Access to Health Technologies, Patents and Prices: Capacity-building Consultation on the Use of Competition Law to Promote Affordable Access

Session 2: Anticompetitive Practices

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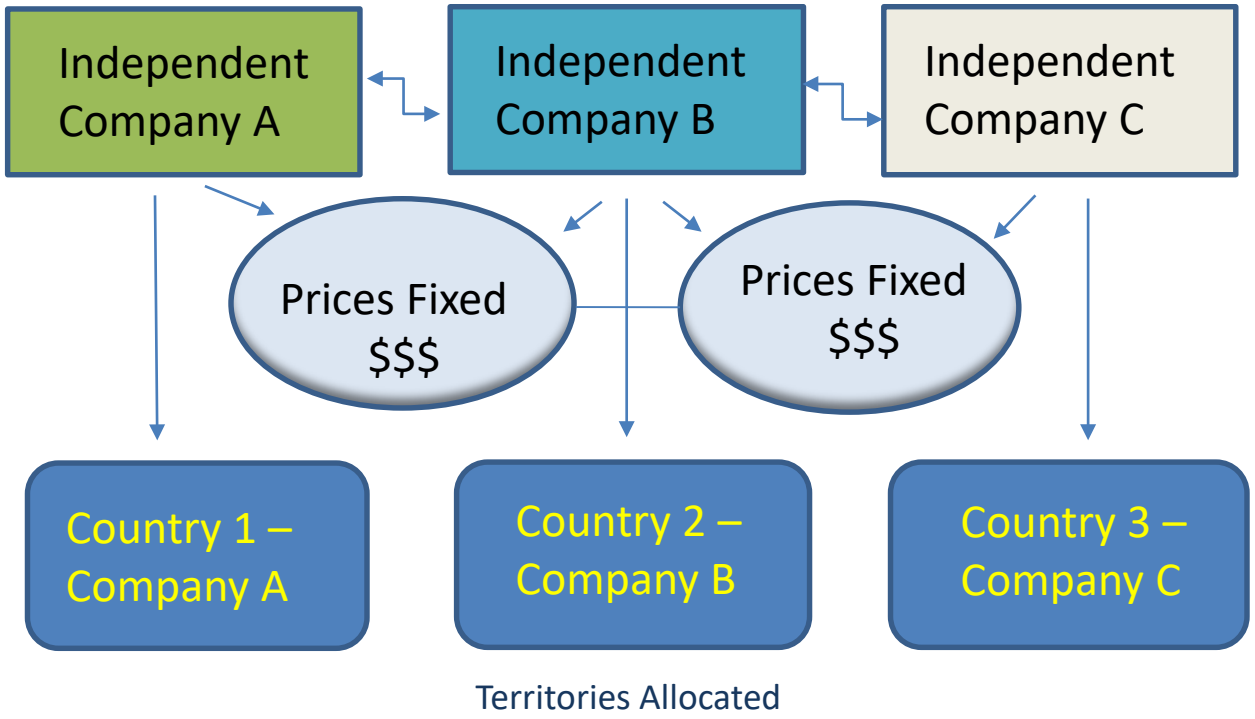
Typology of Anti-competitive Practices

- Horizontal: between independent enterprises that are competitors in the production and/or distribution of the relevant goods or services
- Vertical: the supply and distribution chain from a single producer, such as the chain moving from manufacturing to supply of wholesalers and distributors to retail sellers
- Anti-competitive objectives of behaviors may be similar, but specific competition rules may vary

