EU antitrust enforcement in the pharma sector

Slovenian Competition Day
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European Commission, DG Competition

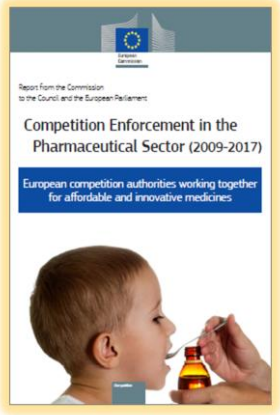
Outline

- Antitrust in the pharma sector: some particularities;
- Article 101 – pay-for-delay;
- Article 102 - exploitative conduct: excessive pricing;
- Article 102 - exclusionary conduct: delaying or hindering generic and biosimilar entry.

Antitrust in the pharma sector: some particularities

Antitrust in the pharma sector

- A sector of major societal importance
- Area of active EU antitrust enforcement
- … but also guidance to companies (Covid-19 comfort letters, *et al.*)
- Exploitative and exclusionary conduct
- International perspective: similar enforcement intensity and orientation in other jurisdictions; regular contacts
- ECN dimension: particularly close cooperation, working as a network; intensive enforcement activity; see e.g. https://ec.europa.eu/competition/sectors/pharmaceuticals/report2019/index.html



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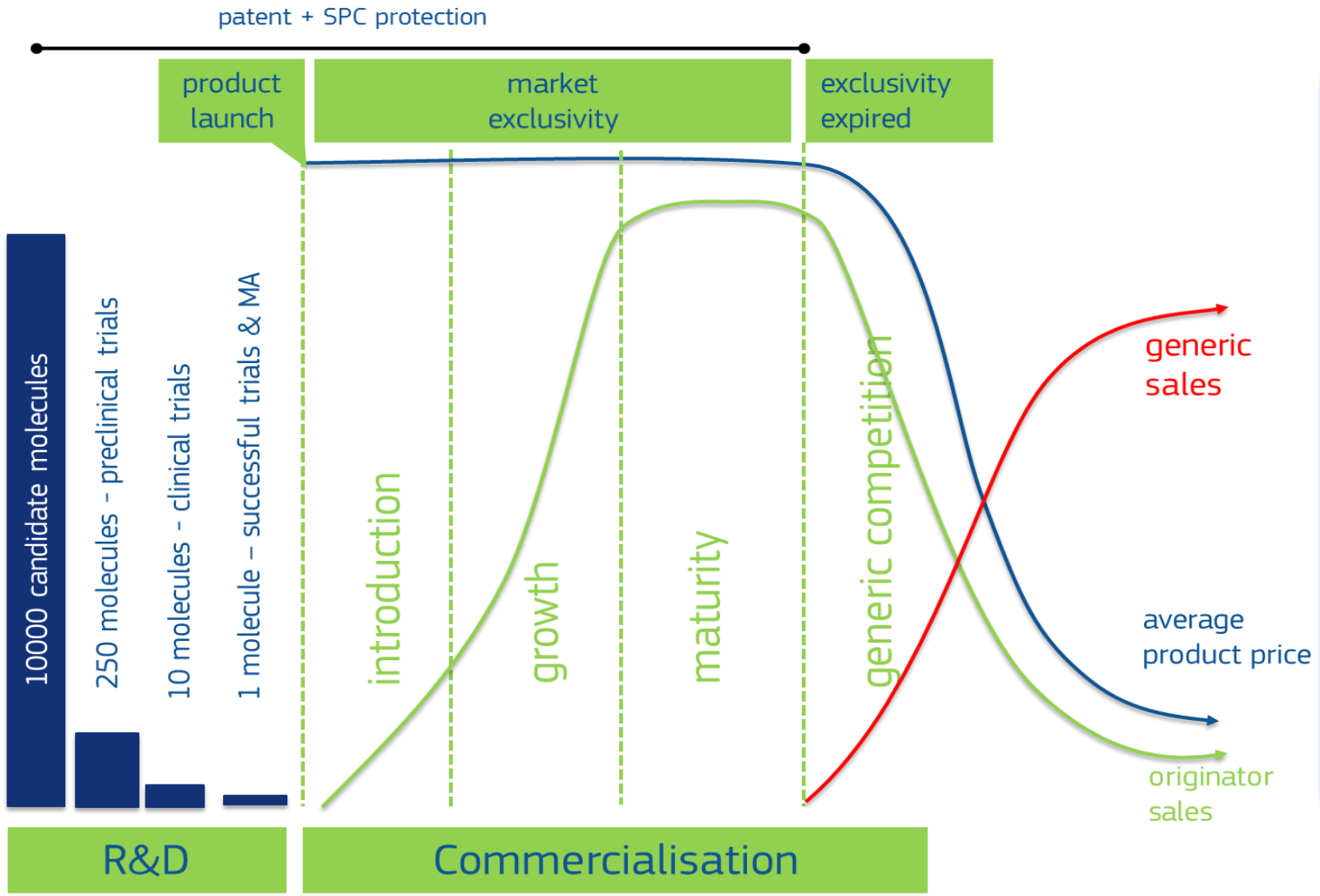
Particularities of competition in the pharma sector (i)
Life cycle of medicines



