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Competition

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Disclaimer regarding substance of presentation

- *Today when I speak about a particular conduct, type of agreement or arrangement between firms, or a particular fact pattern or hypothetical situation, I do not intend to convey an express or implied message that the described conduct, etc violates EU competition law. Instead, I would like to raise awareness of such arrangements, conducts and fact patterns as they* may *raise competition law issues that should be carefully analyzed and considered*

- *Nothing that is presented today should be construed as an official or unofficial position or policy of DG Comp or the Commission, or a personal opinion on my part, that modern antitrust policy should focus more on exploitative abuses than on exclusionary abuses.*

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Outline

- Why to comply with competition law?
- The broader context, life cycle management
- Conducts that may run foul of Articles 101 and 102 TFEU
- Interaction between competition law, regulation and IPR
- EU merger review – innovation and procedural compliance issues

Why to comply with competition law?

- Adam Smith has put it brilliantly:
  - "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."
  - "The interest of the dealers, however, in any particular branch of trade or manufactures, is always in some respects different from, and even opposite to, that of the public. To widen the market and to narrow the competition, is always the interest of the dealers."

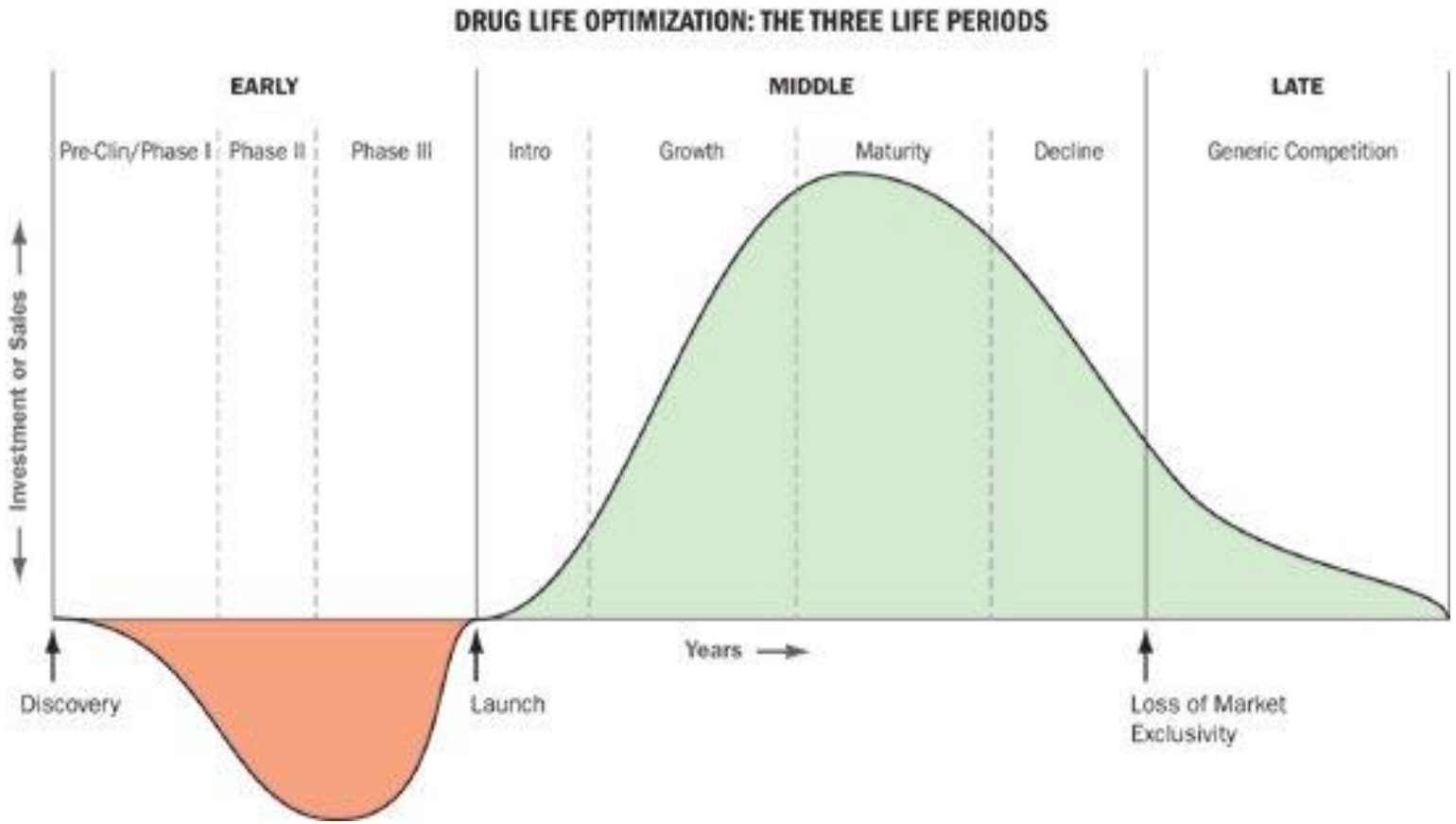
