

# Competition law and the pharmaceutical sector

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## Some preliminary ideas ...

- Rules intended to protect competition in order to maximise market efficiency and consumer welfare.
- Protection of competition versus protection of competitors.
- Many systems of competition law in the world, in all continents and in all types of economies.
- Growing belief that competitive markets are beneficial for all relevant stakeholders.
- US Supreme Court: "unrestricted and open competition is the cornerstone of our free enterprise system" (parallelism with Bill of Rights, US vs Topco 1972)
- European Union: Competition law also as a tool for market integration.
- Consequences of breaching anti-trust law may be very important.

# Overview of practices controlled by competition Law

- **Anticompetitive agreements**

- Agreements that have as their object or effect the restriction of competition are unlawful. In the EU system, exemptions may apply.
- Horizontal agreements - between competitors.
- Vertical Agreements – between firms at different levels of the market.

- **Abusive behaviour**

- by firms with substantial market power that enables them to behave independently on the market without regard to competitors, customers and ultimately consumers.

- **Mergers**

- certain mergers cannot be completed until the approval of the competition authority.

# Institutional structure of EU competition Law

## ▪ **European Commission**

- Responsible for fact finding, taking action against infringements, imposing penalties, conducting sectorial enquiries, developing policy and legislative initiatives.
- Cooperates with competition authorities around the world.
- **DG COMP** is the Directorate responsible of the Commission specifically responsible for competition policy.

## ▪ **Court of Justice of the EU**

- **General Court**: its task is hearing of appeals against Commission decisions.
- **Court of Justice** hears appeals from the General Court on points of law only.

## ▪ **National Competition Authorities and Courts**

- Apply EU competition rules, as they are directly applicable and produce direct effects.
- Apply local competition rules in cases where only national markets are affected.

# Competition law and the Pharma industry

- The pharmaceutical sector has been the focus of competition authorities around the globe, including the EU Commission.
- 2019 Commission Report on competition enforcement in the pharma industry (2009-2017):
  - Anti-competitive practices may endanger patient's access to affordable and innovative essential medicinal products.
  - 29 cases against pharma companies with fines in 87% of all infringement decisions (over EUR 1 billion).
  - Sector-specific regulation does not mean general competition law does not apply.
  - Effective competition from generics and biosimilars represents a vital source of price competition → some strategies intended to extend the commercial life of the reference medicines are under competition law scrutiny.
  - Anti-competitive innovative product development strategies.
- There is also a need to discuss regulatory obstacles to competition.

# Sources of Competition Law

- The EU Treaties – Treaty of Functioning of the EU.
- EU specific regulations.
- Case law of the Courts.
- Soft law and the decisions of the EU Commission.
- National laws and decisions.
- International Competition Network (ICN): virtual organisation which brings together more than 100 of the world's competition authorities.

# Anticompetitive Agreements- Art. 101.1 TFUE

- Art. 101.1 TFUE prohibits:
  - Agreements and concerted practices;
  - Which may affect trade between member states; and
  - Which have as their object or effect is to prevent, restrict or distort competition within the internal market.

# Anticompetitive Agreements - Art. 101.1 TFUE

- **What are agreements?**

- Written (contract, e-mail exchange) or oral agreements.
- Informal are also affected. Irrelevant if it was believed not to be binding.
- Expired agreements which effects continue to take place.
- Even without an enforcement mechanism.
- The mere participation in an illegal meeting between competitors.
- Concerted practice or consciously parallel action. Conducts that cannot be explained absent a mutual interest and consensus.
  
- Both horizontal and vertical agreements are subject to scrutiny.
- Task allocation among a group is not an agreement (intra-entreprise conspiracy is allowed).



# Anticompetitive Agreements - Art. 101.1 TFUE

## HARD CORE RESTRICTIONS

- Agreements that have as their object the restriction of competition (*Per se*).
- No need to prove that the parties have the intention of restricting competition.
- No need to prove the effects on the market.
- In theory, they can be justified in exceptional circumstances, but in practice this happens very rarely (Art. 103 TFEU). (i.e. Covid-19 cooperation).
- Let's see some examples ...

# Anticompetitive Agreements - Art. 101.1 TFUE

## **HARD CORE RESTRICTIONS** - Some examples:

- Horizontal agreements:
  - Prix fixing, exchange of information on prices.
  - Share markets or source of supply.
  - Limit or control production.
  - Prohibit or limit parallel trade within EU.
  - Concertation on public procurement.
  
- Vertical agreements:
  - To impose fixed or minimum resale prices.
  - To impose export bans.
  - Restrictions within selective distribution systems other than prohibiting a member of the system from operating out of an unauthorized place of establishment.

# Anticompetitive Agreements - Art. 101.1 TFUE

## EFFECT RESTRICTIONS

- Necessary to conduct an extensive analysis of its effects on the market.
- Need to be examined considering the context, factual and legal consequences.
- Some examples:
  - Exclusivity or non compete obligations.
  - Non-challenge agreements of a patent or licensed trademark.
  - Territory restrictions.
  - Selective distribution.
- They can benefit from the exemption (Art. 103 TFEU).

