Intellectual Property in Antitrust

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Agenda

• Part 1: Antitrust Basics
  – The main competition laws in the U.S. and EU
  – Patents and market power

• Part 2: Antitrust in high tech/ICT
  – Cooperative technology interoperability standards

• Part 3: Antitrust in Pharmaceuticals
  – Small molecule drugs that are easy to reverse engineer
  – Large molecule biologics that are not
Part I

Antitrust Basics
Relevant Antitrust Laws: US the First in the World

• The Sherman Act (1890)
  – §1: “Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal. …”
  – §2: “Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony …”
Filling in the Holes…

• The Federal Trade Commission Act (1914)
  - §5: “An act or practice is unfair where it:
    • causes or is likely to cause substantial injury to consumers;
    • cannot be reasonably avoided by consumers; and
    • is not outweighed by countervailing benefits to consumers or to competition.”
• The Clayton Act (1914)
  – Defined as illegal certain business practices that are conducive to the formation of monopolies or that result from them
    • Meant to close loopholes in the Sherman Act
  – §3 prohibits:
    • Sales on the condition that (A) the buyer not deal with the competitors of the seller ("exclusive dealings") or (B) the buyer also purchase another different product ("tying") but only when these acts substantially lessen competition
Global Analogues

• European Union: Treaty for the Functioning of the European Union (TFEU)
  – Section 101 is roughly equivalent to Section 1 of the Sherman Act
  – Section 102 is roughly equivalent to Section 2 of the Sherman Act
    • No course of action of illegal monopolization, attempted monopolization
    • Adds “excessive pricing”

• Over 150 antimonopoly laws across the globe, all with their own flavor of the basics found in US and EU
Per Se Violations

- Regardless of the circumstances, these acts are illegal
  - Don’t need to establish any specific harm to competition because more times than not these acts cause harm
  - There is a presumption of anticompetitive harm

- Examples include collusion/cartels, price fixing (Sherman Act §1)
Potential Violations Under the Rule of Reason

• This covers the bulk of antitrust cases in US
  – Illegal monopolization or attempted monopolization
  – Vertical restraints
  – Predatory pricing

• To establish an antitrust violation under rule of reason:
  – Define a clear product and geographic market relevant for the conduct
  – Establish that the accused firm as market power within that market
  – Prove harm to competition in the relevant market
    • Harm to individual competitors is not enough
Do Patents Define Monopolies?

• Patents provide exclusivity rights
  – Patent holders can (attempt to) exclude others from using the technology
    • Holder can employ the technology or shelve it
    • Can license or not
    • If licensed, that can be exclusive or widespread

• Competition agencies and courts agree that a patent does not necessarily define an economic monopoly
  – Because patents don’t necessarily define a relevant market
  – Judge Frank Easterbrook: “That a patent covers an "entire" idea or product no more implies monopoly than the fact that USX Corporation owns the "entire" South Works in Chicago.”
Novelty is not Enough

- Patented technology may lack demand
  - Could the holder of the “dog watch” patent affect any market at all?

- Or it may have substitutes:
  - >4,600 U.S. patents registered for toothbrushes
Part 2

Antitrust in Technology Standards
The Role and Function of Standards

• Standards are common rules whose goal is to reduce variety
  – A coordinated selection of a common technology by more than one actor
    • Firms that will make products embodying the standard often participate as well

• Different types of standards
  – Some standards enforce public policy objectives (safety, health, environment)
  – Quality standards reduce information asymmetries and lower transaction costs
  – Compatibility standards define complex systems of interoperable products and services
The Stakes are High

• Technology standards permeate the world economy:
Are SDOs Cartels?

