



Supplementary Protection Certificates for medicinal products

**Conditions for obtaining a certificate - need for further
clarifications?**

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COUNCIL REGULATION (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products

”Whereas, therefore, the creation of a supplementary protection certificate **granted, under the same conditions, by each of the Member States** at the request of the holder of a national or European patent relating to a medicinal product for which marketing authorization has been granted is necessary; whereas a Regulation is therefore the most appropriate legal instrument; ” (Preamble to regulation)

Article 3. Conditions for obtaining a certificate

A certificate shall be granted if..... at the date of that application:

- (a) the product is protected by a basic patent in force;
- (b) a valid authorization to place the product on the market as a medicinal product has been granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC, as appropriate;
- (c) the product has not already been the subject of a certificate;
- (d) the authorization referred to in (b) is the first authorization to place the product on the market as a medicinal product.

Outline

- Art 3(a). The "Product" and the basic patent – When is the product protected by the basic patent as such?
- Art 3(b). The "Product" and the marketing authorisation – Does the "Product" for the SPC need to be identical to the product(s) according to the marketing authorisation?
- Art 3(c). The "Product" and the first certificate – More than one certificate for the same product?

Article 1. Definition of "Product":

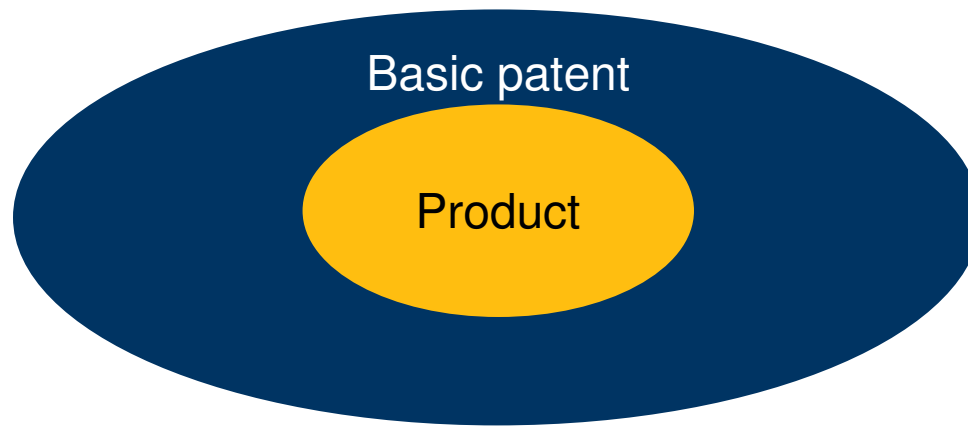
- "Product" means the active ingredient or combination of active ingredients of a medicinal product (Art. 1 (b))
- "Product" cannot comprise preparations or formulations i.e. combinations of active substance(s) and excipients (ECJ C-431/04)
- The intended use does not form part of the definition of the "Product" (ECJ C-202/05)

Art 1(c). The "product" and the basic patent

Definition of "basic patent":

- 'basic patent' means a patent which protects a product as defined in (b) **as such**, a process to obtain a product or an application of a product, ... (Art. 1 (c))
- whether a "Product" is protected by a basic patent as such, is determined by the claims and the rules governing the basic patent (ECJ C-392/97)

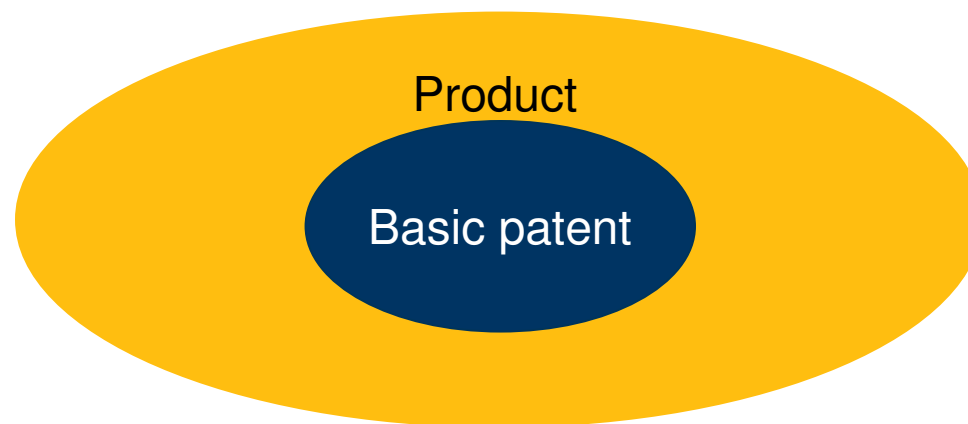
May the basic patent be broader than the "Product"?