# Anticompetitive Agreements - Art. 101.1 TFUE

## CONDITIONS TO BENEFIT FROM EXEMPTION UNDER 101.3 TFUE

- Art. 101.3 provides a legal exception – Art. 101.1 may be declared inapplicable if the following cumulative conditions are met:
  1. Efficiency gains;
  2. Indispensability of the restriction;
  3. Fair share for consumers; and
  4. No elimination of competition in a substantial part of the market.
- Some examples:
  - Synergies resulting from an integration of existing assets: the combination of two existing technologies that have complementary strengths may reduce production costs or lead to the production of a higher quality product.
  - Some distribution agreements may give rise to qualitative efficiencies: specialised distributors, for example, may be able to provide services that are better tailored to customer needs or to provide quicker delivery or better quality assurance throughout the distribution chain.

# Anticompetitive Agreements - Art. 101.1 TFUE

## CONDITIONS TO BENEFIT FROM EXEMPTION UNDER 101.3 TFUE

### Glaxo v Commission case (T-168/01)

- Glaxo dual pricing system.
- Commission's view was that this involved an indirect export ban that had as its object the restriction of competition.
- The General Court rejected the Commission's view: the restriction on trade was necessary to promote investment into research and development in the sector.
- The Court of Justice agreed with the General Court.

# Horizontal Agreements - Art. 101.1 TFUE

## CARTELS

- Agreements to fix prices, divide markets, to restrict output and to fix the outcome of supposedly competitive tenders.
- The most obvious target under competition law.
- US = crime, EU = most serious infringement.
- *Per se* restrictions.
- Proving cartels – strong investigative powers, leniency policy.
- No efficiency justification.

# Horizontal Agreements - Art. 101.1 TFUE

## Exchange of information

- Companies run the risk of infringing art. 101 TFEU when they exchange information with one another.
- Arguments in favour:
  - Some Information about competitors is necessary to make rational and effective decisions regarding production and commercial strategies.
  - Right to adapt to competitors behaviour.
  - Transparency on the market.
- Arguments against:
  - Predict each other's future behaviour and coordinate actions in the market.

# Horizontal Agreements - Art. 101.1 TFUE

## Exchange of information

- Any exchange of sensitive information should be avoided.
- Any commercial, confidential and individualized information is sensitive information: prices, strategic information, clients lists, production cost, sales, etc.
- Special care in public tenders and commercial policies.
- Direct (between competitors) or Indirect (through a third party).
- Unilateral disclosure of information can give rise to a concerted practice → there is a presumption that, by receiving information from a competitor, a firm accepts it and adapts its future conduct on the market.
- The mere assistance to a meeting where competitors are exchanging information can give rise to a concerted practice.



# Horizontal Agreements - Art. 101.1 TFUE

## Exchange of information - How to react?

- Take positive action and communicate in a firm manner that you do not agree with the situation.
- Leave the meeting immediately.
- Keep a written record of the problem.
- Give notice to the Legal Department.

# Horizontal Agreements - Art. 101.1 TFUE

## Exchange of information - Examples

- *T-Mobile Netherlands Case (C-8/08)*
  - Five Dutch mobile network operators held one isolated meeting where they exchanged confidential information on prices.
  - Considered to be an object restriction.
  - Each economic operator must independently determine its commercial policy in the market.
  - Analyze whether the behavior reduces the degree of strategic uncertainty in the market.
  - Simply attending a meeting may constitute a restriction.

# Horizontal Agreements - Art. 101.1 TFUE

## Exchange of information - Examples

- Spanish Case (Expte. S/0086/08. Peluquería Profesional)
  - Some cosmetic companies -L'Oreal, Wella, Henkel and Montibello - exchanged sensible information through the national association of perfumery and cosmetics.
  - Considered to be an object restriction qualified as a Cartel.
  - *"Apart from the participation of a 3<sup>rd</sup> party, the facts prove the perfect functioning of an agreement between the 8 companies to exchange information"*
  - *"It can have no other purpose than to seriously affect competition, nullifying strategic uncertainty, independence in trade policies and the incentive to compete."*

## Vertical Agreements - Art. 101.1 TFUE

- Agreements or concerted practice between undertakings at different levels of the market and relating to the conditions under which the parties may purchase, sell or resell certain goods or services.
- Block Exemption Regulation (EU) 330/2010.
- Generally, less harmful for competition than horizontal agreements.
- Presumption of legality when:

the market share held by  
each of the undertakings does not  
exceed **30%**

+

There is no **hardcore  
restriction**

- ≥ 50% • Presumption of dominant position (Art. 102 TFUE)
- 

- ≥ 40% • May have a dominant position (Art. 102 TFUE)
- 

- ≥ 30% **Block Exemption Regulation** does not apply
- No presumption of infringement of Art. 101.1 TFUE → analysis of the facts.
- 

- ≤ 30% **Block Exemption Regulation**
- Presumption of legality ≤ 30% + **NO hardcore striction**
- 

