Is the SPC regulation (still) fit for purpose?

- SPC eligibility of modern pharmaceuticals

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PhD defence, 5 March 2021

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Agenda

1. Aim of thesis
2. Background for my research
3. Research question
4. Method and delimitations
5. Structure of thesis
6. Findings – answer to research question
7. Future proposals
Aim of thesis

The purpose of my thesis is to analyse whether the SPC system is fit for purpose for modern pharmaceuticals.
“Effective patent life” (time of original patent life left for marketing) had eroded from 20 to 8-10 years due to increasingly complex and time-consuming clinical test procedures before marketing
A purpose of my research is to analyse whether the technological development of the pharmaceutical industry has challenged the SPC system increasing the risk of legal uncertainty and over-/underprotection.
Background for my research (3)

- Technological development of the pharmaceutical industry with regard to
  - Biotechnological innovation
  - Secondary innovation
Background for my research (4) - biotechnological innovation

- From small, well-defined molecules

- To large, complex biomolecules

- What is the scope of protection?
Background for my research (5) - secondary innovation

- New indication/disease of a compound known for treatment
- New dosage regime
- New formulation
- New treatment group (personalised/precision medicine)

- To which extent are products of secondary innovation SPC eligible?
Research question

Does the SPC regulation as interpreted by the CJEU fulfil its purpose of providing protection of modern pharmaceutical innovation?
Methodology

- Legal dogmatic method
- Jurisprudential analysis
  - CJEU decisions
  - National court decisions
Delimitations

- Orphan drug exclusivity – briefly mentioned
- Data and marketing exclusivity – briefly mentioned
- Paediatric extension – briefly mentioned
- SPC regulation for plant protection products – only to interpret SPC regulation for medicinal products
- No comparative analyses with SPC-like systems abroad
Structure of thesis

Ch 1: Introduction, research question, method, delimitations

Ch 2: Technological and legal baseline for the pharmaceutical industry, stakeholders and cost of innovation

Ch 3: Legal analysis of the SPC regulation (de lege lata)

Ch 4: Legal analysis of the SPC regulation with regard to modern pharmaceutical innovation
   o biotechnological innovation
   o secondary innovation

Ch 5: Reply to RQ

Ch 6: General findings, future proposals, de lege ferenda

Ch 7: List of CJEU decisions

Ch 8: Bibliography
Legal analysis of *de lege lata* – main findings (1)

**Products eligible for SPC protection**

- Strict interpretation
- Pharmacological/immunological/metabolic action of their own required
- Case law inconsistent – excipient/adjuvant NO – safener YES
- Distinction between “active ingredient” and “adjuvant” unclear
- Lack of legal certainty
Legal analysis of *de lege lata* – main findings (2)

**Art. 3(a) – protected by a basic patent in force**

- Not an infringement test
- Rather (qualified) scope of protection test
  - “specified”; (*Medeva*); “relate implicitly but necessarily and specifically” (*Eli Lilly*); “necessarily fall under the invention” and be “specifically identifiable” (*Teva*)

- “necessarily come within the scope of the invention” and
- “infer directly and unambiguously” that the product comes within the scope of the invention
- Product based on “independent inventive step” not SPC eligible (*Royalty Pharma*)
Legal analysis of *de lege lata* – main findings (3)

Art. 3(d) – the marketing authorisation is the first MA for the product

- 3 stages of interpretation
  - 1. phase: "use does not form integral part of the definition of the product" (*Yissum*)
  - 2. phase: "new therapeutic application…as protected by the new patent" (*Neurim*)
  - 3. phase: "no need to take into account the limits of the protection of the basic patent" (*Santen*)
Legal analysis of the SPC regulation with regard to modern pharmaceutical innovation (1)

Secondary innovation

- Patentability of products of secondary innovation recognised in Europe
  - Provide sufficient protection to encourage pharmaceutical research
  - Balance of interests
Legal analysis of the SPC regulation with regard to modern pharmaceutical innovation (2)

Secondary innovation

- *Neurim* – applying a teleological interpretation: aim of SPC regulation not only to encourage research into new products but also a new application of a new or known product – aim of SPC regulation to compensate for insufficient patent life

- *Abraxis* and *Santen* – aim of SPC regulation to protect research leading to first marketing of a product
Legal analysis of the SPC regulation with regard to modern pharmaceutical innovation (3)

SPC protection for biotechnological products

- What defines the scope of protection of an SPC?
- What are the criteria for determining the scope of protection of an SPC?
Legal analysis of the SPC regulation with regard to modern pharmaceutical innovation (4)

SPC protection for biotechnological products

- Does the “product definition” have any legal effect?
- Case law* seems to ascribe any legal effect to the product definition
- Lack of clarity

* Farmitalia, Yeda, Pharmaq v Intervet
Legal analysis of the SPC regulation with regard to modern pharmaceutical innovation

(5)

• **Scope of protection**
  
  • **Small molecule products**: SPC extends to derivatives (*Farmitalia*)
  
  • Extends to generics – but probably not any further

• **Biological products:**
  
  • *Pharmaq v Intervet*: extends to “therapeutically equivalent” variants, differences having a “practical and appreciable effect on the quality, safety and efficacy”
  
  • Extends (probably) to biosimilars approved based on originator’s clinical data. Does it extend any further?
Legal analysis of the SPC regulation with regard to modern pharmaceutical innovation

- **Scope of protection**
  - “Therapeutic equivalence” standard transferable to small molecule products?
  - Delicate path between Scylla and Charybdis
Conclusions

• Unclarities remain – even with regard to basic requirements

• Low level of incentive to protect early stage research

• Low level of incentive to protect late stage research

• Not possible to identify clear criteria or principles for determining scope of protection of SPCs for biotechnological products
Results – answer to research question

The SPC regulation only fulfils its purpose of improving protection of modern pharmaceutical innovation to a limited extent
General findings – future proposals, *de lege ferenda*

- Establish a separate regulation for biotechnological medicinal products
- Introduce a definition of the scope of protection
- Clarify the status of the product definition
- Evaluation of correctness of lack of SPC eligibility for products of secondary innovation – taking into account also other incentives
- Introduction of common soft-law provisions for interpretation of the SPC regulation
Thank you for your attention!