Yes.

The basic patent may e.g. protect groups of compounds to which the "Product" belongs

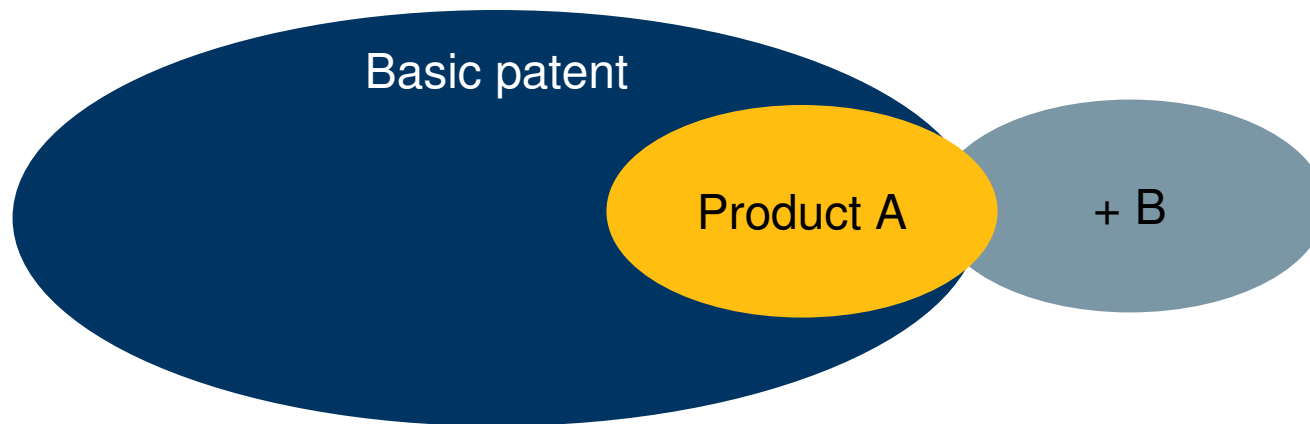
May the "Product" be broader than the basic patent?



No.

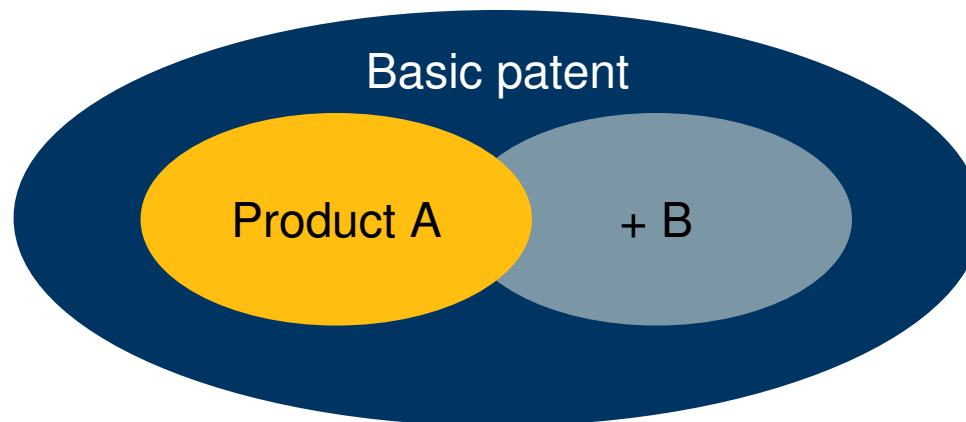
The "Product" may not be broader than the "basic patent" – but may include equivalents covered by the basic patent (ECJ C-392/97)

Combination products: May the basic patent protect only one active ingredient of a "Combination Product"?