Evolving nature of competition:

- ✓ Developing new medicines – competition on innovation
- ✓ Market exclusivity for new medicines is limited in time
- ✓ Loss of protection and generic competition

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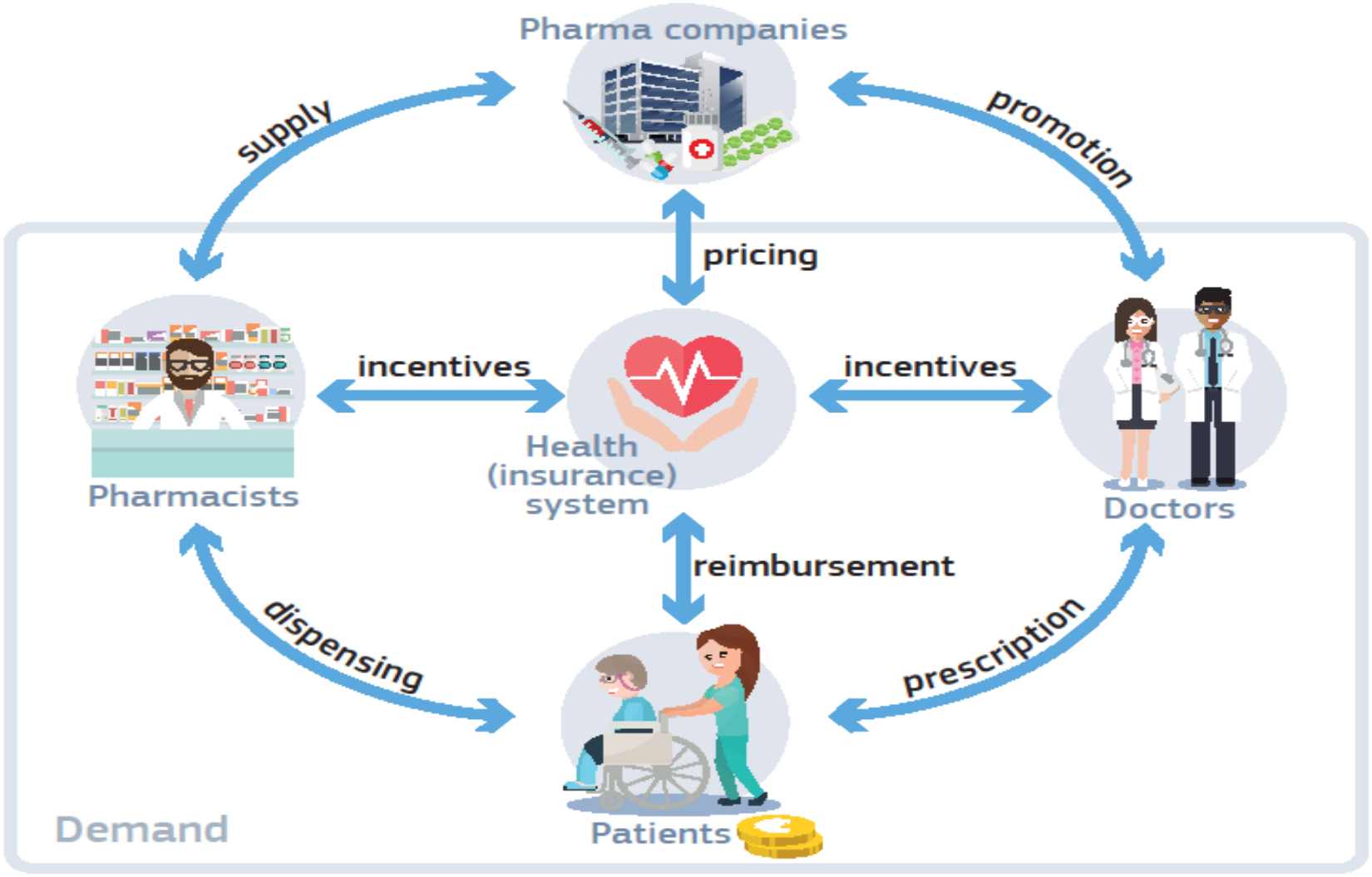
Particularities of competition in the pharma sector (ii) Demand structure



