PHARMACEUTICAL ANTITRUST: Delayed Generic Entry Cases

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Linda Nussbaum

John Radice

What is Pharma Antitrust?

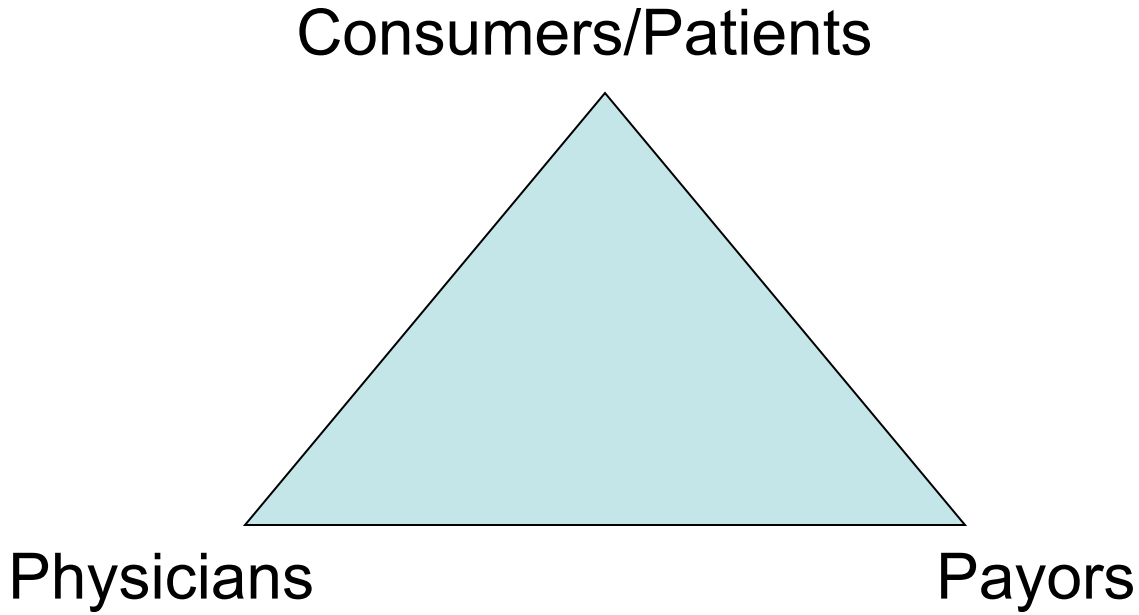
- General antitrust principles applied to the pharmaceutical industry, generally Rx drugs
- Market for Rx drugs does not behave like most other markets
- Intersection of patent, antitrust, and regulatory law
- Billions of dollars at stake for many drugs

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



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