Typology of Anti-competitive Practices

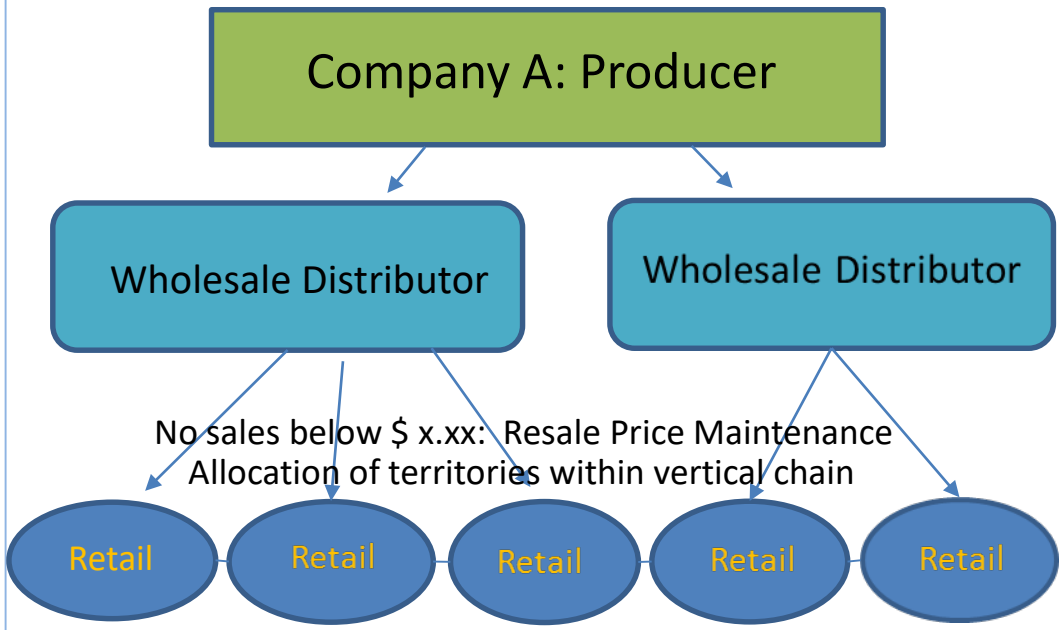
- Horizontal



Territories Allocated

Price Fixing & Allocation of Territories *Per Se* Unlawful

- Vertical



Most vertical restraints assessed under "rule of reason"

Agreements between Undertakings/Abuse of Monopoly-Dominant Position

- Anticompetitive conduct may involve an agreement among two or more parties to restrain trade, whether in horizontal or vertical relationship
- "Monopoly" and "dominant position" generally refer to a single firm capable of dictating pricing and terms of supply in relevant market
  - Ownership of a monopoly is not in itself wrongful
  - Competition law violations require abuse in obtaining or maintaining monopoly/dominant position

Per se and Rule of Reason

- Per se or "hard-core" anticompetitive conduct: understood to be unjustifiably anticompetitive, i.e. not subject to balancing assessment
  - Includes price-fixing among horizontal competitors and horizontal output restraints
- “Rule of reason” assessment: potentially pro-competitive or neutral effects of agreements balanced with potentially market-restrictive effects to decide whether agreements are, on the whole, anti-competitive

Legitimate Profit Maximization

- Horizontal competitors legitimately seek to maximize profits by, *inter alia*:
  - Reducing costs of production and prices
  - Developing improved or innovative products
  - Increasing advertising expenditures (or improving quality of advertising)
  - Improving means of delivery
  - Improving after-sales service
- Aggressive competition is not in itself wrongful; anticompetitive conduct crosses a legitimacy threshold

Reasons for Horizontal Anticompetitive Conduct

- Enterprises in the same sector may have overbuilt production capacity; consumer demand insufficient to absorb
- Natural conditions, including in the agricultural sector, may create excess supply
- Absence of alternative suppliers may insulate group from competitive threats (e.g. with long lead time for additional actors to enter the market)
- Group may agree to restrict output and/or fix prices to secure greater share of national wealth

Restraints among Horizontal Competitors

- Price-fixing: actual or potential competitors agree not to sell their product(s) below a set price
  - Price-fixing among horizontal competitors widely considered *per se* illegal – it cannot be justified by alleged pro-competitive benefits
  - Where health product margins are low, *e.g.*, generic medicines, temptation to fix prices may be substantial (*see* bid-rigging)
- Output restraints: enterprises fix the total aggregate supply of the product on the market, and allocate shares of that supply among the colluding enterprises; supports price
  - Typically *per se* illegal

Restraints among Horizontal Competitors

- Allocation of geographic territories: segment regional, national or subnational markets
- Hard form: potential competitors agree not to sell or supply product into each other's allocated territory
- Softer form: potential competitors agree not to actively pursue sales into each other's allocated territory but leave it open to respond to unsolicited inquiries (i.e. passive sales)
- Allocation of geographic territories, output restraints and price-fixing may form part of the same collusive arrangement