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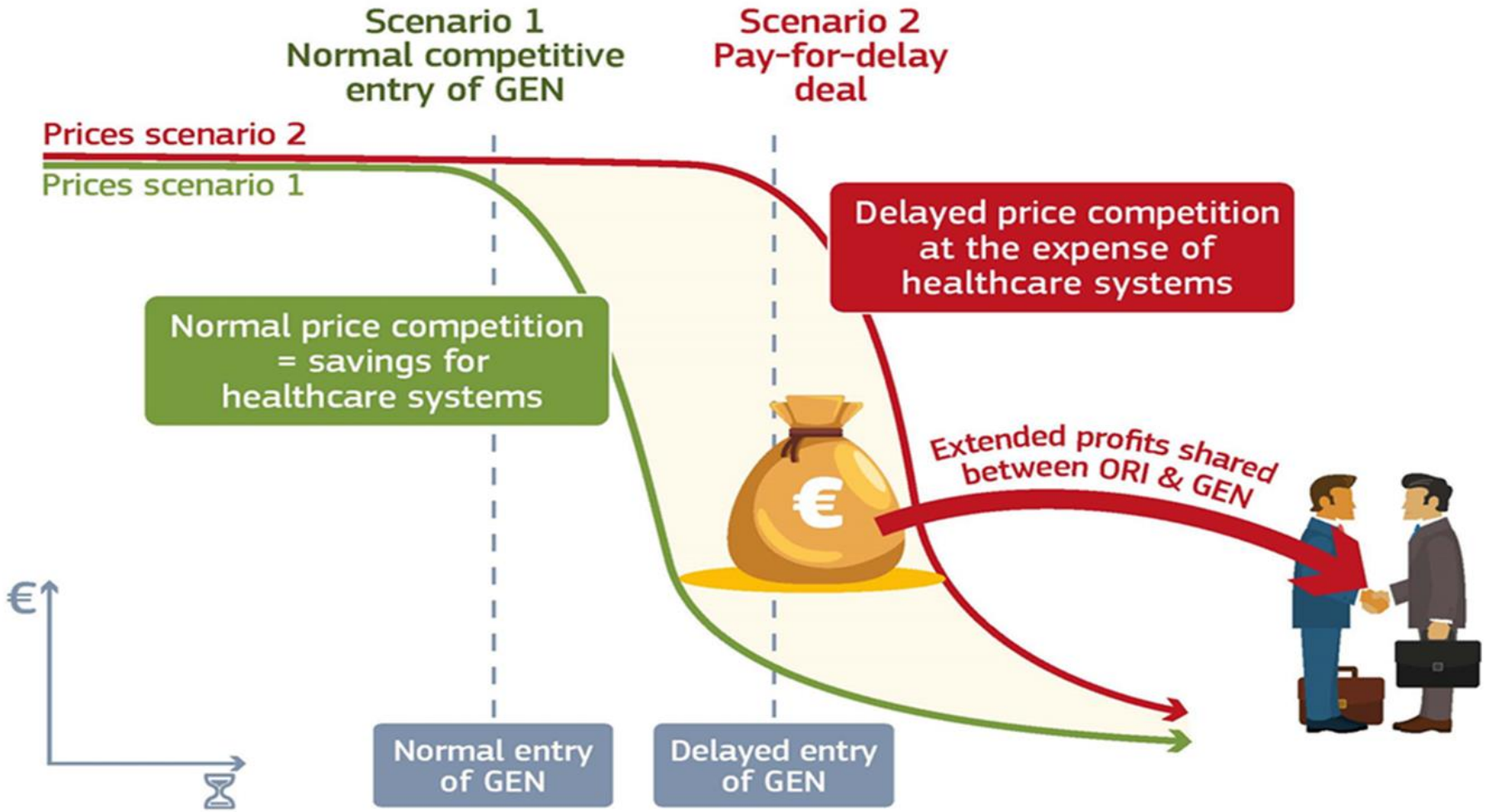
Article 101
Restrictive agreements – pay-for-delay