    » *The Wealth of Nations (1776)*

- Competition law stimulates effective competition to deliver open, dynamic markets and enhanced productivity, innovation and value for customers

Why to comply with competition law?*(cont'd)*

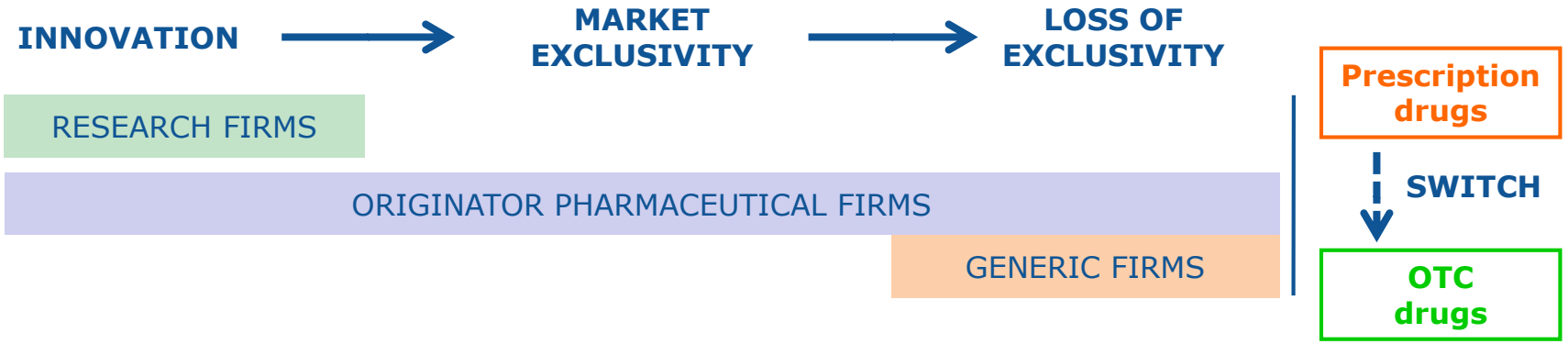
- There are severe consequences for competition law violations
  - Criminal sanctions for individuals in some cases
  - Financial penalties and fines
  - Follow on law suits for damages
  - Agreements being invalidated
  - Various other negative financial consequences such as exclusion from public procurement, possible disqualification for grants, state aid, etc
  - Reputational damage
- Can affect individuals' wealth, compensation and professional career

Life Cycle Management



How Competition Takes Place

- Three stages in the life cycle of a pharmaceutical product:



- Competition stemming from different players at each stage (case-by-case):
  - Innovation: pipeline products
  - Exclusivity: pipeline & marketed products
  - Loss of exclusivity: generic versions of the molecule
  - Over-the-counter: "consumer goods" (non-originator brands, private-label…)

Conducts that may run foul of Articles 101 and 102

- There are three basic types of competition law violations:
  - Cartels (Art 101, but can also be a criminal offence)
  - Other potentially anticompetitive agreements (Art 101)
  - Abuse of dominant position (Art 102)

- Violations of competition law are seldom self-evident; some of them are conducted in secret; often there are factual and perhaps legal uncertainties surrounding the case that make the legal analysis difficult

