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Pharmaceutical Pay for Delay Settlements

UCIP Seminar

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Outline

- Background
  - Goals of the Hatch-Waxman Act
  - Price Effects of Generic Entry
- Pay-for-Delay Patent Settlements
  - Theory
  - Cases
  - Trends
- Counseling & Developments
- Proposed Legislation

Background

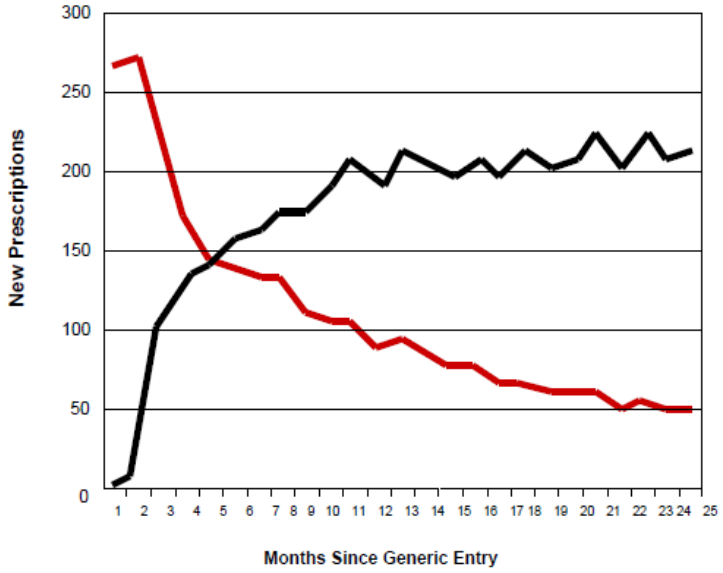
- **Goals of the Hatch-Waxman Act**
  - Maintaining incentives to develop new drugs
    - *patent term extensions,*
    - *5-year exclusivity for new chemical entities*
    - *30-month stays*
  - Increasing availability of lower-priced generic drugs
    - *Abbreviated process for FDA approval*
    - *Special procedures to facilitate patent challenges*

Background

- **Hatch-Waxman Provisions Facilitating Patent Challenges**
  - Patent listing (Orange Book)
    - *Allows generic to identify and study patents at issue for many years*
  - Paragraph IV certification (patent not infringed or is invalid)
    - *Allows generic to challenge strength of listed patents in Court*
  - 30-month stay
    - *Intended to cover period of litigation under Paragraph IV*
    - *Can also be used to negotiate pay-for-delay settlements*
  - "First filer" and 180-day exclusivity
    - *Benefit to first generic to file ANDA as they have exclusivity from other generics*
    - *First filer generic is in a position to restrict entry of other generics if they do not launch*

Background

- **Price Effects of Generic Entry**
  - First generic enters at 75% of the brand's price
  - Takes at least 50% of sales within one year
  - Subsequent generics compete the price down further



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Pay for Delay Settlements

- **Definition**
  - Brand & generic companies in "Paragraph IV" litigation settle case:
    - *Generic agrees to refrain from going to market until an agreed upon date*
    - *Settlement includes payment or other consideration to the generic such as:*
      - Cash
      - Intellectual property license
      - Co-development agreements
      - Manufacturing agreements
      - Supply agreements
      - Distribution agreements

Pay for Delay Settlements: Theory

- **Theory of Anticompetitive Harm**
  - Parties should be able to reach settlement with patent split based upon their objective views of the patent merits
  - If compensation to generic is introduced into the settlement, the entry date (the patent split) must move back in time in exchange for the compensation
  - This delays generic entry and results in consumer harm