No.

Combination products: May the basic patent protect only one active ingredient of a "Combination Product"?



The basic patent must protect the combination product as such and not just one of the products of the combination

Combination products

- Decision introduced by both DKPTO and PRV in 1995
- Confirmed by Swedish Board of Appeal in 1996 and Danish Board of Appeal in 1999
- Confirmed by Regeringsretten in 2000 (3248-96)
- Confirmed by Østre Landsret in 2003 (B-2667-01)

Regeringsretten målnr. 3248-96

- MA for Felodipin in combination with metoprolol
- "Product" for which protection was applied for "Combination of felodipin and metoprolol"
- Patent protection covering Felodipin
- PRV: Not in accordance with Art 3.(a)
- Regeringsretten confirmed – and refused to refer question to ECJ due to obviousness of answer

Regeringsrätten månr. 3248-96

Rubrik:

Enligt artikel 3 punkt a i rådets förordning (EEG) nr 1768/92 om införande av tilläggsskydd för läkemedel fordras för att tilläggsskydd skall medges för en viss produkt att produkten skyddas av ett gällande grundpatent. Detta villkor har inte ansetts vara uppfyllt beträffande en produkt bestående av en kombination av två aktiva ingredienser, av vilka endast den ena ansetts omfattad av det åberopade grundpatentets patentkrav.

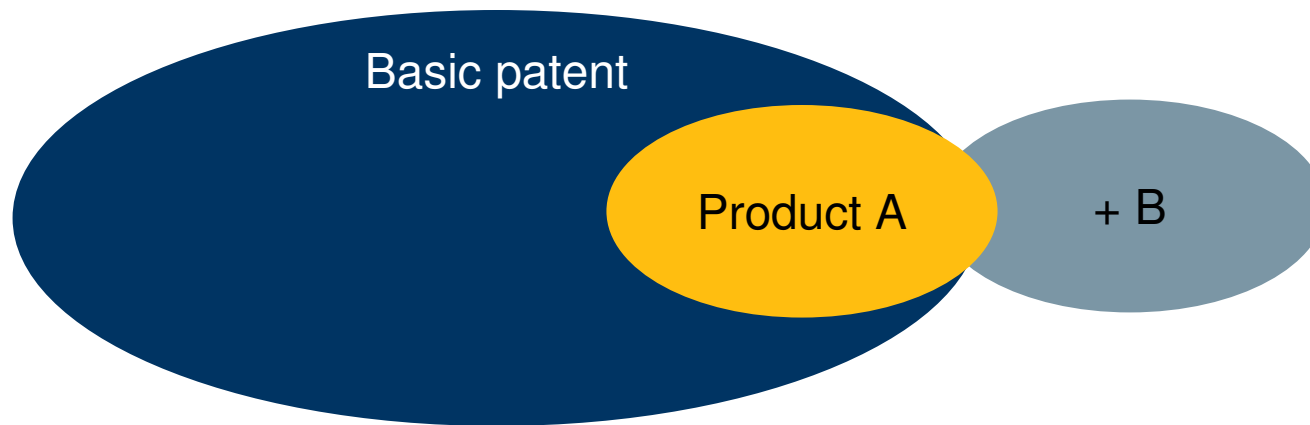
Regeringsrätten målnr. 3248-96

Regeringsrätten finner att rättsläget, såvitt gäller den här berörda tolkningsfrågan, är så pass klart att det inte finns anledning att i den frågan begära förhandsavgörande från EG-domstolen.