Potentially Anticompetitive Agreements

- In addition to cartels, some agreements could be found anticompetitive:
  - Joint selling or purchasing with competitors; resale price maintenance; exchange of sensitive information; standardization agreements; boycotts of customers or suppliers; exclusive dealing agreements
- No exhaustive list of anticompetitive agreements exists!
  - See, for example, pay-for-delay agreements, reverse patent settlement agreements between originators and generics
  - Agreements do not have to be in writing
  - substance over from

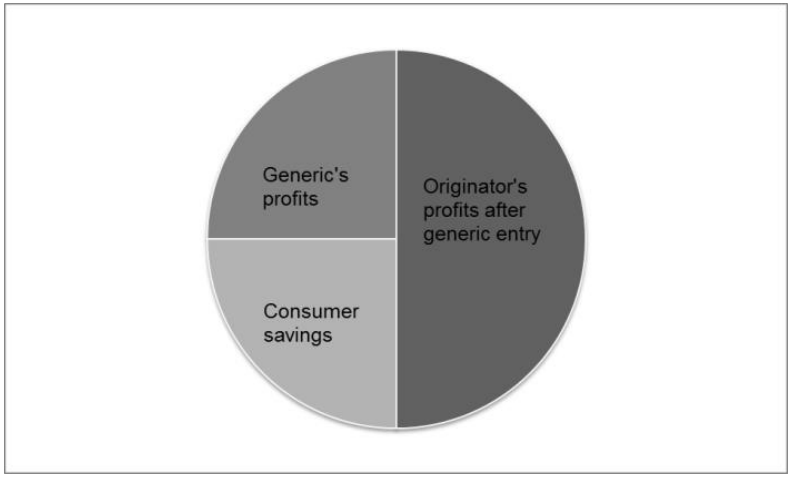
Concerns about patent settlements

- Commission 2009 pharma sector inquiry
  - Inquiry into anticompetitive attempts by pharmaceutical companies to delay entry onto the market of generic drugs once compound/basic patent cover for the original drug expired.
  - Decisional Practice of DG COMP in antitrust since:
    - Lundbeck (appeal to EUCJ pending)
    - Fentanyl (Johnson & Johnson and Novartis Decision - final)
    - Servier (appeal to GC pending)
    - Cephalon (investigation on-going)
- Patent Settlement Monitoring Exercises
  - Purpose is to better understand the use and evolution of patent settlements in the EU
  - Over the years the number of settlements is higher (125 in 2015) than at the time of the sector enquiry (+/- 30)
  - The proportion ***of potentially problematic*** patent settlements ***remains now low*** at around 10%
  - Ongoing enforcement action and monitoring activity have not hindered companies from concluding settlements in general

Incentives to pay to delay

- Generic entry leads to erosion of prices and gains of market shares of previous originator's monopoly. It also results in consumer savings