• In the early days, SDOs needed competition agency approval
  – They are organizations of rivals, cooperating to limit options in the marketplace

  – “People of the same trade seldom meet together, even for merriment and diversion, but the conversation ends in a conspiracy against the public, or in some contrivance to raise prices.”
    - Adam Smith
The Modern View is Far More Tolerant

• Agencies now recognize that the benefits from standard development generally outweigh the risks
• Industrial age tech revolution was often led by individual innovators
  – So need for coordination less prevalent
• Many modern inventions require cooperation
“Coopetition” is high within single products
One Additional US Antitrust Law for Standards

• The Standards Development Organization Advancement Act Of 2004 (15 US Code § 4302)
  – SDO activity “shall not be deemed illegal per se”
    • Standards setting/development conduct judged on the basis of its reasonableness
    • Consider effects on competition in properly defined, relevant research, development, product, process, and service markets.
  – No treble damages
Risk of Anticompetitive Conduct in Standards

• Diversity of member businesses leads to diversity of objectives
  – Upstream competition
    • Firms developing new technologies compete to define the standard
  – Downstream competition
    • Firms implementing the standard compete in component and end product markets

• Numerous interaction points lead to numerous dispute points
  – Supply agreements
  – Joint ventures
  – Patent licensing
Are “Standard Essential Patents” Monopolies?

• SEPs cover patented technologies that define a standard
  – They are likely in demand and the relevant SDO eliminates substitutes

• 100s of patents (or more) can be disclosed as potentially essential for a technology standard
  – Does it make economic sense to have 100+ monopolies for a single product?

• And SEPs are perfect complements with other SEPs
  – Can a patent holder with complementary technology unilaterally raise price, especially when such prices are negotiated bilaterally?

• Complex products can implicate numerous standards
  – Estimate that laptops embed >250 technology standards
Market Power Abuse: Patent Holdup

• Definition:
  – SEP holder uses implementer “lock-in” to standard to extract royalties exceeding the value of the patented technology
  – Exploiting implementer switching costs to move away from standard

• Prerequisites:
  – Incomplete contract
  – Opportunistic behavior with “guile” / surprise
  – No empirical evidence that this is a systemic problem

The economics of standard setting
“FRAND” Licensing

• Anticipating the risk of holdup, most SDOs enact IPR policies
  – Disclosure: rules guiding how and when members should notify the SDO that they hold patents that might be essential to practice the standard
  – Licensing: most adopt rules that ask members with disclosed patents to commit to license them on Fair, Reasonable, and Non-Discriminatory terms and conditions (FRAND)

• Allegations of holdup are made regularly in standard cases
  – Antitrust argument is that supra-FRAND royalty rates distort downstream market competition
  – Some argue this is a contract law issue, not antitrust

• Federal Circuit has ruled that theory or risk is insufficient
  – case-specific proof of holdup or attempted holdup is necessary
Does SEP Holder Have Sufficient Market Power to Practice Holdup?

• To practice holdup, must have market power to leverage
  – Optional and trivial SEPs unlikely to have any leverage power

• The production chain matters as well; downstream use affects upstream market power
  – Example: Advanced TV Standard (ATSC) required by the FCC for digital TV transmission
    • But terrestrial TV is not the only way to view video content
      – Cable, satellite do not require ATSC;
      – Computer monitors can stream Hulu, Netflix, Amazon, etc.
Licensee Holdout

• Anticompetitive behavior possible by all market participants, not just SEP holders
  – Because standards are published with detailed implementation guides, implementers can introduce compliant products without licenses to any SEPs

• Hold out is a refusal to take a FRAND license, refusal to negotiate in good faith, or other delay tactics to pressure no or below-FRAND royalty payments

• Counter argument in FRAND antitrust cases
The Kinds of Cases Brought

• All the traditional antitrust allegations are present
  • Collusion
  • Anticompetitive unilateral conduct
    » Patent ambush
    » Supra-FRAND ("excessive") pricing
• Plus miscellaneous other antitrust charges
  • Royalty stacking
• Breach of contract
  • Implicit assumption that SDO contract breach affects competition
• And patent infringement, with a twist
  • SEP infringement cases frequently include antitrust counterclaims
    (e.g., deception or manipulation of SDO, breach of FRAND)
Key Decisions: Foreclosure

