Health Antitrust Recent Developments

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McDermott Will & Emery LLP
Ashley M. Fischer
312-984-7766
amfischer@mwe.com
Partner
Chicago, IL

Stephen Y. Wu
312-984-2180
swu@mwe.com
Partner
Chicago, IL
FTC Litigation and Advocacy
FTC Hospital Merger Litigation

- The three active FTC lawsuits in pre-trial phase
- Cabell Huntington Hosp./St. Mary’s Med. Ctr (WV)
  - Administrative trial starts April 5, 2016
  - No PI complaint has been filed
- Advocate Health/Northshore Univ. Health (Chi.)
  - PI hearing starts April 6, 2016
  - Administrative trial starts May 24, 2016
- Penn State Hershey/PinnacleHealth (PA)
  - PI hearing starts April 11, 2016
  - Administrative trial starts May 17, 2016
FTC Issues Letter Supporting GA Hygienists

• On Jan. 29, FTC Staff sent a letter to the GA legislature supporting a bill regarding supervision of dental hygienists
  – GA H.B. 684 broadens scope of hygienists’ ability to practice in preventative care without the supervision of a licensed dentist
  – Currently, hygienists must work under direct supervision of licensed dentists with few exceptions
    • “Direct supervision” means dentist is in the office of treatment facility, personally diagnosis the condition to be treated, personally authorizes the procedures, remains in the office while procedures are performed, and examines the patient before she is dismissed.
    • No supervision required for dental screenings at public dental health facilities
  – Bill expands ability of hygienists to provide dental screenings “at approved safety-net facilities, including nonprofit clinics, health care facilities, long-term care facilities, and school-based programs
FTC Sends Letter to WV Regarding APRNs

- On Feb. 10, FTC Staff sent a letter to the WV state legislature regarding proposed legislation (S. 516) to regulate advanced practice registered nurses (APRNs)
  - Staff cautioned WV legislature to avoid restrictions not narrowly tailored to address well-founded patient safety concerns
  - Bill would allow Board of Medicine and Board of Osteopathy authority to license APRNs to prescribe medicines without a formal, written collaborative agreement
    - Concern of conflict of interest by having BOM and BOO regulate APRNs
    - Benefit patients by allowing some APRNs to independently write prescriptions
    - But, places heavy conditions imposed on independent APRN prescribing
- FTC Staff published a policy on APRNs in 2014.
State Law Developments
Fourth Circuit Upholds Virginia CON Regulations

• Fourth Circuit ruled that VA’s certificate of need regulations do not illegally discriminate against out-of-state providers
  – Plaintiffs were out-of-state outpatient providers seeking to open medical imaging services in VA
  – Requests for CON were denied
Fourth Circuit Upholds Virginia CON Regulations

• Fourth Circuit affirmed district court ruling that the CON regulations neither discriminated nor placed an undue burden on interstate commerce
  – Both in-state and out-of-state providers subjected to regulations
• In Oct. 2015, FTC & DOJ’s Antitrust Division issued a joint statement urging VA to consider changes to CON laws.
  – CON laws create significant competitive concerns
  – Suppress supply and misallocate resources
  – Not shown to lower costs or improve quality of care
• 36 states have CON regulations
Florida Insurance Regulator Approves Aetna/Humana Transaction

- Florida Office of Insurance Regulation ("FL OIR") issued Consent Order on February 15, 2016 approving the transaction on certain conditions
- FL OIR found no “strong evidence” of a significant reduction in competition in Florida's private health insurance markets
  - Interestingly, FL OIR found that MA competes directly with traditional Medicare
- Nevertheless, the Order requires certain behavioral remedies related to Aetna’s Florida Individual Health Insurance Exchange portfolio:
  - By 2018, Aetna must enter into 5 new counties not in its 2016 Florida Individual Health Insurance Exchange portfolio
  - By 2020, Aetna must develop a plan to enter the counties not in its 2018 Florida Individual Health Insurance Exchange portfolio
Florida Insurance Regulator Approves Aetna/Humana Transaction

• In the Order and accompanying press release, FL OIR questioned divestiture as an effective remedy
  – Divestiture is not in the best interests of policyholders “because of its potential to disrupt quality of services, benefits, networks, and cost-sharing provisions.”
  – Divestiture may not be effective at managing market concentration in the long term because “policyholders have the option to elect a different company every year.”

• DOJ and Florida AG still investigating the transaction
State Action Immunity
West Virginia Bill Seeks Antitrust Immunity for Hospital Mergers

- A bill introduced in the West Virginia legislature would exempt hospitals and health care providers from state and federal antitrust laws when they act in compliance with orders or approvals from the West Virginia Health Care Authority.
- The bill has passed the state senate and a version is working its way through the state house of representatives.
Nevada Pharmacy Board Accused of Restricting Competition

  - Alleges violations of federal and state antitrust law
  - Filed after Supreme Court’s *N.C. Dental* decision.