Pay for Delay Settlements: Theory

- **Legal Issues**
  - Are there antitrust limits to patent settlements?
    - *FTC: Yes, sharing of monopoly profits to eliminate a potential competitor is an antitrust violation. The existence of a patent doesn't change that because of validity challenges.*
    - *Defendants: Patent laws trump the antitrust laws. An antitrust violation exists only if the exclusionary effect of the agreement exceeds the scope of the patent.*
  - Does the legitimate use of a patentee's "right to exclude" extend to paying an accused infringer to stay off of the market?
    - *FTC: No, the "right to exclude" means invoking the power of the courts to exclude the alleged infringer by seeking a preliminary injunction.*
    - *Defendants: Yes, there is no reduction in competition because a patent entitles its holder to exclusively practice the patent during its term.*
  - When a patentee pays an accused infringer to stay off the market, what is the source of the exclusion?
    - *FTC: The monopoly profits*
    - *Defendants: The patent*

Pay for Delay Settlements: Cases

- **Appeal Court Decisions Finding Settlements Illegal**
  - *Cardizem (6th Cir. 2003)*
    - *Interim patent settlement held per se unlawful*
    - *Contained reverse-payment, and agreement by generic not to introduce "non-infringing product"*
  - *In re Terazosin (S.D. Fla. 2005)*
    - *District Court rules in favor of FTC in case on remand from 11th Cir.*
- **No recent cases finding settlements as illegal**
- **FTC pursuing other means to stop Pay for Delay settlements**

Pay for Delay Settlements: Cases

- **Appeal Court Decisions Finding Settlements Legal**
  - *FTC v. Schering-Plough (11th Cir. 2005)*
    - *Reversed FTC Opinion finding agreement unlawful*
    - *Must examine "exclusionary power of the patent"*
  - *Tamoxifen (2d Cir. 2006)*
    - *No antitrust liability where reverse payment present, unless patent suit was sham or otherwise baseless*
  - *Ciprofloxacin (Fed. Cir. 2008)*
    - *No antitrust liability where reverse payment present, unless patent suit was sham or otherwise baseless*
    - *Request to hear case en banc denied by 2d Cir. In 2010*
- **Trend by Courts to find settlements as legal**
- **FTC wants the opposite**

Pay for Delay Settlements: Cases

- **Key Cases Pending**
  - FTC v. Cephalon (E.D. Pa.)
    - *Complaint filed in February 2008.*
    - *FTC survived Cephalon's motion to dismiss and discovery completed*
  - FTC v. Watson (N.D. Ga.)
    - *Complaint filed in January 2009.*
    - *After the case was transferred from C.D. Ca. to N.D. Ga., the FTC lost on Defendants' motion to dismiss. Presently, the FTC is appealing to the 11th Circuit*
  - Purchaser Suits Against Pfizer and Ranbaxy for Lipitor Settlement
    - *In November 2011, several complaints were filed alleging that Ranbaxy agreed to a later entry date for generic Lipitor in exchange for Pfizer's agreement to allow Ranbaxy to sell an authorized generic version of Lipitor in seven foreign countries*

Pay for Delay Settlements: Cases

- **Approach of Courts in these Cases**
  - Must consider the "scope of the patent"
  - A violation occurs when exclusionary effect of the agreement exceeds potential exclusionary scope of the patent
    - *Exclusionary effect of agreement exceeds the exclusionary scope if:*
      - Patent was obtained by fraud
      - Patent infringement litigation was a sham
      - Agreement covers unrelated or obviously non-infringing products

Pay for Delay Settlements: Trends

- In its final authorized generic report issued in 2011, the FTC concluded that strong evidence exists indicating that agreements not to compete with an authorized generic have become a way for brand name companies to compensate generic competitors for delayed market entry.
  - Between 2004 and 2010, 39 of 157 patent settlements with first-filer generics (approximately 25 percent) contained such provisions.
  - The average generic entry delay for the 39 agreements was 37.9 months, and the total market for the drugs involved in these settlements exceeded $23 billion.
  - The length of time during which the brand agreed not to launch or sponsor an AG ranged from 10 days to 45.5 months, with the average length of the restriction being 9.6 months and the median restriction being 6 months.

