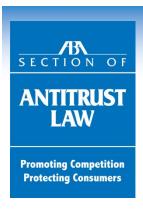


Health and Pharmaceuticals Committee: Recent Developments Series April – May 2012

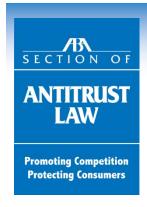
June 13, 2012 12:00pm EST

Morgan Lewis 1111 Pennsylvania Ave., NW Washington, DC 20004-2541



Agenda

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



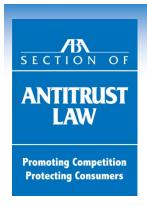
FTC v. Watson Pharms, et al., No. 10-12729 (11th Cir. Apr. 25, 2012)

- 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



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)



- 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



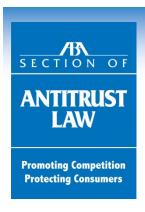
- FTC challenged settlement in court
- Case originally filed in CD Cal, but transferred to ND GA
- FTC alleged that the agreement was a naked restraint of trade
- Defendants' motion to dismiss granted
- Appeal to 11th Circuit



- "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



- 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?



Hospital Mergers

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



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



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



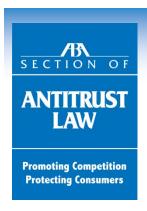
OSF / Rockford

- 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



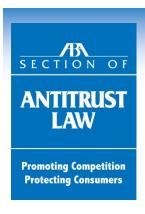
What to Expect

- 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?



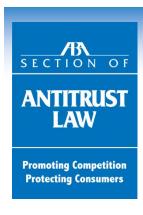
Bilateral Monopolies & Vertical Mergers UPMC/Highmark/West Penn Allegheny

- 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



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.

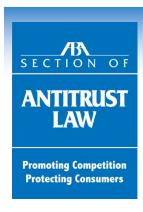


ACO Antitrust Policy Statement

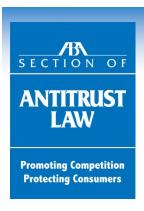
- Antitrust Agencies will Apply "Rule of Reason" treatment to ACOs that:
 - Meet CMS eligibility requirements
 - Participate in the Medicare Shared Savings Program (MSSP).
 - Use with commercial plans the same governance, leadership structure, and clinical and administrative processes that they use under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



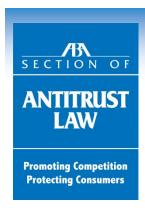
- Antitrust agencies will assume that ACOs:
 - Are bona fide arrangements intended to improve quality and reduce costs
 - Allow joint negotiations with health plans as necessary to ACOs primary purpose of improving health care delivery.
- CMS-type ACO will automatically pass antitrust scrutiny



- 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 nonexclusive to the ACO.
- Likely that few ACOs will meet the 30% safety zone requirement



- 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....

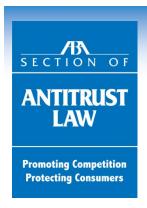


- 4 types of potentially unlawful conduct (by ACO with high PSA shares):
 - preventing or discouraging private payers from steering patients to certain providers
 - tying sales of ACO services to a private payer's purchase of other services outside the ACO
 - e.g., requiring payer to contract with all 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.



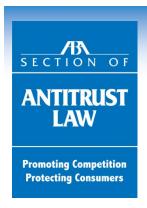
Express Scripts / Medco

- \$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



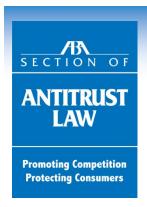
Express Scripts / Medco (cont.)

- 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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