- Alleges NV’s State Board of Pharmacy is controlled by active market participants that compete in market for sale and distribution of pet medications
  - Plaintiffs provide direct home delivery of pet medications
  - Board of Pharmacy issued cease and desist letter and initiated proceedings to revoke plaintiff’s pharmacy license
  - No independent, politically accountable state official has power to review acts of the Board of Pharmacy
State Action Immunity Denied to UNC in Medical Hiring Suit

- On Feb. 12, a NC district court judge refused to grant UNC *ipso facto* state action immunity and denied a motion to dismiss without prejudice
  - Discovery needed to determine whether UNC automatically entitled to state action immunity
  - UNC is constitutionally-established entity
  - Case law presented mixed outcome on a controlling question
    - Several cases granted state university system’s *ipso facto* immunity
    - Supreme Court, however, has never granted *ispo facto* immunity beyond state legislatures and state supreme courts
- Certified issue for interlocutory appeal to Fourth Circuit
Patent Settlement Agreements
Loestrin

• *In re Loestrin 24 Fe Antitrust Litigation*, 2016 WL 698077 (1st Cir. Feb. 22, 2016)

• Issue – whether brand’s payment of non-cash compensation to generic to settle patent litigation can be a reverse payment under *FTC v. Actavis*
  – Brand agreed, among other things, not launch an authorized generic in exchange for later generic entry
  – District court dismissed complaint, holding that *Actavis* is limited to reverse payments in pure cash form. 45 F.Supp. 3d 180 (D.R.I. 2014)

• 1st Circuit reversed, holding that “non-monetary reverse payments” are subject to *Actavis*
  – Decision aligns with the only other appellate court to address the issue (3d Cir., in *Lamictal*) and with many district court decisions
  – Court did not address whether the specific no-AG and other settlement terms were adequately pled as reverse payments, because district court did not do so, and remanded
On Mar. 2, 2016, the U.S. Supreme Court granted purchasers of Lamictal, used to treat epilepsy and bipolar disorder, until April 1 to respond to GSK and Teva’s cert petition; plaintiffs had previously *not* filed an opposition.

GSK and Teva argued in their cert petition that the 3d Circuit read *Actavis* too broadly to include non-cash consideration in the form of a promise by GSK not to launch its own authorized generic during Teva’s 180-day exclusivity window.

The district court originally dismissed plaintiffs’ claims, but the 3d Circuit reversed and held *Actavis* did not require cash consideration to be a transfer of value that could be subject to antitrust scrutiny.

In their cert petition, GSK and Teva argue that the agreement by GSK not to launch an authorized generic is really an exclusive license to Teva, and that licensing is an indispensable part of patent holder’s rights.
Nexium

  - Jury said reverse payments were “unreasonably anticompetitive” but could not conclude parties would have settled for earlier entry but for agreement
    - Judgment entered for defendants, because jury could not establish that agreement materially caused the alleged overcharges
- FTC says court “mistakenly conflated” antitrust violation with standing:
  - Former requires a general showing of harm to competitive process; latter requires a private plaintiff to show injury-in-fact caused by violation
  - “The district court’s erroneous analysis threatens to impede federal antitrust law enforcement efforts by, in effect, requiring the government to take on additional proof requirements that, under the law, are to be borne only by private plaintiffs”
K-Dur

- Summary judgment **denied** as to Schering settlement with Upsher-Smith
  - Genuine dispute of material fact whether brand’s $60 million payment to ANDA first-filer for licenses to other products, coupled with generic entry delay, was justified under *Actavis*
- SJ **granted** as to Schering settlement with ESI-Lederle (2nd ANDA filer)
  - Plaintiffs did not intend to prove ESI was actually delayed and conceded ESI settlement did not cause competitive harm; it was 2nd-filer and subsequently exited oral generics business
  - Plaintiffs instead alleged that Schering, Upsher and ESI collectively conspired to share brand’s monopoly profits; court said no evidence that Upsher and ESI conspired
- Case back before district court after Supreme Court, post-*Actavis*, vacated 3d Cir. ruling that “quick look” rule of reason test applied to both settlements
- FTC found in 2003 that both settlements were anticompetitive; 11th Cir. reversed based on scope-of-patent test that *Actavis* later rejected

• Motions to dismiss denied (except for certain end-payor state law claims)

• Suits allege reverse payments by Endo (brand) to Impax (generic) in form of (1) “credit” provision, by which Endo would pay Impax if brand sales declined by certain amount pre-generic entry, (2) no-AG provision and (3) $10M upfront payment for development and co-promotion agreement
  – Endo said to have shifted market to patent-protected crush-resistant Opana ER shortly before Impax’s entry, resulting in $102M payment to Impax under credit provision

• Court: allegation “plausible and persuasive” that Impax was ensured of a “large” payment either via credit provision, if brand sales fell, or from a more valuable 180-day exclusivity due to no-AG, if sales were steady

• Defense’s justifications “believable” but not ripe for a motion to dismiss
Seroxat (Paxil) – U.K.