Pay for Delay Settlements: Trends

- **Current FTC Posture on "Pay-for-Delay"**
  - **Settlements**
    - *Despite Three Adverse Circuit Court Rulings FTC continues to investigate pharmaceutical patent settlements*
    - *Since loss in Schering at Eleventh Circuit in 2005, FTC has continued to bring additional suits against patent settlements*
      - Cephalon (complaint filed February 2008; FTC survived motion to dismiss and discovery completed)
      - Solvay/Par/Watson (complaint filed January 2009; FTC lost on motion to dismiss and is appealing district court decision to Eleventh Circuit)
  - Pursuing "pay for delay" cases remains a top priority for FTC

Pay for Delay Settlements: Trends

- **FTC Three-Pronged Approach on "Pay-for-Delay" Patent Settlements**
  - **Prong One: Litigation/Investigations**
    - *Goal: Create Circuit split so that Supreme Court will set legal standard*
    - *May take years for this to occur and final outcome is uncertain*
  - **Prong Two: Legislation on "Pay for Delay" Patent Settlements**
    - *Litigating another case to conclusion will take years with outcome uncertain in view of prior precedent*
    - *"Legislation could provide a speedier and more comprehensive way to address this pressing concern" (March 2009 Testimony of FTC Commissioner)*
  - **Prong Three: FTC Rulemaking**
    - *FTC has suggested that it may seek to exercise its rulemaking authority, for example, by issuing a rule providing that "pay for delay" patent settlements are "inherently suspect" under the FTC Act*

Counseling & Developments

- **MMA Patent Settlement Filing Requirements**
  - Pharmaceutical patent settlements required to be filed with FTC (per 2003 Medicare Modernization Amendments)
  - Why Congress Enacted This Requirement
    - *"to re-emphasize the Hatch-Waxman Act's original intent of enhancing competition, not collusion, between generic and name-brand drug manufacturers"*
  - Only *NOTICE to FTC* **NOT approval**
  - No waiting period
  - Lack of FTC inquiry does not mean than FTC cannot challenge later

Counseling & Developments

- **MMA Patent Settlement Filing Requirements**
  - **Types of agreements required to be filed:**
    - *Brand-generic agreements where generic filed Para IV, and*
      - Enters into an agreement that relates to marketing, manufacture, or sale of brand or generic product, or
      - Enters into an agreement relating to the 180-day exclusivity period as it applies to the generic or another generic applicant
    - *Generic-generic agreements where*
      - Two Paragraph IV ANDA-filers enter into agreement that relates to the 180-day exclusivity period
  - **Other Requirements:**
    - *File within 10 business days after agreement executed*
    - *Submit entire agreement including provisions "not reduced to text" (See BMS/Plavix criminal plea)*

Counseling & Developments

- **BMS/Apotex Settlement on Plavix**
  - **Settlements at Issue**
    - *Original Settlement – FTC did not approve because included provision that BMS would not launch authorized generic*
    - *Revised Settlement – Did not include authorized generic provision, but BMS orally represented it would not launch authorized generic*
  - **Both Settlements Submitted to FTC**
    - *Required under prior BMS consent, which required FTC approval*
    - *Required under MMA filing requirement*
    - *Apotex submitted letter with MMA filing noting oral terms*
    - *BMS signed FTC certification confirming no oral terms*

Counseling & Developments

- **BMS/Apotex Settlement on Plavix**
  - **Ramifications for BMS**
    - *DOJ Criminal Investigation and Plea Agreement with BMS*
      - two felony counts and criminal fine of $1 million USD
    - *BMS Senior Vice President*
      - $100,000 fine & one year jail time
    - *State Attorneys General*
      - $1.1 million USD fine for misleading States regarding settlement
      - Violation of 2003 Order with States
    - *FTC*
      - $2.1 million USD in civil penalties for misleading FTC regarding settlement
      - Violation of 2003 FTC Order and MMA violation