Impact of pay-for-delay deals on healthcare systems



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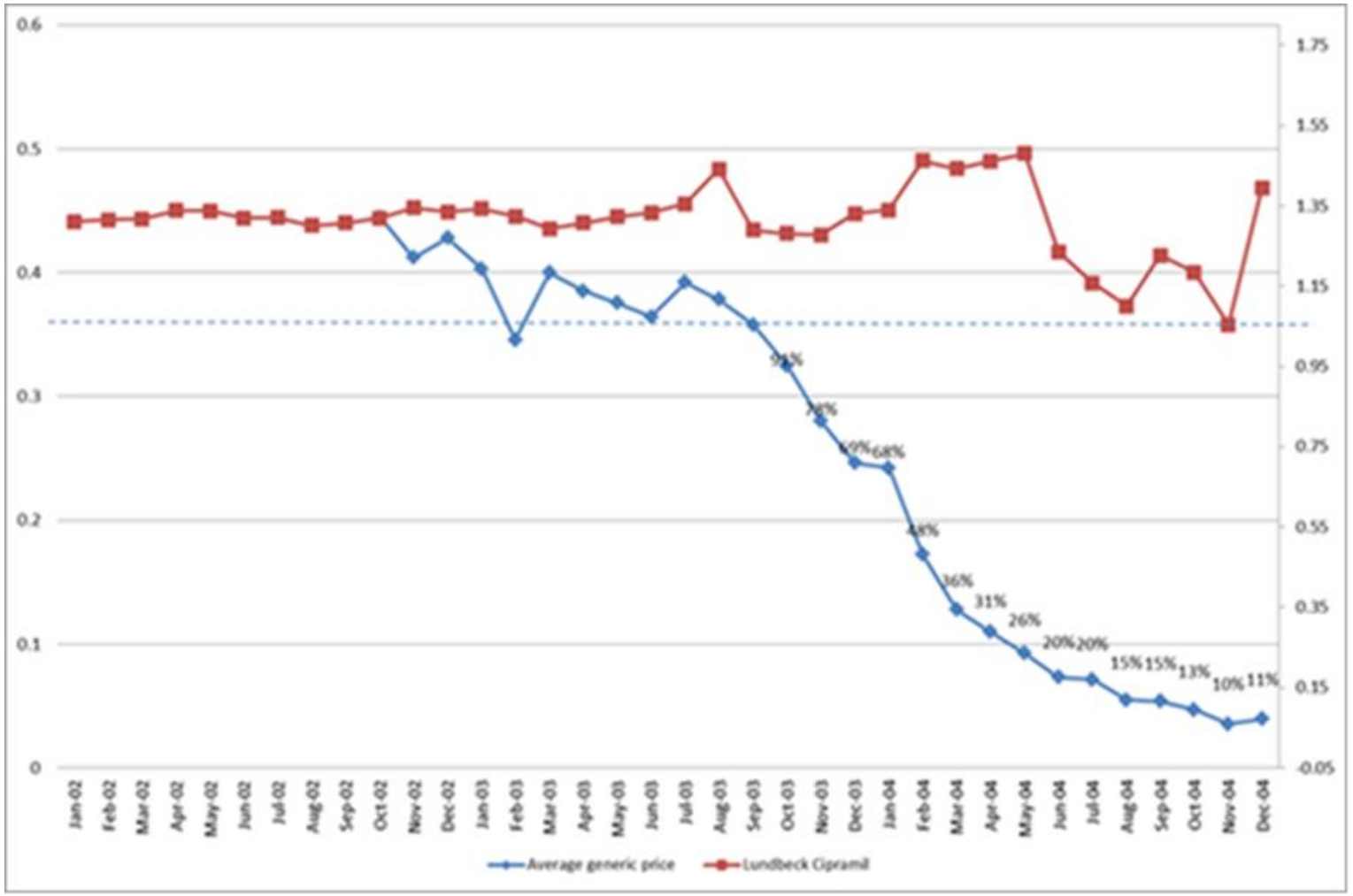
Real life illustration: generic citalopram entry (*Lundbeck* case)



Red line: Lundbeck price

Blue line: generic citalopram price
(per DDD weighted average, in GBP).