Restraints among Horizontal Competitors

- *Secretive practices*: participating enterprises and their employees may avoid committing an agreement to writing, and may instead rely on oral agreement. Participating enterprises may discuss arrangements in “secret” locations to make detection by authorities difficult
- *Industry group meetings*: while executives within same industry are gathered at single location for *bona fide* reason (*e.g.*, to discuss prospective regulatory standards), risk is raised of agreement on anti-competitive arrangements

Bid-rigging, corrupt payments and related practices in procurement

- In LMICs governments may be largest procurers of health products and services
- Competitive bidding used frequently, typically through secret bids
  - Lowest priced qualified bid meeting specifications accepted
- Creates temptation for prospective bidders to "rig" bidding by fixing lowest-priced bid, and allocating current (e.g., dividing supply under awarded contract) and/or future tenders among suppliers

Bid-rigging, corrupt payments and related practices in procurement

- Collusive bidding arrangements not infrequently accompanied by corrupt payments to government officials
  - To assure that evidence of bid-rigging is not explored or reported
- From competition law standpoint, bid rigging represents price-fixing among typically horizontal competitors (though may be "intra-brand" (i.e. same product) collusion among independent distributors)
- Examples of bid-rigging extend to provision of health-care services

Buyouts of Patent Challenges

- Generic producers challenge the validity of patents for early market entry; patent owners decide their better financial interest served by “buy-out” of generic challengers rather than to risk adverse court decision invalidating patents
- Various forms of compensation
  - Straightforward cash payment
  - License to generic producer to market patented or other products
  - Allocation of geographic markets
- Objective to extend patent owner control to end of patent term

Buyouts of Patent Challenges

- From standpoint of patent owner and generic producer, transaction is "win-win"
- Patent owner retains high revenue stream; generic producer may earn substantial income without litigation risk
- Prospective *loser is consumer/patient*, assuming generic challenge successful
- In 2013 US Supreme Court decided that buyout settlements of generic producer patent challenges are subject to “rule of reason” assessment under the antitrust laws

Federal Trade Commission (FTC) v. Actavis, U.S. Sup. Ct., 526 U. S. 756 (2013)

"Given these factors, it would be incongruous to determine antitrust legality by measuring the settlement's anti-competitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well. And indeed, contrary to the Circuit's view that the only pertinent question is whether 'the settlement agreement ... fall[s] within' the legitimate 'scope' of the patent's 'exclusionary potential', ... this Court has indicated that **patent and antitrust policies are both relevant in determining the 'scope of the patent monopoly'—and consequently antitrust law immunity—that is conferred by a patent**." (bold added)

Unlawful monopolization/ abuse of dominant position

- "Monopoly" used in the early development of antitrust law in USA to describe single firm that dominates relevant market
- "Dominant position" adopted in European competition law to describe same phenomenon
  - Monopoly or dominant position may be shared by more than one enterprise, though the exception
- To hold monopoly position firm must have sufficient power in its relevant market to raise prices above competitive market prices and maintain those prices for a substantial period of time
  - Reflects absence of concern that potential competitors will enter market and undermine the monopolist's market power

Unlawful monopolization/ abuse of dominant position

- Abuse of dominant position does not require a consensual contractual relationship between the dominant enterprise and those with which it is doing business
- Predicate to determining that monopoly position exists is defining *relevant market*
  - Individual firm may dominate sales in narrow product line but not be able to raise prices (above competitive market prices) because of availability of substitute products offered by competitors
  - Relevant market defined by product/service and geography

Unlawful monopolization/ abuse of dominant position

- Generally not unlawful for firm to hold monopoly provided it has obtained by lawful means, such as by producing better product
- Not unlawful for firm to be dominant in relevant market
- Unlawful for firm to acquire or seek to acquire monopoly *through anti-competitive means* or to *abuse* dominant position
- Potential abusive practices include “exclusive dealing arrangements”, “predatory pricing” (e.g., pricing below cost of production with intent to drive competitors from market), blocking interoperable technical standards, unjustifiable refusal to license, etc.