Counseling & Developments

- **Sanofi/Watson/Synthon Settlement on Ambien CR**
  - In May 2011, the FTC sent letters to Sanofi-Aventis, Watson, and Synthon, alleging that the companies violated the MMA by failing to file agreements (specifically, joint stipulations) related to patent litigation settlements concerning Sanofi's insomnia drug Ambien CR
  - While the Bureau of Competition ultimately recommended that the Commission not pursue an enforcement action, it put the industry on notice that it "will consider enforcement recommendations, including appropriate penalties, in the future when the MMA filing requirements have not been met"
  - Letters made clear that the FTC takes an expansive view of the language requiring agreements to be filed under the MMA. Specifically, "agreements" that must be filed include joint stipulations, regardless of whether the terms have binding effect without court action, and regardless of whether there is any exchange of consideration

Counseling & Developments

- **How FTC Investigations Start**
  - MMA Filing
  - Conduct initial staff review
    - *Read the agreement(s)*
    - *Conduct market research from public sources*
    - *Talk to counsel, if necessary*
  - Convene “pharmaceutical screening committee”
  - Decide whether to initiate an investigation

Counseling & Developments

- **Three Questions FTC Asks When Analyzing MMA Agreements**
  - Does the agreement restrict generic entry?
  - Is there compensation to the generic?
  - Are the parties sharing monopoly profits?

Counseling & Developments

- **Investigations of Settlements**
  - Staff seeks documents and sometimes testimony, using voluntary and compulsory process (e.g. civil investigative demands)
  - FTC first reviews:
    - *Parties' competitive expectations before settlement (the "but for" world)*
    - *Settlement negotiation history*
    - *Sales and financial analyses pre- and post- settlement*
    - *Patent prosecution history and litigation docket*

Counseling & Developments

- **What Settlements Pose the Greatest Risk: Evaluating the Antitrust Risks**
  - **The "Pay for Delay" Parties involved in settlement**
    - *FTC*
    - *Private Parties*
    - *States*
    - *DOJ*
  - **The risks associated with these parties**
    - *FTC as an "investigatory" threat*
    - *FTC as a litigation threat*
    - *Private follow-on suits*
    - *Criminal prosecution*
  - **Factors**
    - *Aggressiveness of conduct (e.g., large payments, long delay relative to remaining patent life)*
    - *Size of market (e.g. Plavix)*
    - *FTC resources*
    - *Company's risk aversion*