Generic price from Sept. 2003 to Nov. 2004 in UK:
90% price decline

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When do patent settlements infringe competition law?

Legal test under Article 101(1) TFEU

Originator and generic companies at least potential competitors

- real and concrete possibilities of entry
- **patent** for **manufacturing process not insurmountable barrier**
- **no requirement** to predict the outcome of patent litigation

Commitment to limit *independent* efforts to enter the market

- non-commercialisation
- non-challenge …

Significant value transfer from originator to generic

- sufficient to distort incentives to enter
- **all transfers of value** to be taken into account (indirect and non-pecuniary)/ “net gain” to be established
- **“net gain”** may have justifications, but these need to be **legitimate and proven**;
- no requirement for net gain to be larger than expected profits

- Lundbeck, Servier, J&J / Sandoz, GSK / Generics UK

Perindopril (Servier) – July 2014

- **Perindopril** was a best-selling anti-hypertension medicine. Servier's „*dairy cow*" product;
- In 2003, perindopril molecule patent expiry; over 20 secondary patents/applications;
- Servier and generic entrants **litigated on validity and infringement** of a secondary patent; **5 out of 6 settled** between 2005-2007;
- Servier prevented price drops up to 90%: "*great success = 4 years won*".

- **Servier's payments** for settlements and acquisition of competing generic technology **in excess of EUR 100 million**
- for one agreement (Krka), no link between cash payments and settlement could be established => market allocation;
- 5 agreements found to restrict competition by object and by effect (Article 101), also exclusionary strategy under Art. 102 (pay-for-delay plus a killer acquisition); fines: EUR 427.5 million

- **appeals**: General Court confirmed most parts of decision and fines, but annulled the parts concerning the Krka agreement and Art 102 => appeals on both sides;
- Oral hearing before Court of Justice held in October 2021, AG opinion in January 2022.

Article 102
Exploitative conduct: excessive pricing

The EU Aspen case

- **six niche oncology (leukemia) medicines** for human use, some essential and life-saving;
- high **price increases** started 2012, sometimes **by several hundred percent**, leading to consistently **very high profit margins;**
- **(quasi)-monopoly** for several years, or at least a very strong market position throughout EEA;
- **no timely** or **no competitive entry**; no countervailing buyer power;
- **United Brands - 2 limb test:**
  - prices are excessive;
  - unfair in themselves or in comparison.

Assessment: excessive & unfair price

Excessive

- Detailed analysis of **cost, net prices** and **profitability**
- "**Cost-plus**" measure
- Reasonable profit margin based on **sample of pharma companies** with similar portfolio

Cost **plus** reasonable profits | exc. profits

- Concerns of excessiveness where **profits significantly exceed** "cost-plus" measure

Unfair in itself*

- characteristics **of the product** (e.g. essential medicine, **off-patent** vs. exclusivity protected)?
- a particular commercial **risk-taking**?
- innovation: **therapeutic improvement** or **efficiency in production**?
- improvement of **distribution**?
- **reasons** and **motives** for pricing policy
- unfair **means of implementation**?

*** Alternative – compared to competing products**:

- difficulty - suitable comparators?