Dominant Position and Patents

- Patent confers on its owner right to exclude third parties from introducing an identical or equivalent (i.e. infringing) product onto the market
  - Despite legislative monopoly, patents may be abused
- For medicines, each patent owner possesses monopoly for specific product but does not necessarily enjoy monopoly in therapeutic class (i.e. there may be acceptable substitutes)
- Abusive or excessive pricing difficult area of competition law: when is patent owner's "right" to establish price used to unfairly extract payment from consumers?
  - Is there an unreasonable relationship between the price being charged for a medicine and the expenses of the patent owner?
- Excessive pricing also relevant to generics markets where supplier acquires or maintains dominant position

Dominant Position and Patents

- In perfectly competitive market, sellers and purchasers determine prices based on supply and demand
- Market for health products, including medicines, is not perfectly competitive; subject to numerous interventions by government regulators and others
- Patient/consumer demand distorted by potentially absolute need for treatment; demand "inelastic“ (higher price does not diminish demand)
- Consumer protection objective of competition law may take precedence

Excessive Pricing Doctrine

- Excessive Pricing Doctrine
  - Most competition laws expressly or by application of general principles authorize actions against excessive pricing
  - Treaty on Functioning of European Union

    Article 102

    Any abuse by one or more undertakings of a dominant position within the internal market or in a substantial part of it shall be prohibited as incompatible with the internal market in so far as it may affect trade between Member States. Such abuse may, in particular, consist in:

    (a) directly or indirectly *imposing unfair purchase or selling prices* or other unfair trading conditions

*See Frederick M. Abbott, *Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health*, Dec. 2016; available at SSRN: https://ssrn.com/abstract=2719095

Paradigm Case

- Paradigm case Sovaldi/sofosbuvir introduced by Gilead at $84,000 for 12-week course of treatment
  - Acquired through purchase of Pharmasett for US$11 billion in 2011
    - Planning to introduce at US$35,000 for course of treatment
  - Gilead revenues approximately US$14 billion in each of first two sales years
    - Pure financial engineering
- Three pricing options proposed by investment bankers: red light, yellow light, green light
- Gilead selected yellow light that represented price that would not quite bankrupt state public health purchasing authorities, while generating mid-range pricing backlash

Establishing Benchmark

- Excessive pricing evidentiary issues (e.g., establishing reasonable benchmark prices), transparency
- Transparency issue: pharmaceutical originators have not been required to disclose R&D costs, especially at "granular level"
  - Originators provide information to investment bankers in context of prospective mergers and acquisitions
  - Factual/evidentiary issues not uncommon in litigation, including expert assessment of whether particular R&D efforts within scope of approved product

Reasonable Price Methodologies

- Cost-plus profit, adjusted for risk
  - Preferred approach
- Reference pricing
- Bargaining between monopoly supplier and monopsony purchaser
- Cost based on corporate assessments of acquisition targets
- Cost based on reporting of R&D and related expenditures to tax authorities
- Cost based on securities and exchange commission reporting

Adjusting for Risk

- Establishing risk-adjusted R&D costs and mark-up
    - Pharmaceutical industry R&D budgets are carefully managed, not a "black box"
    - Contrary to originator position, the cost of R&D reflecting successful and unsuccessful efforts reasonably proximate to approved product can be determined
- Drug development risk varies in relation to number of unknowns
- Government (e.g., NIH) funds basic research seeking to reduce unknowns and concomitant risk factors
- Level of risk varies depends on structure of investigating institutions (e.g., single or multi-focus)
  - Multi-focus institutions typically subdivide budget among research units
- Certain costs should be excluded
  - Basic research funded by government, executive salaries above established limits, opportunity cost of money, tax incentives

Supra-baseline “Excess”

- After determining cost: must establish what constitutes a price "excessive" in relation to it
- Establishing an acceptable norm of profitability can be accomplished by comparison with others in the same industry, or with others in other industries
- Difficulty with comparing other Pharma originators is that historical pricing practices may reflect excess
- In recent cases where the medical community and public have been "shocked" by pricing practices, may not be difficult to determine that prices are excessive, but establishing reasonable price plus profit may be necessary for remedial purposes

Patent Pools

- Two or more companies in the same sector combine resources to undertake R&D activities and/or to produce products based on contributed technology
- Potentially places former or potential competitors in advantageous position vis-à-vis third-party competitors without access to pool
- Pooling has potential procompetitive advantages (e.g., increased innovation) where it does not lead to overly concentrated market

Patent Pools

- Competition authorities typically assess patent (and other IP) pools on case-by-case basis (i.e. rule of reason), looking at specific features of pool (*e.g.*, extent to which open to third parties, whether pool subject to independent management, extent to which access to technologies provided)
- Medicines Patent Pool illustrates public-interest benefit of voluntary contribution of patents into pool from which generic producers may draw, subject to product and geographic limitations

