



# Focus on competition law and how it intersects with other areas of laws; discussions on abuse of dominant position in the EU

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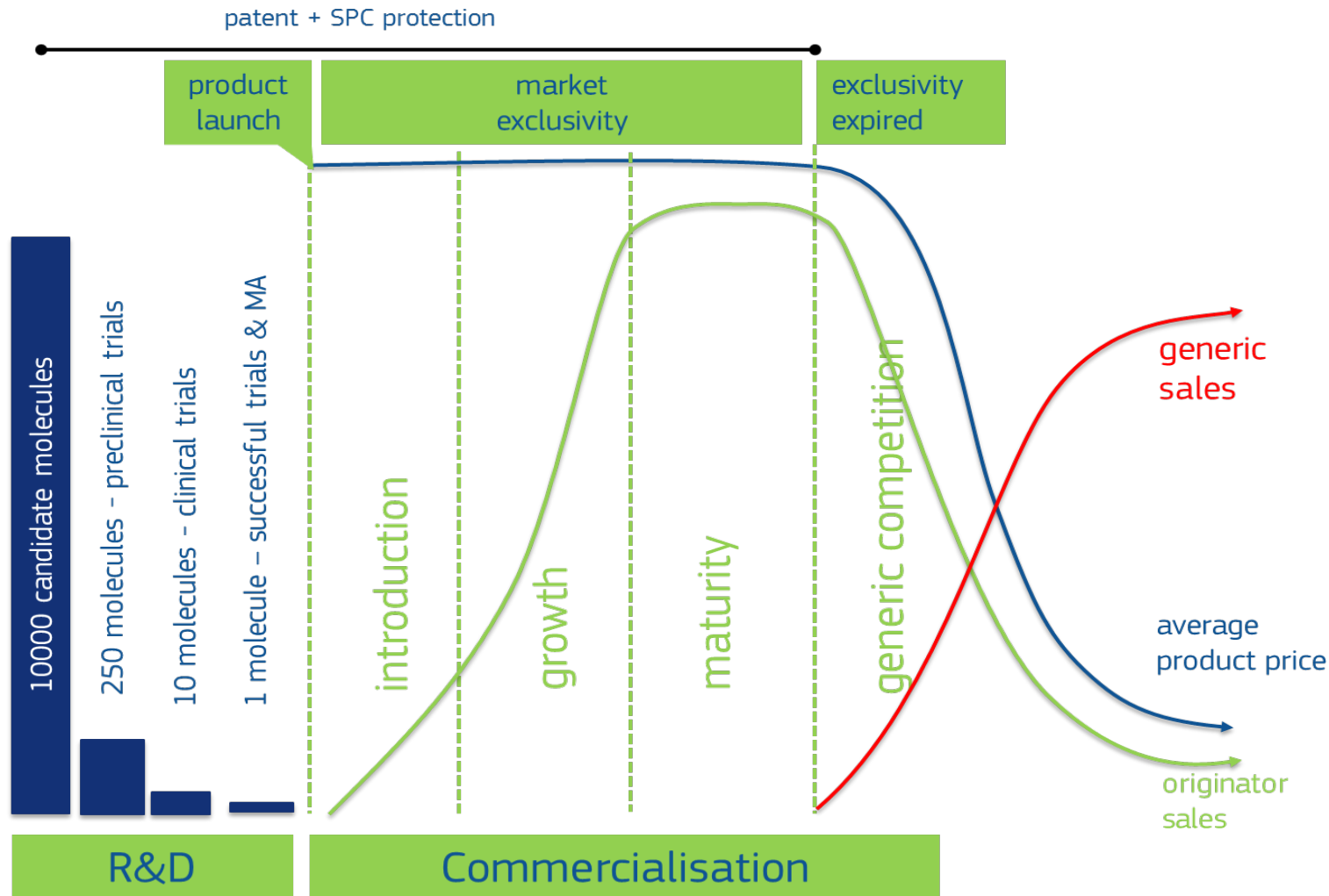
# Antitrust in the pharma sector

- A sector of major societal importance
- Political mandate: *access to affordable and innovative medicines to EU citizens*
- Area of active EU antitrust enforcement, including effective merger review
- ... 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>



# Particularities of competition in the pharma sector

## 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

# Beyond pay for delay: unilateral practices

- In focus already of Commission 2009 Sector Inquiry
- Decisions exist on numerous practices
  - **Withdrawal & delisting of the reference product (product hopping):**  
2011 (UK): *Reckitt Benckiser*
  - **Misuse of rights / abuse related to procedures:**  
2012 (IT): *Pfizer*
  - **Misleading information to obtain SPC/withdrawal of MA:**  
2005 (EU): *Astra Zeneca*, CoJEU in 2012
  - **(Killer) 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 discounts:**  
2001, 2017 (UK): *NAPP* (and excessive pricing); *Merck Sharp & Dohme* *Remicade* (SO, closed)
  - **Loss-leading/predation:**  
2021 (AT): *Merck Sharp & Dohme*  
*Temozolomid*

# Interplay between IP and comp law, abuse of dominance

## Article 102 TFEU:

- **does not prohibit** the exercise of an IPR in itself and its vigorous enforcement (eg *Volvo*);
- **but** Art 102 **may apply to cases** where such IP rights were unduly acquired or exercised to prevent or delay entry, i.e. **in a way that departs from competition on merits**, for example:
  - misrepresentations to patent offices (*AstraZeneca*);
  - vexatious litigation (no EU precedent, *FTC vs AbbVie* in the US);
  - acquisition of exclusive rights (*Servier*);
  - misuse of patent rights / procedures (*Pfizer Italy / Xalatan*).

# 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.

# Competition law enforcement alone cannot address general issues – “no silver bullet”

- foregoing practices *could* qualify as an abuse of dominance (Article 102 TFEU), but no decision by the Commission or NCAs yet;
- There are **limits** to competition law enforcement
  - requires strong evidence that patent holder was ***dominant***
  - very ***difficult without internal documents***, for example to rebut arguments that withdrawals were objectively justified, etc
  - ***limited to case-by-case*** assessment and ex post investigations

# Conclusion

- Competition authorities across the EU actively investigating exclusionary and exploitative conducts in the pharma sector, including IP related conducts
- Commission's recent investigation focussed on exclusionary conduct, unilateral practices more likely than blatant pay-for-delay payments
- Drawing a line between *abuses* and *competition on the merits* and the legitimate exercise of rights can be difficult
- Distortion of competition through delaying strategies has major impact for patients and health systems (price, innovation)
- Investigations beyond end-of-lifecycle cases, possibly also into conduct impacting competition between innovators