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Competition Enforcement and Policy Developments at the FTC in 2013

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Competition Enforcement and Policy Developments at the FTC in 2013

Timothy T. Hughes
Attorney, U.S. Federal Trade Commission*

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*The views expressed are those of the speaker and not of the Commission or any individual Commissioner

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Healthcare Sector Continues As An FTC Priority in FY 2013

- ***Healthcare accounts for 17.9% of U.S. GDP (http://data.worldbank.org/indicator). Therefore, FTC continues to devote significant resources to insuring competition is alive and well in this sector.***
- ***Significant developments in this sector:***
  - ***Revised premerger notification rules clarifying when a transfer of exclusive rights to a patent in the pharmaceutical industry results in a potentially reportable asset acquisition.***
  - ***U.S. Supreme Court ruled favorably on two FTC matters. My colleague reported to CPLG last year that these matters were pending. They have now been decided:***
    - ***FTC v. Actavis (agreement between branded and generic pharmaceutical);***
    - ***FTC v. Phoebe Putney Health System, Inc. (hospital acquisition of another hospital)***
  - ***4th Circuit Federal Court of Appeals ruled favorably on:***
    - ***North Carolina State Board of Dental Examiners v. FTC (agreement by board members to exclude competing non-dentists from teeth-whitening market)***

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Healthcare – Pay for Delay
FTC v. Actavis, 133 S.Ct. 2223 (June 2013)

- ***Facts: Solvay Pharmaceuticals held a patent on a testosterone replacement drug. Actavis sought FDA approval to introduce a generic testosterone replacement drug. Solvay brought suit against Actavis for infringement of Solvay's patent. About 3 years into the suit, Solvay and Actavis entered an agreement in 2003. Terms of agreement included Actavis agreeing not to market generic until August 2015 which is about 5 years before Solvay's patent expires.***

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FTC v. Actavis (continued)

- ***Questions before the Court:***
  - ***1. Was the Appeals Court correct in upholding the trial court? The trial court had dismissed the FTC's complaint because the agreement did not extend the exclusivity of the branded product's patent beyond the potential it would have if it were valid?***
  - ***2. If FTC's complaint was wrongly dismissed, what standard should the trial court use in analyzing the agreement: a presumption of illegality under a quick look rule of reason analysis, or, straight forward rule of reason analysis without a presumption?***
- ***Decision of the Court:***
  - ***1. Case sent back for trial. Dismissal by trial court was error. Simply because the agreement does not extend Solvay's exclusivity rights beyond the time of the expiration of Solvay's patent, the agreement is not exempt from antitrust scrutiny.***
  - ***2. Use straight forward rule of reason analysis without a presumption of illegality.***

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Healthcare – Hospital Merger
FTC v. Phoebe Putney Health Systems, 133 S.Ct. 1003 (Feb. 2013)

- ***Facts: Phoebe Putney sought to acquire Palmyra Park, both hospitals in Albany, Georgia, a city of 77,000 people in the middle of farming country. FTC sought to block the deal. The hospitals argued successfully at the trial and appeals level that the transaction was exempt from the antitrust laws under the "state-action" doctrine. Phoebe Putney was controlled by a hospital authority created by the state of Georgia.***

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FTC v. Phoebe Putney (continued)

- ***Question before the Court:***
  - ***Did the fact that the legislature must have foreseen this possibility when it created the hospital authority confer the state-action exemption on the hospital?***
- ***Decision of the Court:***
  - ***Conduct is exempt when the state, acting in its capacity as sovereign, clearly articulates that the conduct is exempt and actively supervises it. In this case, the legislation creating the hospital authority did not clearly articulate the State of Georgia's desire to exempt the conduct of the hospital authority from the antitrust laws.***

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Healthcare – Boards of Professionals
N.C. Board of Dental Examiners v. FTC, 717 F.3d 359 (4th Cir. May 31, 2013)

- ***Facts: The legislature of North Carolina created a Board to regulate dental services in North Carolina. Most members were dentists practicing their profession. The Board sent notices to non-dentists who provided teeth-whitening services, ordering them to stop, telling them it was a crime for them to continue because they were practicing dentistry, and notifying building owners not to lease to them. FTC conducted an administrative trial and found an anticompetitive agreement among competitors aimed at eliminating lower-priced competitors. The Board appealed.***

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N.C. Board of Dental v. FTC (continued)