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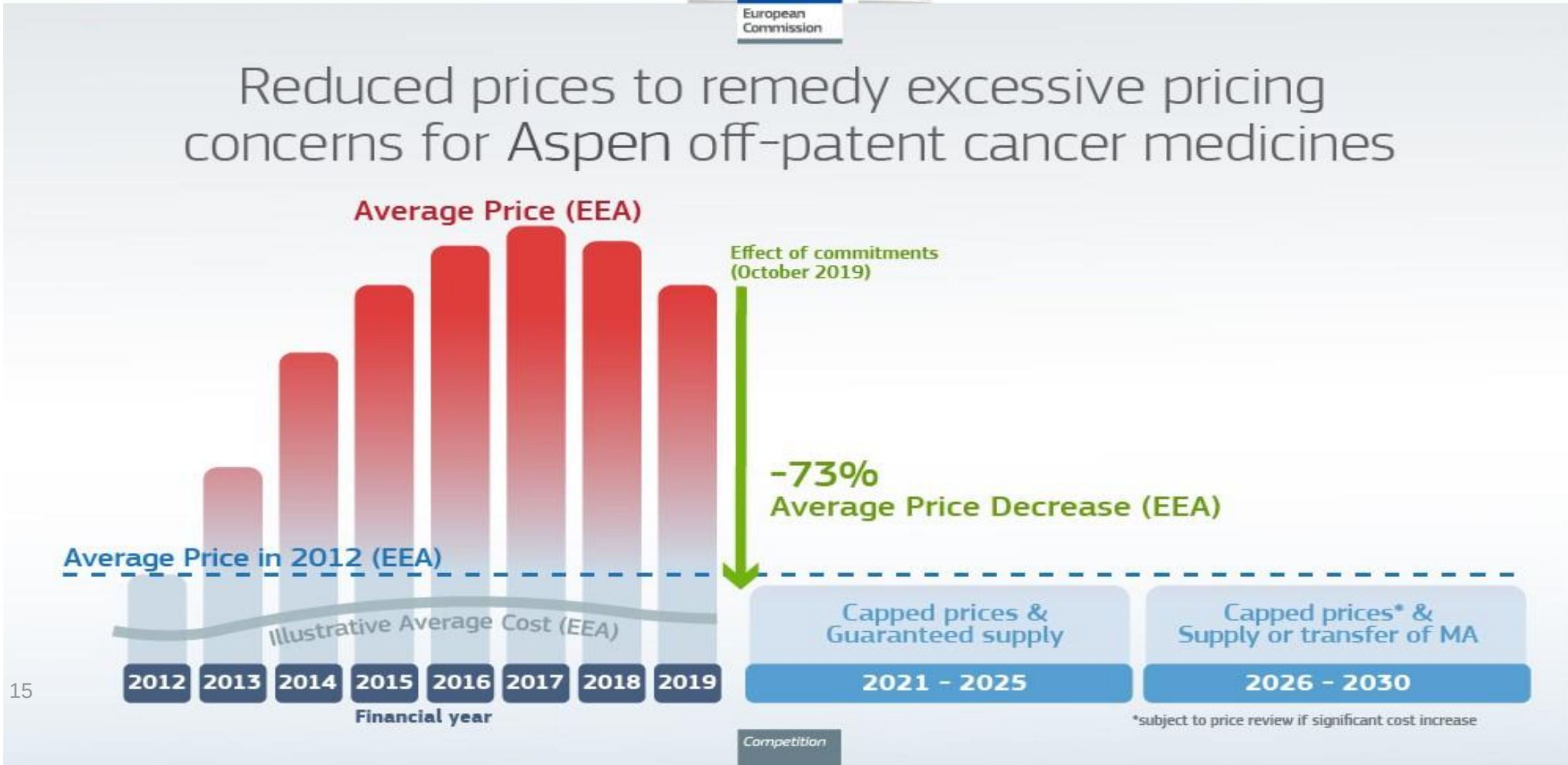
Commitments



Article 102
Exclusionary conduct:
delaying generic and biosimilar entry

Past investigations into unilateral conduct to prevent or hinder generic entry

- **Misleading information to obtain SPC/withdrawal of MA:**

2005 (EU): *Astra Zeneca*, CoJEU in 2012

- **Withdrawal & delisting of the reference product (product hopping):**

2011 (UK): *Reckitt Benckiser*

- **Misuse of rights / abuse related to procedures:**

2012 (IT): *Pfizer*

- **Acquisition of technology foreclosing generics:**

2014 (EU): *Servier*, on appeal

- **Disparagement:**

2013 and 2017 (FR): *Schering-Plough, Sanofi-Aventis, Janssen-Cilag* and *Johnson & Johnson*
2014, 2020 (IT, FR): *Roche & Novartis* Avastin Lucentis

- **Exclusionary pricing**

2001, 2017 (UK): *NAPP* (and excessive pricing); *Merck Sharp & Dohme* Remicade (SO, closed)
2021 (AT): *Merck Sharp & Dohme* Temozolomid

Ongoing?

- Commission opened proceedings in Teva Copaxone (March 2021), investigating:
  - misuse of patent system (divisionals);
  - disparagement;
- unannounced inspection in the animal health sector in October 2021;
- Commission is investigating several complaints / market information.

Can the ‘divisionals game’ breach competition law?