- De minimis doctrine**
- ≤ 15%
- Individual market share ≤ 15% + **NO object restriction**
  - ≥ 15% → no presumption of infringement of Art. 101.1 TFUE

## Resale Price Restrictions (RPM)

- The imposition upon distributors and retailers of minimum or fixed resale prices.
- Direct or indirect (discounts).
- The imposition upon the distributor and retailers of a maximum or recommended price is allowed.
- Case example: ***S/DC/0592/16: LABORATORIOS MARTI TOR***
  - Retail distribution of perfumery and cosmetic products in the pharmaceutical channel and online sales.
  - The undertaking was a laboratory occupying the 14th position on the market.
  - Evidence: emails where the laboratory clearly imposed the resale prices under threat of refusing to supply.
  - It was a hardcore restriction, but market share was less than 15 %.
  - According to the legal and economic context it could not significantly affect competition.

# Parallel trade

- Parallel imports are products imported into one EU member state from another, outside the manufacturer's formal distribution channels.
- Commission views parallel imports as playing a vital role in invigorating the EU single market, as its policy is that consumers in high-price countries should have the opportunity to source elsewhere in the EU at more favorable prices.
- National price regulation for pharmaceutical products – significant price differences across Europe.
- Leads to arbitrage opportunities between “low price” countries and “high price” countries.
- Loss of profit for pharma companies – gain for parallel traders.
- Typical business practices:
  - Prohibition to resell or export in supply agreement;
  - Dual pricing policies (for home use/ for export);
  - Limitation of supply (Stock Allocation Schemes);
  - Rearrangement of distribution systems;
  - Direct to pharmacy sales;
  - Measures that make import effectively more difficult (packaging, labeling, etc.).

# Export Bans

- A producer may agree with a distributor that it will sell only to that distributor in a particular territory and that it will impose a term on its other distributors banning them from selling into the allotted territory.
- Normally infringe Art. 101.1 TFEU.
- Not justified under Art. 101.3 except in exceptional circumstances.



## Adalat Case - *Bayer* (1/2)

- European distribution of Adalat, a drug manufactured and marketed by Bayer to treat cardio-vascular diseases.
- Adalat was priced in France and Spain at 40% below the UK price.
- Bayer's French and Spanish wholesalers ordered large quantities in excess of their domestic needs and exported surplus to the UK.
- This parallel trade caused sales of Bayer's UK subsidiary to drop by almost 50%.
- Bayer reacted by ceasing to fulfil the increasingly large orders for Adalat from its wholesalers in France and Spain.
- It implemented a quota system based on orders from those wholesalers in the previous year, telling them that stock shortages necessitated the adjustment of its supply policy.

## Adalat Case - *Bayer* (2/2)

- EU Commission → Following a complaint from the wholesalers, the EC concluded that Bayer had violated EU competition rules (Art. 101.1 TFEU) by imposing an export ban as part of its commercial relations with Adalat wholesalers.
- EU Court→
  - Unilateral conduct rather than an export ban falling within the scope of Article 101 TFUE.
  - EC had failed to establish that the wholesalers acquiesced in a ban imposed by Bayer to prevent parallel imports of Adalat into the UK.
  - No evidence proving either that Bayer intended to impose an export ban on its wholesalers or that supplies were made conditional on compliance with that such a ban.
  - Bayer's unilateral supply policy did not depend on the co-operation of the wholesalers, who attempted to make Bayer believe – by switching their patterns of ordering – that the needs of their national markets had grown.

## Coty Case (1/2)

- Dispute between a luxury cosmetic supplier in Germany, Coty Germany GmbH, and one of its authorised distributors, Parfümerie Akzente GmbH.
- Parfümerie Akzente distributed Coty's products in physical stores and online.
- Online sales were made through Parfümerie Akzente's own website and the amazon.de marketplace.
- Coty's selective distribution contract provided that distributors must meet certain standards, which Coty considered necessary to "support the luxury image" of its brands.
- This included, for example: a provision that *"the décor and furnishing of the sales location, the selection of goods, advertising and the sales presentation must highlight and promote the luxury character of Coty Prestige's brands"*.
- In 2012, Coty amended their contracts to include a provision that prohibited its authorised distributors from selling Coty's products on websites bearing the name of a 3rd party.
- Parfümerie Akzente refused to accept.

## Coty Case (2/2)

- Coty brought an action in the German courts seeking an order to prohibit Parfümerie Akzente from selling Coty's products on amazon.de.
- EU Court:
  - Purely qualitative selective distribution arrangements are compatible with Article 101 TFEU.
  - Protecting allure and prestigious image of a product is a valid reason for selective distribution, but ...
  - Only qualitative criteria may be required.
  - A restriction to sales on third party platforms is acceptable because it enables the supplier of luxury goods to "check that the goods will be sold online in an environment that corresponds to the qualitative conditions agreed with its authorised distributors" in the absence of a contractual relationship between the brand owner and the online platform.

# Thank you!