

Fordham IP Conference 2012

Supplementary Protection Certificates

Some answers and more questions

PART ONE: Introduction, Medeva and the German Reaction

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Agenda

- Brief recap – overview of the right and outline of the big issues as at April 2011
- Some answers re: Articles 3(a) and 3(b): the Medeva/Georgetown rulings from the CJEU
- Has Medeva/Georgetown provided all the answers? – a German perspective

Brief Recap – Supplementary Protection Certificates

- *Sui generis* right protecting a drug by maximum of up to five years beyond the life of the patent
- **“Product”** = active pharmaceutical ingredient or combination of active pharmaceutical ingredients;
“medicinal product” = the finished medicine;
“basic patent” = a patent protecting:
(i) a product as such; (ii) a process; or (iii) an application for a product

Conditions for Obtaining an SPC (Article 3)

- a) the product is **protected by a basic patent** in force;
- b) a **valid authorisation** to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate;
- c) the **product has not already been the subject of a certificate**;
- d) the authorisation referred to in point (b) is the **first authorisation** to place the product on the market as a medicinal product.” (Emphasis added)

Big Issues as at April 2011?

1. Article 3(a) – What does “protected by a basic patent” mean?
Infringement test v subject matter/disclosure test

- Would a patent for A, serve as a basic patent for an SPC application for A+B?



- Apply the infringement test
- Uncertain / changing
- Very strict (must be specifically claimed)
- Strict (combination must be disclosed)
- Less strict (any reference to a combination will suffice)

2. Article 3(b) – how should “a valid authorisation to place the product on the market” be interpreted?

- Would an MA for A+B serve as a valid authorisation to place A or B on the market?

CJEU Rulings in Medeva & Georgetown

(References C-322/10 and C-422/10, 4th Chamber, 24 November 2011)

- **Art. 3a** precludes the granting of an SPC for active ingredients that are not specified in the wording of the claims of the basic patent
- “protected by a basic patent” requires specification in the claims
 - ⇒ basic patent for A does not provide a basis for SPC covering A+ B
 - ⇒ basic patent for A+B does not provide a basis for SPC covering A or B

CJEU Rulings in Medeva & Georgetown (cont.)

- **Art. 3b** does not preclude the granting of an SPC for an active ingredient even if the MA contains not only that active ingredient but also other active ingredients
- In other words, an MA for A + B can serve as the MA for A (or B) alone
- Objective of Regulation No 469/2009 is to ensure sufficient protection to recover investment in order to encourage pharmaceutical research including improvements and development of complex products

German Response to Medeva (i)



- German courts have traditionally accepted reference in the patent description to a combination of active ingredients sufficient to obtain a SPC on that combination even if the combination itself was not claimed
- Medeva is considered to change this approach but the decision poses questions and causes uncertainties
- SPC holders fear to lose their SPCs on combination products
- Critical points of the ruling:
 - Extent of required specification – chemical formula in the claims or sufficiency of a functional description?
 - Possibility of limitation of the patent claims to incorporate combinations mentioned in the description but not explicitly mentioned in the claims

German Response to Medeva (ii)



- Attempts to comply with requirements set out in the Medeva judgment by limiting the claims according to sec. 64 German Patent Act
 - Limitation proceedings possible in case the claim covers an active ingredient A but the description refers to a combination A+B?
 - First attempts prove more difficult than expected: German PTO considers a limitation of a claim covering A to a claim covering A + B (even if B is disclosed) to be different subject matter.
 - Limitation of independent subclaim could lead to the result that SPC on A remains and in addition limited subclaim provides basis for SPC on the combination of A+B
- ⇒ May Render CJEU judgment to contain purely formalistic requirement
- ⇒ Failure of the judgment to provide any guidance