- ***Questions before the Appeals Court:***
  - ***Did the fact that the legislature had created the Dental Board to regulate dental services in the state, exempt it from the antitrust laws under the state-action doctrine?***
  - ***Did substantial evidence support the FTC's finding that the actions of the board constituted an anticompetitive agreement among competitors?***
- ***Decision of the Appeals Court:***
  - ***State agencies in which a decisive coalition (usually a majority) is made up of participants in the regulated market who are chosen by and accountable to their fellow market participants are private actors subject to the antitrust laws unless actively supervised by state.***
  - ***The actions of the board to thwart lower-priced teeth-whitening services was an anticompetitive agreement.***

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Assessing Regulatory Impacts on Competition/Advocacy

- ***The benefit to consumers from sound and effective advocacy that promotes competition in entire sectors or subsectors of an economy is often enormously larger than the benefit derived from individual cases.***
- ***The FTC, therefore, devotes resources specifically to identifying, analyzing and advocating on behalf of pro-competitive legislative and regulatory changes.***
- ***The following are highlights from developments in an FTC regulatory impact assessment of biologic drugs that has extended over years, including two workshops, one of which was held a few weeks ago .***

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Assessing Regulatory Impacts on Competition/Advocacy/Biologics

- ***Biologic drugs are protein-based and derived from living matter or manufactured in living cells using recombinant DNA biotechnologies. The therapeutic proteins that form the basis of these biologic drugs are far more complex and much larger than the chemically synthesized, small molecules that form the basis of most pharmaceutical products.***
- ***Problem: Biologic drugs are becoming more common and are expensive. As examples, annual treatment for breast cancer with the biologic drug Herceptin can cost $48,000 and the annual treatment for rheumatoid arthritis with Remicade can cost approximately $20,000.***
- ***Biologics account for approximately 25 percent of the $320 billion spent annually in the U.S. for pharmaceutical treatments.***

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Assessing Regulatory Impacts on Competition/Advocacy(continued)

- ***FTC researched and published a notice to stakeholders that it would hold hearings and take input from them.***
- ***Early Questions:***
  - ***To what extent, if any, would we expect competition to reduce the price of biologic drugs if there were a drug regulatory approval process to encourage "follow-on biologics" ("FOBs") to enter and compete with pioneer biologics?***
  - ***To what extent, if any, can we expect drug approval processes similar to those that worked to incentivize generics to enter and drive down prices in the small molecule drug sector to also work to encourage entry of follow-on-biologics into the complex biologic molecule sector?***

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Assessing Regulatory Impacts on Competition/Advocacy

- ***The hearings Resulted in an FTC Report, "Emerging Healthcare Issues: Follow-On Biologic Drug Competition," http://www.ftc.gov/os/2009/06/P083901biolgicsreport.pdf The Report examined the incentives used to encourage entry of generics in small molecular drug sector, e.g.:***
  - ***Eliminate the need to replicate all of the costly testing required for a brand name drug. To be approved the applicant must show that its generic drug product is ''bioequivalent'' to (basically, as safe and effective as) the branded drug product.***
  - ***The first generic to seek approval receives an exclusive approval period of 180 days during which other generics will not have approval.***
  - ***Many states allow pharmacists automatically to substitute a generic for the branded drug without consulting the physician who wrote the prescription.***

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Assessing Regulatory Impacts on Competition/Advocacy

- ***Many differences were found in the need for and effect on competition in biologics of various incentives that work in promoting competition for small molecule generics.***
- ***Passage of national health insurance legislation "Affordable Healthcare Act," also called" Obamacare," included a requirement for an abbreviated licensing process and implementing regulations.***
- ***FTC held a second workshop, February 2014, to examine:***
  - ***The potential impact of state regulations affecting competition.***
  - ***How regulations, if necessary, might be structured to facilitate competition while still protecting patient health and safety.***
  - ***How naming may affect competition.***
  - ***The experience of other countries with follow-on biologic competition.***

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Assessing Regulatory Impacts on Competition/Advocacy

- ***The process that FTC used in assessing biologics began and continues to demonstrate a commitment to assessing regulatory impacts on competition, transparently and seeking public consultation from stakeholders:***
  - ***2008-2009. FTC Hearings with stakeholders conducted and results published in a 2009 FTC Report trying to predict potential benefit to consumers from competition by "follow-on-biologics (FOBs), (bioequivalent to innovative branded biologic).***
  - ***2010. Congress passed "Biologics Price Competition and Innovation Act" authorizing the Food & Drug Administration to establish accelerated approval procedure.***
  - ***2013. FDA issued draft guidance.***
  - ***2013-2014. FTC conducts additional stakeholder hearings.***

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