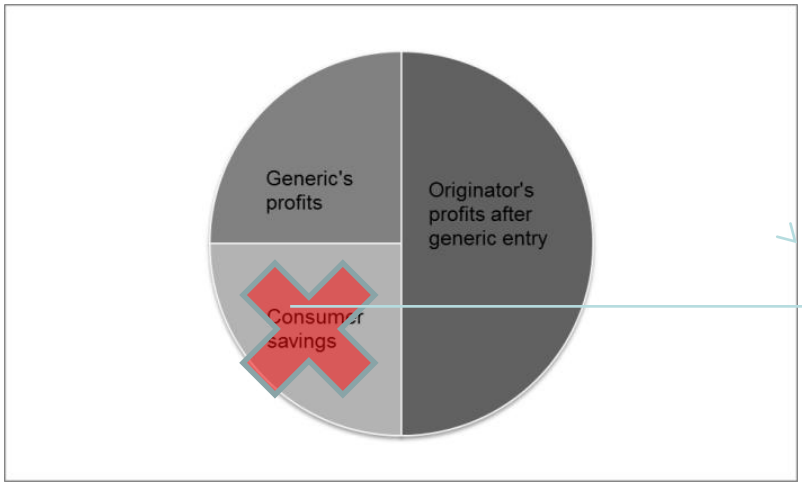
Before generic entry



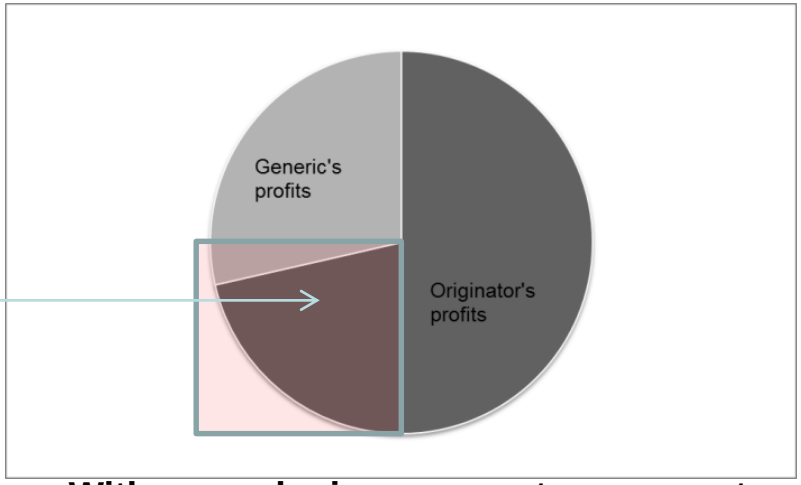
After generic entry

Incentives to pay to delay *(cont'd.)*

- To avoid the above effects of generic entry the originator by paying to delay continues to earn monopoly profits. In addition the potential consumer gains are shared between the originator and the generic(s)



With generic entry



With an exclusion payment agreement preventing generic entry

→ The one who loses is the consumer!

A Case study: Fentanyl

- Involved a 2005 co-promotion agreement between J&J and Novartis/Sandoz concerning a pain killer stronger than morphine, originally developed by J&J, used for chronic pain in the form of two transdermal patches in this case

- The Commission concluded that the object of this agreement was anticompetitive and thus infringed Article 101 of the Treaty because the agreement aimed at delaying the market entry of a cheaper generic version of fentanyl in the Netherlands

- What were the facts of the case?

Abuse of Dominant Position – Art 102

- A firm enjoying substantial market power over a period of time may be deemed dominant
  - Market definition issues
- Dominant position is not based solely on the size of the firm and/or its market share (40%?)
- Is it able to behave independently of its competitors, suppliers, customers and ultimately of its consumers?
- Having established that a business is dominant, anticompetitive conduct which exploits consumers (exploitative abuse) OR tends to have an exclusionary effect on competitors (exclusionary abuse) is likely to constitute an abuse
- No exhaustive list of anticompetitive conducts exists!

Is excessive pricing an abuse?

Excessive Pricing in Pharma

- Views are split on excessive pricing as an antitrust violation
  - trust in the self-correcting mechanism of markets; opportunity to charge monopoly prices leads to more risky R&D; only transfer of wealth from consumer to monopolist involved, not loss of wealth to society generally; price regulation never works
  - *cf*. markets may fail; when output is restricted there is welfare loss; additional social costs of monopoly; ***legislative mandate to address***

- Additionally, commentators point to practical difficulties with the doctrine and its enforcement
  - "formidable difficulties" in telling when a price is excessive; difficulty in translating policy into administrable legal test

Excessive Pricing in Pharma *(cont'd)*

- In the EU, Art 102 TFEU expressly provides that imposing unfair prices may constitute an abuse by a dominant undertaking
  - "… abuse [of a dominant position] may, in particular, consist in: (a) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions;…"
  - EU jurisprudence (*United Brands, AKKA*)

- Other jurisdictions also aim at controlling high drug prices
  - *Eg, US State of Maryland law enabling the State Attorney General to sue makers of generic or off-patent drugs for an "unconscionable" price increase (US Court of Appeal struck it down in April 2018)*

A Case study: Astra Zeneca

- Product Hopping is not inherently wrong but not all types of conduct can be used to limit generic access to the market

- ECJ's 2012 judgment in favor of the Commission fining AstraZeneca €60 million for abusing its dominant position relating to its best-selling anti-ulcer medicine Losec

- Two infringements by AZ through the misuse of regulatory procedures:
  - providing misleading information to national patent offices with the aim of preventing or delaying market entry of competing generic products
  - deregistration of the market authorization of an earlier version of Losec in selected countries with the aim of raising barriers against generic entry

- *NB: At the time of the infringements in the absence of a valid marketing authorisation of an originator product generic products could not use the test and clinical trial data of the originator to obtain marketing authorisation*

A Case study: Astra Zeneca *(cont'd)*

- What are the boundaries of permitted life cycle management strategies?