Mergers and Acquisitions

- Mergers and acquisitions are a significant phenomenon in healthcare industries generally
  - Merger is two or more enterprises combining their assets, liabilities and business (combination may take a variety of legal/financial forms)
  - Acquisition is one enterprise taking over assets, liabilities and business of another enterprise (may be accomplished through different legal/financial mechanisms)
- Mergers and acquisitions affect hospitals, doctors' practices, insurance providers (both medical care and pharmaceutical benefits), pharmaceutical researchers and producers

Mergers and Acquisitions

- Market definition important
  - Combination of hospitals or doctors' practices may create anticompetitive situation in comparatively small geographic area as consumers/patients range of travel limited
  - In the pharmaceutical sector, combining companies may have overlapping portfolio of therapies (patented or non-patented), and elimination of competing therapies may raise prices of reduced portfolio to purchasers
- Pharmaceutical originator merger may result in reduction of R&D targets and expenditures

Mergers and Acquisitions

- Market concentration may limit opportunities for smaller scale researchers to out-license or sell medical innovation
- Competition authorities typically have power to review mergers and acquisitions, and to establish conditions for approval (e.g., divestiture of part of drug portfolio to third-party)
- In absence of voluntary divestiture or agreement to conditions, competition authorities may need to sue to block combination
  - Global scale of some businesses makes control by national competition authorities problematic

Vertical Restraints

- For health technologies, typical product is physical good (a pharmaceutical), combination of chemicals, biological materials, excipients, etc. delivered through some means (e.g. tablet, capsule, injectable)
- May be manufactured within country or imported, in whole or part
- A number of steps in manufacturing chain where efforts may be made to limit competition
  - E.g., acquisition of raw materials (basic chemicals), manufacture of APIs, distribution through wholesalers, retail sale by pharmacies

Vertical Restraints

- API producer may seek to restrict uses by formulators
- Finished product producers may seek to impose selling price restrictions on distributors or retailers (i.e. resale price maintenance)
  - Resale price maintenance formerly *per se* illegal in the USA; now assessed under rule of reason
- Requirement to purchase additional parts of product line as a condition to purchasing desired product (i.e. product "tying" or "package selling")

Vertical Restraints

- Requiring purchaser to acquire all products from single source (i.e. *exclusive dealing*)
- Refusing to do business with particular market actors (i.e. *refusal to deal*)
- Charging different prices to similarly situated purchasers with intent to eliminate competition (i.e. *unlawful price discrimination*)
- Restricting purchaser/reseller to use in particular markets (i.e. *field of use restrictions*)

Vertical Restraints

- Limiting geographic territory in which purchasers may distribute/resell (i.e. territorial allocation)
  - Whether parallel trade into market may be restricted depends on relevant intellectual property law rule of exhaustion
  - Where parallel trade otherwise allowed by IP law, territorial restraints may be anticompetitive
    - An attempt to limit price competition from imported products
    - IP owner may attempt to circumvent IP rule by limiting quantity of goods placed on market
- Foregoing practices typically assessed under rule of reason (i.e. do procompetitive benefits outweigh anticompetitive harms?)

Vertical Restraints in Technology Market

- Health technologies affected by various intellectual property (IP) rights: patent, trademark, trade secret, copyright and regulatory data protection
  - Each potentially may be used anti-competitively
  - IP may be used by owner or licensed to third-party
- EU and USA guidelines establish combined market share thresholds pursuant to which technology licensing presumed not anticompetitive

Vertical Restraints in Technology Market

- Patent owner may require that licensee "grant back" innovations made with respect to patented technology. When licensee may not use technology, referred to as "exclusive grant back".
  - In EU, hard-core prohibition of exclusive grant backs. In USA assessed under rule of reason.
- Licensee may be precluded from challenging the validity of patent (i.e. no challenge clause)
  - Prohibited by EU, rule of reason assessment in USA

Vertical Restraints in Technology Market

- Patents generally allow owners to prevent others from making, using or selling invention. Patent owners may have somewhat more flexibility then ordinary market actor in licensing based on right to alternatively block competition (i.e., within legitimate zone of patent protection)
- But, patent licensing remains subject to competition law control. Recall US Supreme Court holding in *FTC v. Actavis*: extent of "immunity" conferred by patent subject to competition law control