PHARMACEUTICAL ANTITRUST:
Delayed Generic Entry Cases

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What is Pharma Antitrust?

• General antitrust principles applied to the pharmaceutical industry, generally Rx drugs
• Market for Rx drugs does not behave like most other markets
• Intersection of patent, antitrust, and regulatory law
• Billions of dollars at stake for many drugs
Relevant Pharma Markets

• In antitrust we often need to define “relevant markets” impacted by the conduct.

• Cross- and own-price elasticity analyses can help show presence or absence of price-based competition.

• Antitrust law is focused on price-based competition.

• Most competition between branded pharmaceuticals is not price-based.
Rx Pharmaceutical Market

- Tripartite structure complicates the analysis

Consumers/Patients

Physicians

Payors
Pharma Market Distortions

• People who use the product are insulated from most costs of the product
• Doctors are completely insulated from costs
• Pharma manufacturers exploit these distortions and generally do not compete on price so little to no price elasticity
  – Competition generally focuses on features and benefits
Generic Entry

- Branded Rx drugs often are protected by patents or FDA marketing exclusivity
- Each drug is a specific “molecule”
  - Generics are the same “molecule”
  - Other drugs in therapeutic class are different molecules
- Price competition ensues only upon generic entry
- The “molecule” is the market
Economics of Generic Entry

• Substantial price drop (>30% immediately, >60% after six months)

• Volume shifts automatically
  – Generic mandatory substitution laws

• Brand begins to compete on price
  – Authorized generics
  – Increased rebates or discounts
  – Or not: Harvesting of brand loyalists
Generic Entry: An Existential Threat

• Branded companies lose hundreds of millions or billions of dollars

• Brand pulls marketing to Drs. and DTC
  – Sales would go to generics

• Threat of generic competition is different in kind from other competition
Branded Pharma’s Response

• Delaying generic entry means $$$
• Margins on Rx drugs are >70%
• Even short delays in generic entry mean big $$$
Hatch-Waxman Act

• Governs FDA approval of generic drugs
• Generics have an expedited path to approval
  – ANDAs piggyback on brand’s safety and efficacy data
  – Generics must prove only bioequivalence
• Hatch-Waxman aims to get less expensive generics to market
Hatch-Waxman (con’t)

• Generic manufacturers often challenge brands’ patents covering Rx drugs
  – Generics’ challenges are often successful

• Hatch Waxman allows brands to immediately sue for patent infringement
  – Law prevents FDA from granting “final approval” for 30 months – this is incredibly valuable to the brand
  – FDA may grant “tentative approval”
Schemes to Delay Generic Entry

- Reverse Payment Agreements, § 1
- Sham Litigation, § 2
- Sham Citizen’s Petitioning, § 2
- Walker Process Fraud, § 2
- Product Hopping, § 2
- Cases often involve multiple types of conduct; must analyze the conduct as a whole
Reverse Payment Agreements

• Brand pays generic to drop its patent challenge – and stay off the market
  – Win-win for the brand and generic; purchasers lose
• Courts are mixed on legality
  – *Per se illegal* in 6th Cir.
  – Arguably *per se legal* in 2d Cir.
• Top priority for the FTC
Sham Litigation

• Brand sues generic for patent infringement
• Court finds for generic, often on SJ, and holds patent invalid or unenforceable
• Hatch-Waxman 30-month stay allows brand to win even if they lose
• Plaintiffs must prove brand’s infringement suit is objectively and subjectively baseless
Sham Citizen Petitioning

• Companies can petition FDA to not approve an ANDA
  – Should be based on safety or formulation concerns

• Citizen’s Petitions delay approval of ANDAs
  – Ripe for abuse, and often abused

• Delay itself is the goal

• Same standard as Sham Litigation
**Walker Process Fraud**

- Antitrust violation premised on fraud on the PTO
- Patent applicants have a duty of candor to PTO because applications are ex parte
- Elements track fraud claims
- Often coupled with Sham Litigation and other theories
Product Hopping

- Delay sometimes allows brands to introduce new versions of the product
- Changes are often minimal but can defeat generic competition
- Brands actively convert the market
  - Free samples
  - Pulling the “old” product from the market
Practicalities: Assignments

- Many parties sue based on assignments.
- Indirect purchasers sometimes sue based on assignment of claims from their suppliers.
- Assignees stand in the shoes of assignors.
- Defendants sometimes seek discovery from assignors.
  - Courts are skeptical, see *Androgel* (court denied defendants’ motion to compel individual DPs pursuing by assignment from searching for and producing documents and data held by their assignors).
Indirect Purchasers

• Indirects can sue only for injunctive relief under Sherman Act
  – Indirects pursue damages under state antitrust laws

• Some defendants invoke *Illinois Brick* to dismiss Indirect cases but then argue that “overcharges” are not the proper measure of damages
  – under this argument, no one has any damages

• Damages in Direct and Indirect cases cannot be tried together