system would be a "must have" resulting in unfair bargaining leverage that would result in supracompetitive pricing
- Defenses
  - Steering mechanisms constrain bargaining leverage
  - Weakened competitor defense.
- Outcome
  - Commission agreed with ALJ; divestiture of St. Luke's ordered
  - Parties plan to appeal to Sixth Circuit

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OSF / Rockford

- FTC challenged merger between Rockford and OSF in Rockford IL
  - DOJ investigated Rockford and third competitor in Rockford, IL in 1989
- Rockford: Merger not anticompetitive in new healthcare world
  - Affordable Care Act emphasizes efficient delivery of healthcare services over redundant accessibility
  - Redundancies in Rockford IL caused by defunct government subsidies eliminated by merger
  - Narrow networks more popular
  - Health plans have informational advantage
- Preliminary Injunction granted
  - Efficiency arguments debunked
- Parties abandoned merger plans in April

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What to Expect

- Challenging hospital mergers an FTC priority
- FTC not receptive to defenses (e.g., weakened competitor, changing environment, bargaining power) in presence of high market shares
- Implications of Phoebe:
  - As of 2008, nearly 20% of hospitals were owned by States and local governments.
  - These hospitals serve Medicaid patients at nearly twice the rate of private hospitals
  - FTC priority
  - Supreme Court review?

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Bilateral Monopolies & Vertical Mergers UPMC/Highmark/West Penn Allegheny

- Round 1 – West Penn (small hospital system) sues Highmark (dominant payer) and UPMC (dominant hospital) for reciprocal exclusive dealing agreement aimed at West Penn
  - Complaint dismissed but reinstated by 3d Circuit and District Court judge replace via writ of mandamus for inaction
- Round 2 – Highmark "affiliates" with West Penn and provides West Penn with $475 million
  - DOJ closes investigation of "affiliation agreement" in April 2012
  - Affiliation likely to make West Penn a stronger competitor vs. UPMC
  - West Penn drops claims against Highmark

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Accountable Care Organizations (ACOs)

- ACOs are intended to reduce costs and improve quality through greater collaboration and coordination
  - But present a risk of collusion or exercise of market power in dealings with health plans leading to higher prices
    - No direct impact on prices to Medicare where payment levels are set by CMS.
- If ACOs are important to ACA reform, providers considering ACOs must not be deterred by antitrust laws.

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ACO Antitrust Policy Statement

- Antitrust Agencies will Apply "Rule of Reason" treatment to ACOs that:
  - Meet CMS eligibility requirements
  - Participate in the Medicare Shared Savings Program (MSSP).
  - Use with commercial plans the same governance, leadership structure, and clinical and administrative processes that they use under the MSSP.
- Antitrust agencies will complete voluntary requested antitrust reviews of ACOs within 90 days

ACO Antitrust Policy Statement (cont.)

- Antitrust agencies will assume that ACOs:
  - Are bona fide arrangements intended to improve quality and reduce costs
  - Allow joint negotiations with health plans as necessary to ACOs primary purpose of improving health care delivery.
- CMS-type ACO will automatically pass antitrust scrutiny

ACO Antitrust Policy Statement (cont.)

- In addition, safety zone for certain ACOs
  - Calculate share in each participants Primary Service Area (PSA) among ACO for physician services, major diagnostic categories (hospital services), outpatient categories;
  - If ACO share is below 30% where two or more ACO participants provide that service to patients in the PSA.
  - Hospital and ambulatory service center must be non-exclusive to the ACO.
- Likely that few ACOs will meet the 30% safety zone requirement

ACO Antitrust Policy Statement (cont.)

- No longer requires mandatory antitrust review where market share above 50% in PSA.
- Cautions against sharing competitively sensitive information among competing participants that could facilitate collusion
- Identifies 4 types of potentially unlawful conduct….

ACO Antitrust Policy Statement (cont.)

- 4 types of potentially unlawful conduct (by ACO with high PSA shares):
  - preventing or discouraging private payers from steering patients to certain providers
  - tying sales of ACO services to a private payer's purchase of other services outside the ACO
    - e.g., requiring payer to contract with all of the hospitals in a system
  - contracting on exclusive basis with ACO providers so that providers are unavailable to contract with payers outside the ACO arrangement
  - Restricting a private payer's ability to make available its enrollees information about cost, quality, efficiency, or performance that could aid enrollees in selecting providers in the health plan.

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Express Scripts / Medco

- $29 Billion transaction in the PBM space closed without remedy by the FTC after an 8 month investigation
  - Commissioner Julie Brill dissented
  - 32 State Attorney Generals involved
  - Congressional Hearing
  - Private Litigation
- Competitive Landscape
  - Original thought was 3 to 2 – “The big 3”
  - FTC found 10 “significant” competitors plus fringe

Express Scripts / Medco (cont.)

- Market Shares (~40%) not indicative of market conditions
  - Bidding market with numerous smaller competitors consistently showing up
  - Evidence suggested that customers were able to use bids to get lower prices
  - Dynamic
    - Medco lost 1/3 of its business in the past year
    - CVS Caremark had been growing very quickly
- Low Diversion Ratio
  - The parties are not each other's closet competitors

Express Scripts / Medco (cont.)

- Coordinated effects would be unlikely
  - Complicated pricing makes it hard to set prices
  - Competitive aggressiveness and size of smaller players makes customer allocation unattractive
- No monopsony power
  - Lowered costs for PBMs likely to be passed on to consumers
- No Anticompetitive Effects with respect to Specialty Drugs
  - Less concentrated
  - Rare for exclusive distribution rights and generally at the behest of the manufacturer

Express Scripts / Medco (cont.)

- Lessons
  - When faced with a challenging merger – understanding the competitive restraints are key
  - Market Shares can be overcome
  - When there is strong public backlash, it is important to focus the reviewing agencies on the relevant facts

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