Supplementary Protection Certificates (SPCs) – fit for purpose?

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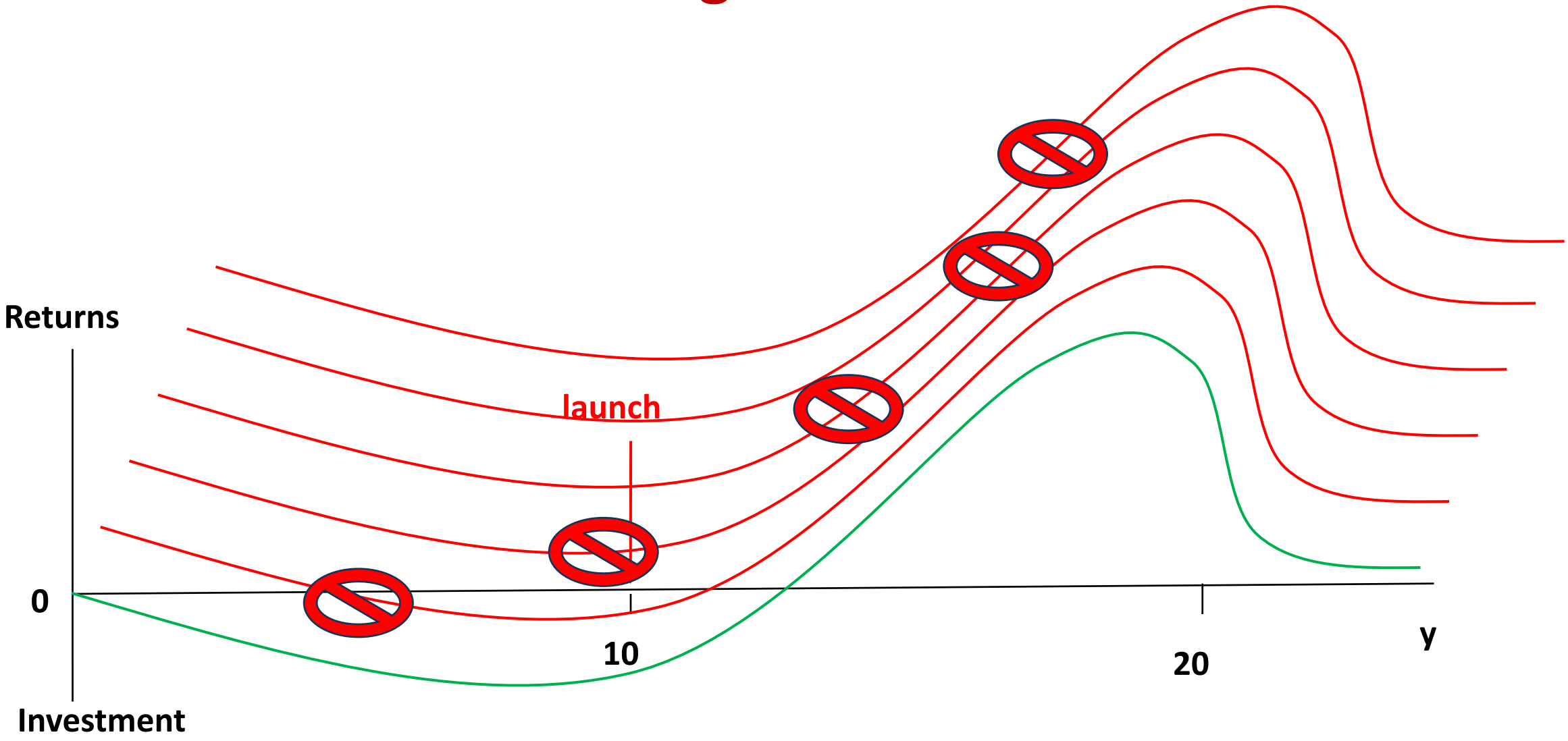
FICPI Open Forum