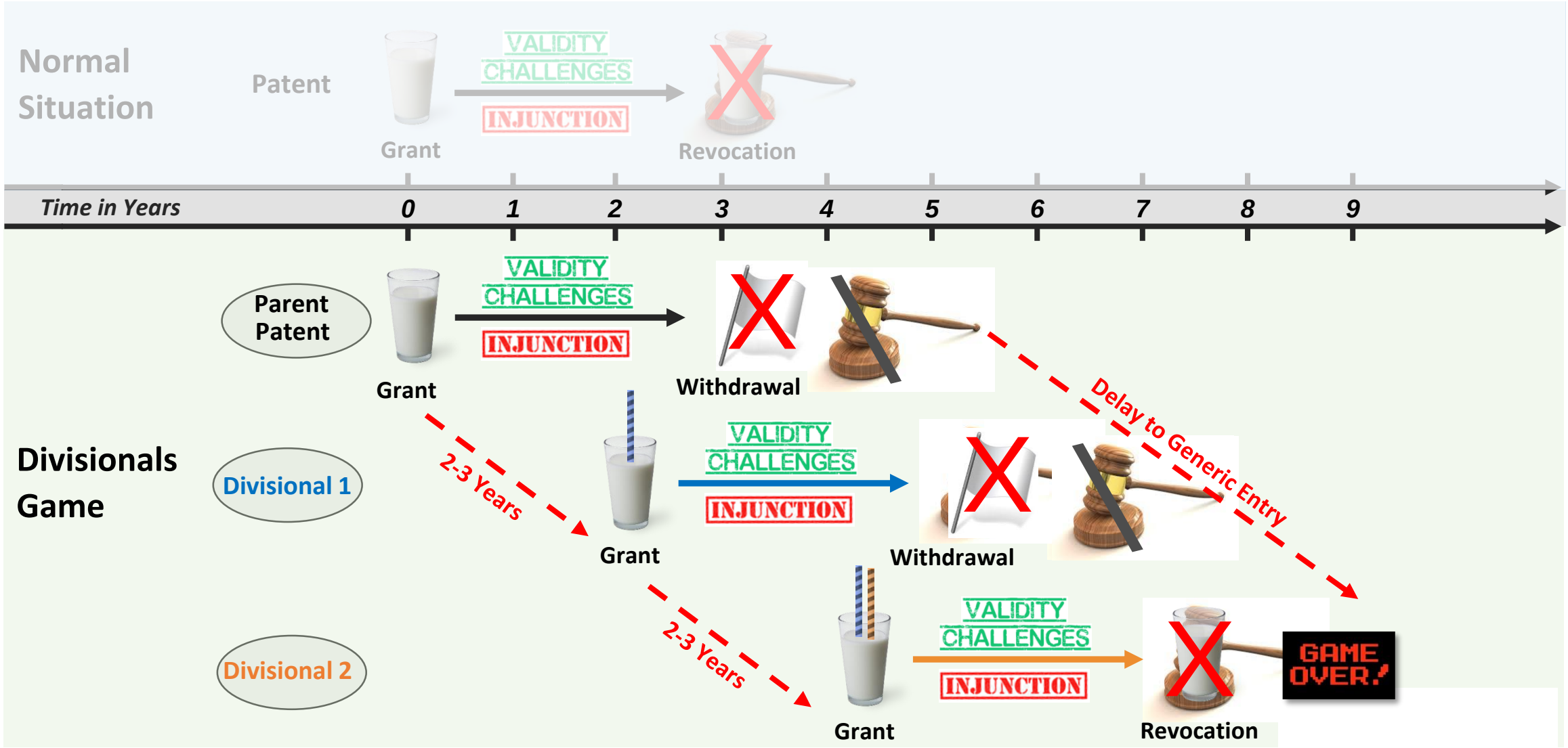
Commission Sector Inquiry, July 2009: “*filing divisional applications for the same secondary patent... can… be used strategically to create further uncertainty and delays for new entrants*“

Medicines for Europe report, November 2020: ‘divisional game’ is a practice “*whereby the divisional patent system is used to frustrate the judicial and administrative procedures inherent in the patent system, thus prolonging the life of patents that may not be able to stand up to judicial scrutiny*”

4 elements:

1. filing cascades of divisional patents;
2. defending patents against invalidity challenges;
3. enforcing patents in national courts, preliminary injunctions;
4. strategically withdrawing an earlier, challenged patent to avoid negative ruling.

The “Divisionals Game”



Thank you

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