- **Allied Tube v. Indian Head, Inc. 486 U.S. 492 (1988)**
  - Safety standard for electrical conduit
    - Relied upon by electrician and construction industries
  - Incumbents all made metal conduit; Allied Tube made PVC conduit
  - Incumbents stacked working group meetings to prevent PVC conduit from being included in the standard
    - Not based on quality or safety reasons
    - Prevented the use of PVC conduit, foreclosing Allied Tube from the market
Key Decisions: FRAND Licensing Process

  – SEP holder must make a FRAND licensing offer before seeking an injunction for infringement

• EU: *Huawei v. ZTE*, ECJ (2014)
  – SEP holder must contact alleged infringer, explain infringement, and make an opening license offer in writing
  – Licensee must respond to the opening offer in a timely fashion, and if the offer is not accepted, must provide a counter offer in writing in a timely fashion
  • Licensee must negotiate in good faith, without delay or SEP holder can seek an injunction
Key Decisions: Patent Ambush as an Antitrust Violation

• *Broadcom Corp. v. Qualcomm Inc.*, 501 F. 3d 297 - Court of Appeals, 3rd Circuit 2007
  – Broadcom alleged that Qualcomm didn’t properly disclose all of its relevant patents and didn’t abide by a FRAND commitment it had made
  – Parties settled before final decision
  – But in summary judgement ruling, the court found that (if proven) the allegations would comprise an antitrust violation
Key Decisions: Anticompetitive Tying and Bundling

• *Princo Corp. v. International Trade Com'n*, 616 F.3d 1318 (2010)
  – Patent pool accused of anticompetitive tying
  – Court ruled found otherwise

• *MPEG LA v. Toshiba America Info Systems*, Index No. 162716/2015, 2019
  – Toshiba counterclaim of patent misuse through tying in a patent pool
  – Case goes to trial later this year
Key Decisions: Royalty Stacking and Holdup

  - D-Link presented a theoretical argument:
    - If every SEP holder charged what Ericsson charged, the aggregate rate would exceed 100%
  - Court ruled that case specific evidence is needed to establish stacking claim
    - Patents are not created equally, so rates are not equal
    - D-Link could have presented the aggregate royalty burden it faced, but never presented any such evidence
Part II

Antitrust in Pharmaceuticals
Additional Laws for Small Molecule Drugs

• Hatch-Waxman (1984):
  – Governs FDA approval of new small molecule drugs and their generics
  – Balances incentives for new drugs with easier entry for generics
    • Provides patent extension to compensate for time lost in FDA approval
    • Additional 5-yr market exclusivity for new chemical entities
    • Generics got abbreviated FDA filing – rely on bioequivalence to brand drug
    • Generics can “enter” a market by announcement – Paragraph I-IV
    • Brand firm can sue generic for patent infringement after announcement

• State Generic Substitution Laws
  – All states have some form of this law
  – Provides automatic substitution of generic for brand at the pharmacy, unless the doctor prescribing writes “dispense as written”
Are Small Molecule Drug Patents Monopolies?

- More than one kind of pharma patent
  - Patent on active pharmaceutical ingredient (API)
  - Patent on pill coating or other non-API element of the drug
  - Patent on manufacturing process (cost savings, efficacy enhancement)
Defining Pharma Markets and Measuring Market Power

• Key question here is substitution
  – Does the API define a unique market (e.g., Namenda for Alzheimer’s)?
  – Or are multiple similar treatments available (e.g. numerous statins for cholesterol treatment)

• Antitrust plaintiffs nearly always argue that only the brand and its generics define the relevant antitrust market
  – Whether that is true requires empirical analysis
  – Competition from other brand drugs is often important
“Pay for Delay” or Reverse Settlement

• Hatch-Waxman created a new kind of antitrust threat: the reverse settlement
  – In traditional patent infringement litigation, the accused infringer pays the patent holder to settle, compensating for damages and/or for a future license
  – In pharma, the accused infringer (generic) doesn’t make any sales, so no damages
  – Generic has little at risk: to induce settlement the brand pays the infringer
Pharma Collusion?