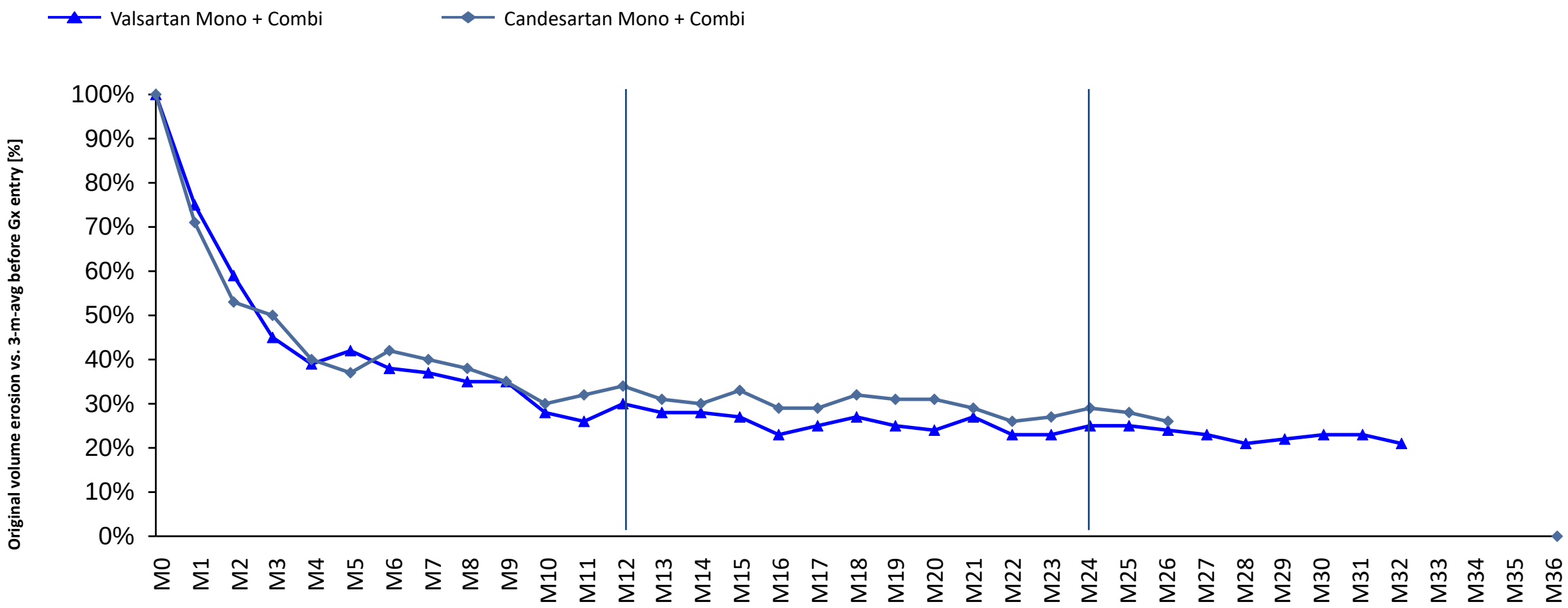
Vienna, 11 Oct 2019

Life of a successful drug



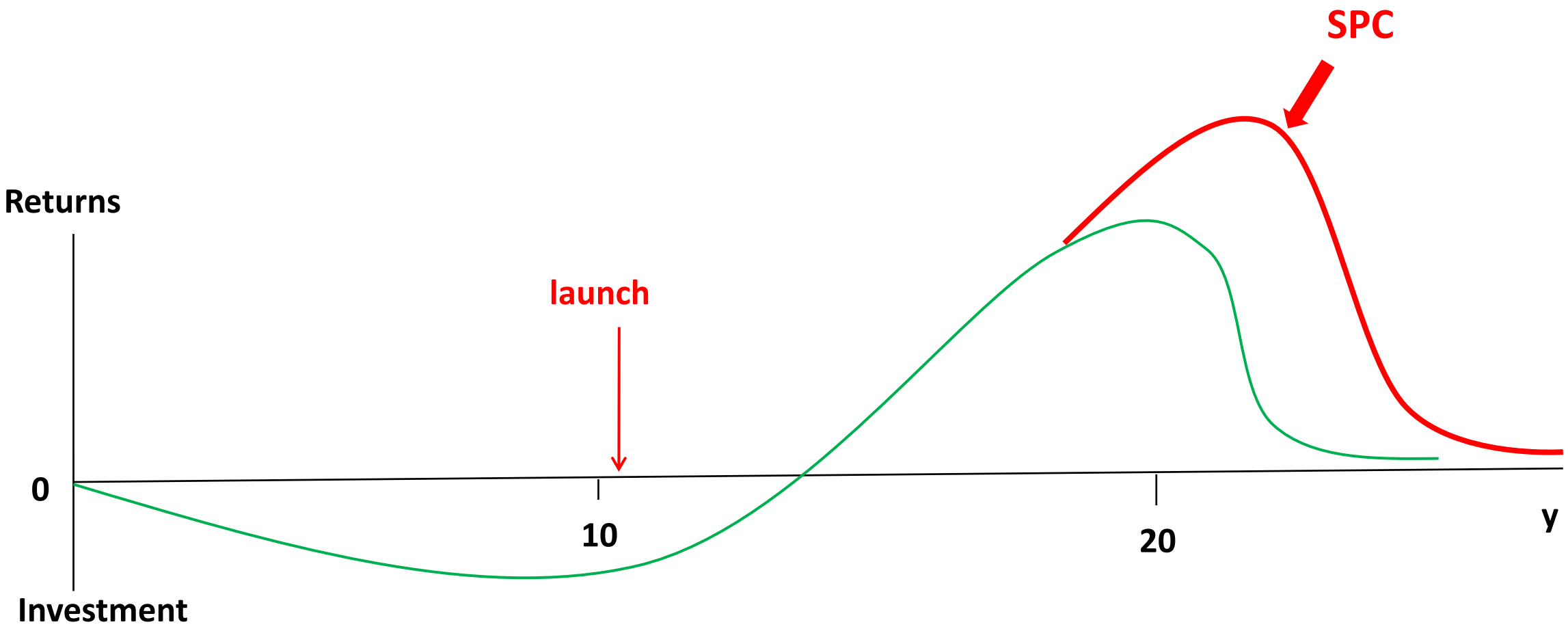
Generic erosion in Germany

Volume erosion of original molecules in month x after Gx entry

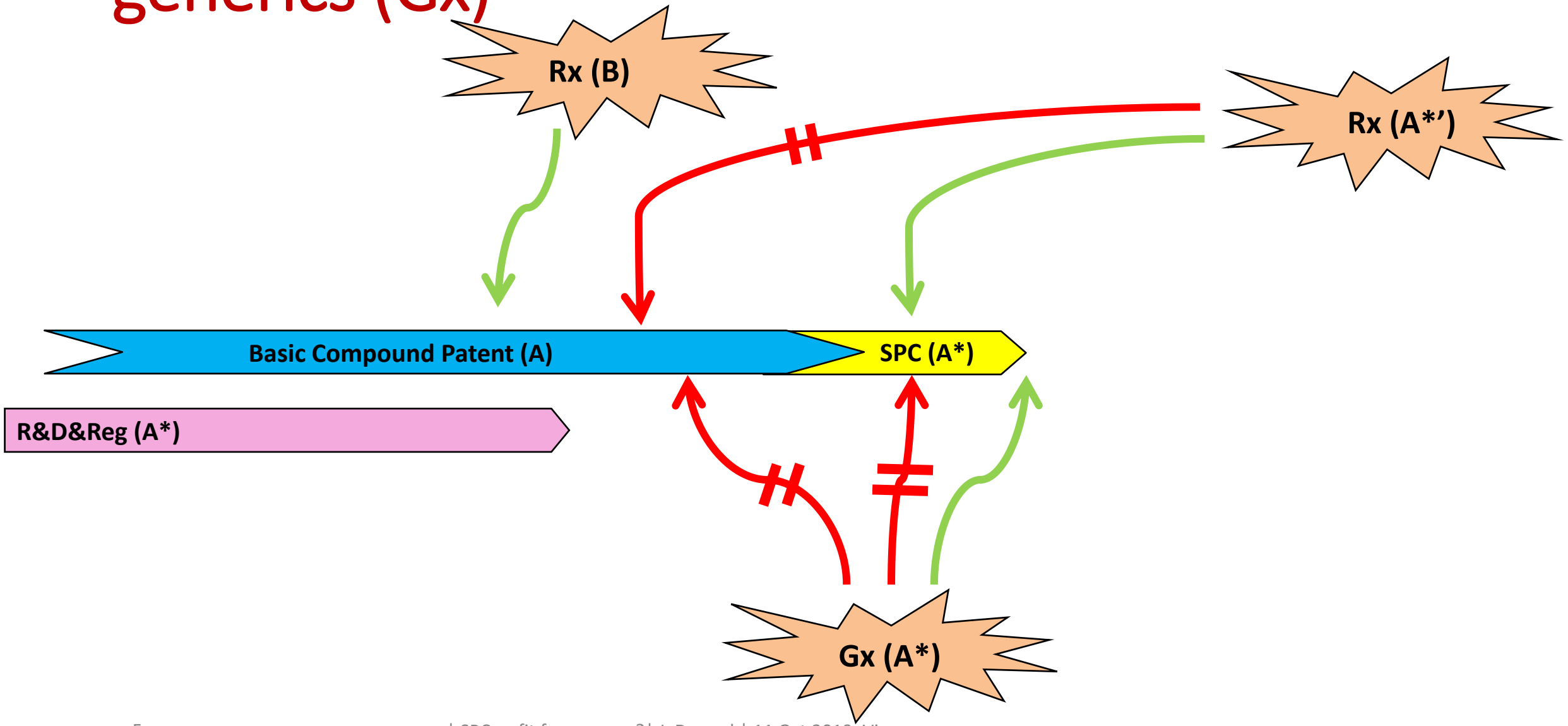


Source: IMS Pharmascope Units

Importance of SPCs



Effect of SPC on other originators (Rx) and on generics (Gx)



Business requirements for SPC-system

- Effective
- Fair
- Simple and efficient
- Predictable
- Harmonized across EU

=> Legal and business certainty for Rx, Gx, and healthcare systems

Main issues for SPC-system

- Very different technologies: Pharma, Agro, Vaccines, Veterinary
- Meaning of ‚protect' in Art.3(a)
  - Clarification from *Teva* (Grand Chamber), and AG-Opinion for joined *Royalty Pharma* (C-650/17) and *Sandoz* (C-114/18)
- Combinations (*Medeva* et al.)
- Third Parties [Art.3(c); *Biogen* (C-181/95), *AHP*]
  - *Eli Lilly v Genentech* (C-239/19) inadmissible
- Second MA [Art.3(c,d); *Neurim*]
  - Clarification from *Santen* (C-673/18), *Novartis v PMÖC* (C-354/19)?

Consequences of not changing the SPC-system

- More harmonized interpretation of Art. 3(a) by national patent offices and courts expected due to *Teva*-two-part test