- The U.K. Competition and Markets Authority imposed fines on GSK (brand) and Generics UK and Alpharma (generics) totaling £45 million ($64 million) for patent settlement agreements entered between 2001 and 2004 involving Seroxat (paroxetine, sold as Paxil in U.S.)
- Settlements involved value transfers of more than £50 million ($71 million in current dollars)
- Prior to infringement trial, GSK settled with generics
  - GSK appointed GUK and Alpharma as distributors of Seroxat
  - CMA says generics “accepted value transfers [including cash payments] from GSK as compensation for their agreement to delay their efforts to enter the market independently of GSK”
Pharmaceutical Mergers
Mylan/Perrigo

• On Feb. 22, 2016, FTC approved a modified final consent order settling charges that Mylan N.V.'s proposed hostile takeover of Perrigo Company plc would harm competition.

• Notably, Mylan failed to succeed in its hostile takeover of Perrigo and abandoned the proposed acquisition.
Mylan/Perrigo

- FTC previously issued order requiring Mylan to divest rights and assets for 7 generic drugs to Alvogen Group, Inc.
- 4 drugs involved current competition; both Mylan and Perrigo currently sell or having FDA approval to sell:
  - Bromocriptine mesylate - treats conditions including type 2 diabetes and Parkinson’s disease
  - Clindamycin phosphate/benzoyl peroxide - treats acne
  - Liothyronine sodium - treats hypothyroidism and enlarged thyroid glands
  - Polyethylene glycol 3350 - treats occasional constipation
• 3 drugs involved future competition:
  – Acyclovir - slows the growth and spread of the herpes virus in the body
  – Hydromorphone hydrochloride - treats moderate to severe pain in narcotic-tolerant patients
  – Scopolamine - prevents symptoms associated with motion sickness and helps patients recover from anesthesia and surgery
Mylan/Perrigo

• Notwithstanding failed hostile takeover, FTC issued a modified final order relieving the previously appointed monitor, but still requiring Mylan to submit annual compliance reports for three years (instead of previous 10 years)
Hikma/Boehringer Ingelheim

- Hikma acquired Roxane from Boehringer Ingelheim
- On Feb. 19, 2016, FTC ordered Hikma to divest assets for 3 products, 2 of which are currently marketed by both Hikma and Roxane
  - Prednisone (5->4)
  - Lithium carbonate (4->3)
• For 3rd product, flecainide acetate tablets, FTC alleged acquisition would reduce *future* competition by eliminating 5th independent supplier
  – Hikma owned 23% minority interest in firm that filed ANDA for the product
  – FTC requiring Hikma to return rights to market flecainide acetate tablets in US *and* to sell its minority interest in other firm
  – FTC concerned Hikma would have reduced incentive to compete if it held 23% interest in rival
Other Private Enforcement
Glynn-Brunswick Hospital Authority et al. v. Becton Dickinson and Co., No. 2:15-cv-00091 (S.D. Ga.)

- Plaintiffs alleged defendant monopolized syringe and IV catheter markets purchased under cost-plus contracts from distributors requiring pass-on of all of defendant’s pricing
Glynn-Brunswick Hospital Authority et al. v. Becton Dickinson and Co., No. 2:15-cv-00091 (S.D. Ga.)

• On Jan. 29, 2016, U.S. District Judge Lisa Godbey Wood granted motion to dismiss
  – The Court found that plaintiff Georgia Health System did not have standing to bring the putative class action
  – The complaint had alleged that Becton excluded competitors that were making safer hypodermic syringes from the market
  – But, the Court held that the hospital was not a direct buyer of the syringes and did not fall under any exceptions to the *Illinois Brick* direct purchaser rule
  – Additionally, the Court ruled that the hospital failed to properly identify a legitimate market by artificially limiting the types of customers included (only acute care centers vs. other providers)
Distributors filed class action complaints against dental suppliers in New York and Texas

Complaints allege that:

- Defendants engaged in an anticompetitive conspiracy to boycott distributors and foreclose competition in the market for the distribution of dental supplies and equipment in violation of Sherman Act Section 1
- Defendants control over 80% of all sales in the market
- Defendants have charged supracompetitive prices

Follows a Texas Attorney General consent judgment against defendant Benco in April 2015
Oklahoma health system filed a complaint against BCBS and rival health systems alleging that defendants colluded to fix prices and eliminate plaintiff from the market.

Complaint alleges that:

- BCBS’ share of the market in Northeast Oklahoma/Tulsa is 64% or higher
- BCBS and the defendant health system conspired to exclude one of plaintiff’s facilities from BCBS’ network
Questions