Supplementary Protection Certificates (SPCs) – fit for purpose?

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Life of a successful drug

Returns

Investment

0

10

20

launch
Generic erosion in Germany

Volume erosion of original molecules in month x after Gx entry

- Valsartan Mono + Combi
- Candesartan Mono + Combi

Source: IMS Pharmascope Units
Importance of SPCs

![Graph showing importance of SPCs with axes labeled Returns and Investment. The graph includes a peak labeled SPC and a launch point at investment 10.]
Effect of SPC on other originators (Rx) and on generics (Gx)

Basic Compound Patent (A)

R&D&Reg (A*)

SPC (A*)

Rx (B)

Rx (A*)

Gx (A*)
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
• 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