- Many SPCs for combinations and single products based on patent claims with functional definitions and Markush formulae and no specific disclosure of product likely invalid
- Most third party SPCs with an earlier filing date of the basic patent than that of the specific product patent likely invalid
- Risky choices of genus v species basic patents due to validity challenges of selection inventions
- Secondary and selection patents likely to become more important as basic patents

SPC-system cannot solve all incentive problems

- Most early research not compensated
- Why favor fixed dose over free combinations
- Difficulty of getting valid (secondary) patents for clinical innovation
  - Plausibility
  - Early transparency requirements for clinical trials
  - Non-obviousness of combinations
- Difficulty of enforcing Second Medical Use-patents
  - Carve-out and cross-label use
- New data exclusivity for second medical uses plus segmentation of markets as incentive for pharmaceutical innovation

Alternative: (Re-) Simplify SPC-system

- MA-holder chooses basic patent (strongest, longest)
  - no unauthorized Third Party-SPCs
- Only one SPC per active ingredient for first human MA of active as single or combination product
  - no combi and *Neurim-type* SPCs
- For active ingredients first approved as combinations no limitation of scope of basic patent by approved combi product (cf. *Georgetown*)
  - MA (A+B), patent (A) -> SPC (A)
- Infringement test for Art. 3(a)
  - traditional interpretation of Art.69 EPC + Protocol

Advantages of (re-) simplified SPC-system

- MA-holder who should be the one compensated for long clinical trials and regulatory delays back in control of SPCs
- Fewer and stronger SPCs better at giving business certainty than more and weaker SPCs with unpredictable fringe benefits
- Better alignment with other SPC/PTE-jurisdictions, e.g. US
- BUT: Additional (data) exclusivities needed to incentivize important secondary clinical innovation

uSPC

- Unitary Patent (UP) and Unified Patent Court (UPC)
  - (No deal) Brexit
  - German constitutional complaint and ratification
- One institution for examining and granting SPCs
  - EPO
  - Virtual office of SPC-experts from experienced patent offices
- New EU-law
  - Amendment of SPC-Regulation
  - Additional uSPC-Directive/Regulation

Fit for Purpose?

Thank you for your attention