- Antitrust issue is collusive monopoly market sharing
  - Are brand and generic conspiring to prevent generic entry, which harms consumers?
    - Is the settlement payment a fair market value to end the patent infringement litigation and provide entry for generic before patent expires?
    - Or is it brand paying generic to delay its entry into the market beyond the entry date most likely if litigation had continued?
Rule of Reason Analysis for Reverse Settlement

- *FTC v. Actavis* Supreme Court (2013) set the rules for evaluating reverse settlement cases
  - Rule of reason standard
  - If payment is “large and unjustified” it is anticompetitive
- Lower courts have struggled with what is “large” and what is “unjustified” ever since
- Court tried to avoid “strength of patent” assessments
  - Patent trial inside of antitrust trial
  - But if patent is likely valid, then no “delay” to generic entry, so cases tend to present evidence on patent strength during the antitrust trial
“Product Hopping”

• Antitrust allegation that brand firm introduces new version of successful drug just before its patent expires
  – Get a patent on the “new” version to prolong the monopoly
  – Generics point to “trivial” changes, such as from tablet to capsule form, or small changes to API strength (e.g., 100 mg to 150 mg)
    • Argue that “tweaks” prevent automatic state substitution
    • Generics claim they cannot advertise/market drugs, profit margin too small
    • So the product switch effectively foreclose generic entry
Rule of Reason for Drug Switches

• No Supreme Court guidance on this issue yet
  – District Courts have been applying rule of reason analysis to these cases
    • Is consumer choice affected?
    • Does the product change reflect innovation? Does it increase consumer welfare?
    • But are courts equipped to evaluate what is and isn’t innovative?

• Soft switch vs. hard switch
  – Did the brand remove the old version from market when it introduced the new version (a hard switch)?
    • If so, generics cannot enter for old, off patent version
    • And consumers may be forced to switch to new version when they don’t want to
  – Under soft switch, old version is left on market and modified version added
    • Consumer choice increased, welfare enhancing
    • Some generics still argue soft switch is anticompetitive, but no court rulings on this yet
Antitrust Issues in Biologic Drugs (Large Molecule)

• Most biologics are complex mixtures that are not easily identified or characterized
  – No single API; made from living microorganisms, plant tissue, animal cells
  – Examples: Humira, Enbrel, Avastin

• Not governed by Hatch-Waxman
  – No “generic” versions per se; get “biosimilars” instead
  – No “Orange Book” for patent listings

• Still have patents on the innovations and processes involved
Additional Law for Large Molecule Drugs: Biologics Price Competition and Innovation Act (BPCIA)

• BPCIA (2009) analogous to Hatch-Waxman:
  – Provides abbreviated pathway for biosimilars to gain FDA approval through submission of an abbreviated Biologics License Application (aBLA)
  – Facilitates litigation during the period preceding FDA approval

• Creates a “patent dance”
  – Within 20 days of aBLA acceptance, biosimilar applicant provides the reference product sponsor confidential access to its aBLA
  – 60 days later, reference product sponsor must provide the biosimilar applicant with a list of unexpired patents; series of info exchanges
  – Biosimilar second notice when 180 days out from product launch
  – Either party can sue at this point
Key Cases: Biologics Exclusive Dealing

• Pfizer Inc. v. Johnson & Johnson, E.D. PENN (2:17-cv-04180)
  – Pfizer alleged anticompetitive exclusive dealing
  – J&J forced exclusive deals on insurance companies, pharmaceutical benefits managers (PBMs)
    • Cannot reimburse any other biologic; only non-biologic alternative treatments
    • Use rebates and discounts to induce insurance company and PBM to enter the deal
  – Case has survived summary judgement…
Key Cases: Foreclosure of Biosimilars

• Consolidated class actions filed against Abbvie, N.D. IL
  – Classes allege that “AbbVie has erected significant barriers to entry to block biosimilar competition” for Humira
  – Harmed consumers by restricting competition, raising Humira prices over time, preventing prices from falling with competition