Counseling & Developments

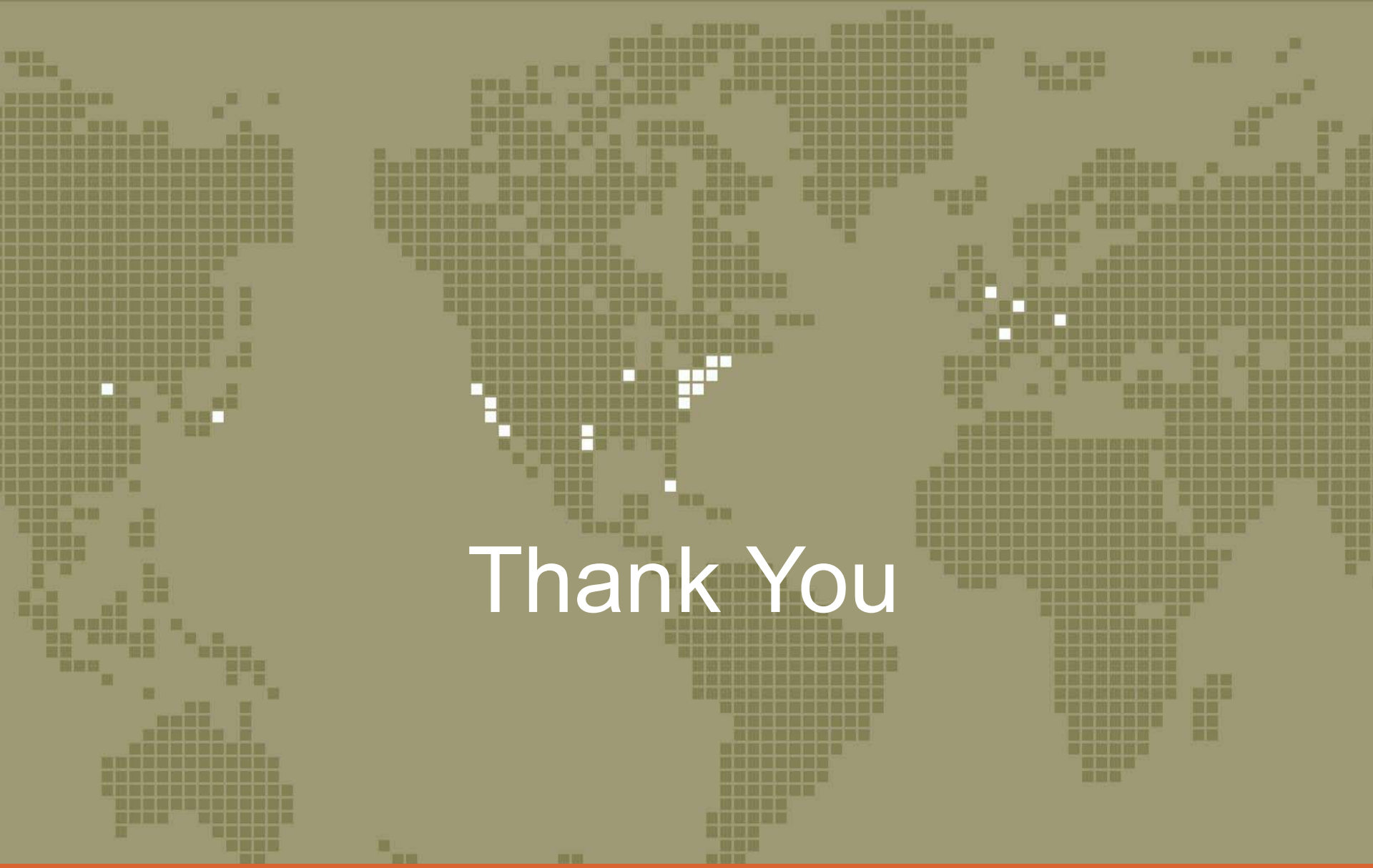
- **Likelihood of FTC Investigation**
  - **Agreements UNLIKELY to raise antitrust scrutiny**
    - *"Patent split" with no compensation or side deals*
    - *Compensation limited to brand firm's litigation costs*
  - **Agreements that are LIKELY to draw FTC interest**
    - *Outright cash payment*
    - *Side deals where terms are unusual or do not look commercially objective*
    - *Brand agrees not to introduce authorized generic*
    - *Agreements where terms or negotiations indicate "pay for delay" settlement*
    - *Restrictions on non-infringing products*

Counseling & Developments

- **Private "Follow-On" Suits**
  - **FTC Actions Followed by Private Antitrust Actions**
    - *Occurs when FTC settles case or brings suit*
      - Hoescht/Andrx (Cardizem patent settlement)
      - Schering/Upsher-Smith/AHP (K-Dur patent settlement)
      - Mylan (supply agreement)
      - Warner Chilcott/Barr (Ovcon supply arrangement)
      - Solvay (AndroGel patent settlement)
    - *Occurs in some instances upon FTC investigation*
      - Cephalon (Provigil patent settlement)
  - **Burdens of Private Antitrust Litigation**
    - *Complex proceedings: involve purchasers at various levels (possibly States and FTC as well), class action certification (patients)*
    - *Lengthy proceedings: Tamoxifen antitrust suit (patent settlement) lasted six years (followed by Supreme Court decision not to review)*

Legislation on Patent Settlements

- **Likelihood of legislation being enacted**
  - Generics & brands in rare agreement: both oppose ban on settlements
  - FTC has renewed focus on this issue
  - Current Chairman has strong ties in Congress
    - *FTC has urged Congress to include the legislation in its deficit reduction plan*
  - President on record that his Administration will seek to prevent anticompetitive agreements between brand name and generic drug manufacturers intended to keep generic drugs off the market
    - *As a Senator, President was cosponsor of Senate bill to ban "pay for delay" settlements*
    - *Unable, however, to include in Healthcare Act*
  - Support for legislation from other groups (AARP, AMA)


Thank You