- Article 102 imposes on a dominant company, irrespective of reasons for which it has such a dominant position, the ***special responsibility not to impair***, by using methods other than those which come within the scope of competition on the merits, ***genuine undistorted competition***

- the Court observed that the withdrawal of Losec capsules from the market and the introduction on the market of Losec MUPS were not capable, in themselves, of producing the anticompetitive effects

A Case study: Astra Zeneca *(cont'd)*

- Some additional conduct, such as in the case at hand, may go beyond the boundaries of permitted life cycle management strategies
- Effects, purpose and economic sense of the conduct?
- Conduct may well be lawful under other branches of the law
- Case by case analysis is needed
  - the question whether representations made to public authorities for the purposes of improperly obtaining exclusive rights are misleading must be assessed *in concreto* and that assessment may vary according to the specific circumstances of each case
- It can be a "novel" conduct that was not examined before
- Other jurisdictions?

Interaction between competition law, regulation and IPR

- Competition instruments and regulatory instruments are complementary

- ***For example, on IPR and Art. 101:***

*"The fact that intellectual property laws grant **exclusive rights of exploitation does not imply that intellectual property rights are immune from competition law intervention**…*

***Nor does it imply that there is an inherent conflict between intellectual property rights and the Union competition rules**. Indeed, both bodies of law share the same basic objective of promoting consumer welfare and an efficient allocation of resources. Innovation constitutes an essential and dynamic component of an open and competitive market economy…*

*Therefore, **both intellectual property rights and competition are necessary to promote innovation** and ensure a competitive exploitation thereof."*

(*Guidelines for the assessment of technology transfer agreements, pt. 7*)

Merger review of pharma mergers

- Most notified mergers are resolved in Phase I
  - Deal size compared with affected markets → incentive to offer remedies early
  - Relatively good co-opearation with industry
- Preservation of dynamic competition requires to look into innovation competition and future competition issues
  - Lessons from *DowDuPont* merger?
  - Similarities and differences in industry characteristics
- Like in other industries, procedural compliance is a must

Access to medicines

- **Access to medicines - a concern**
  - Council Conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States (17 June 2016)
    - *Recognises that a balanced and strong, functioning and* ***effective intellectual property environment*** […] *is* ***important for*** *supporting and promoting access to* ***innovative, safe, effective and quality medicinal products*** *in the European Union* (§7)
    - Invite… *"…to* ***safeguard*** *common interests, ensuring access of patients to safe,* ***effective and affordable medicinal products*** *as well as the sustainability of national health systems"* (§29).

    [Specifically concerning COMP:]
    - *"****Continue and where possible intensify****, including through a* ***report*** *on recent competition cases following the pharma sector inquiry of 2008/ 2009, the merger enforcement pursuant to the EC Merger Regulation (Regulation 139/2004) and* ***the monitoring, methods development and investigation*** *- in cooperation with national competition authorities in the European Competition Network (ECN) -* ***of potential cases of market abuse, excessive pricing as well as other market restrictions*** *specifically relevant to the pharmaceutical companies operating within the EU, such in accordance with Articles 101 and 102 of the Treaty on Functioning of the European Union"* (§48).
  - European Parliament "***Resolution on EU Options for Improving Access to Medicines***" (2 March 2017)

- **Industry – regulation/competition law**
  - Best way sometimes: to change the regulations
  - Under conditions (cf. United Brands), EC and NCAs could act under Art. 102 TFEU on a case-by-case basis considering the relevant facts and circumstances

Thank you for your attention!

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