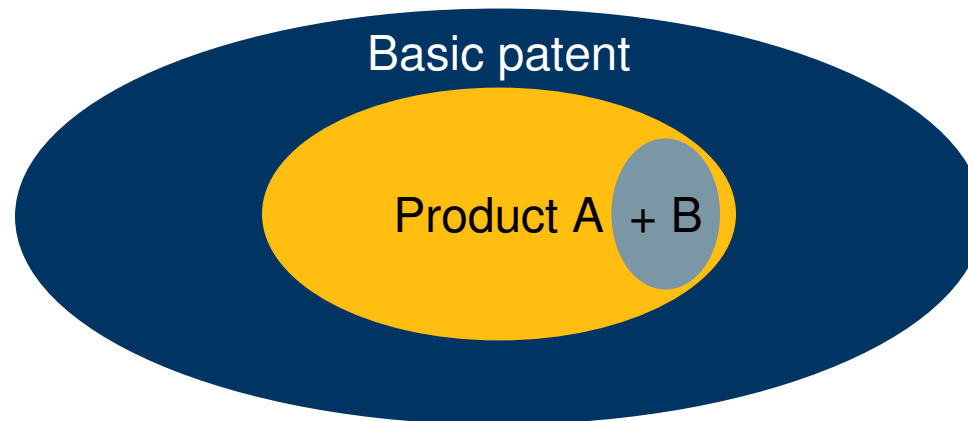
Combination products

- Conclusion followed by UKPTO and confirmed by UK High Court of Justice in 2003 (CH 2002/APP/0072)
- Also followed in Netherlands
- Others?

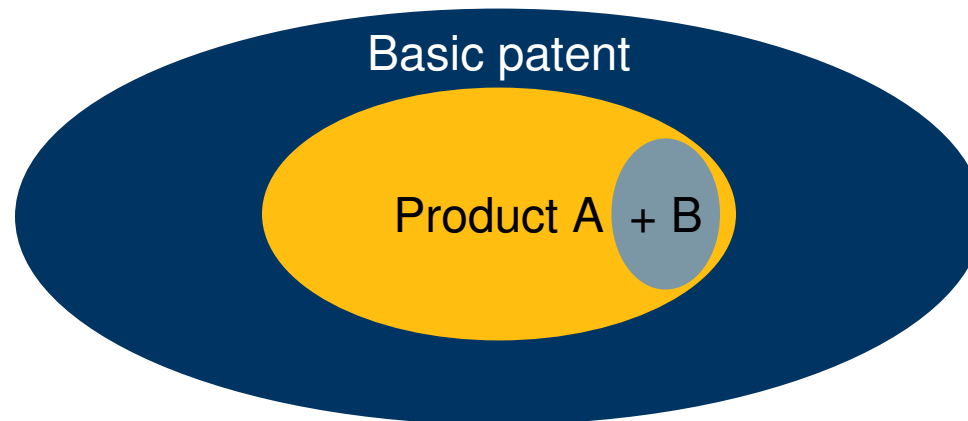
Is the decision reasonable?



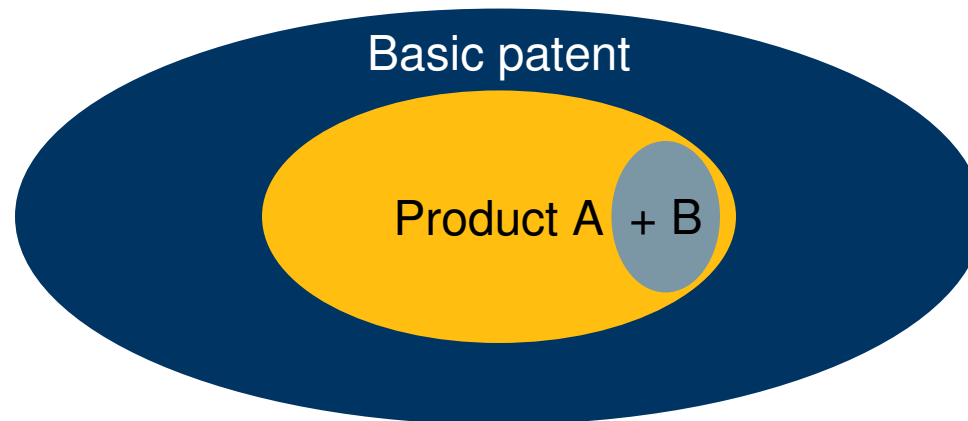
Or have the authorities made a mistake?



The "absurd" remedy



The "absurd" remedy

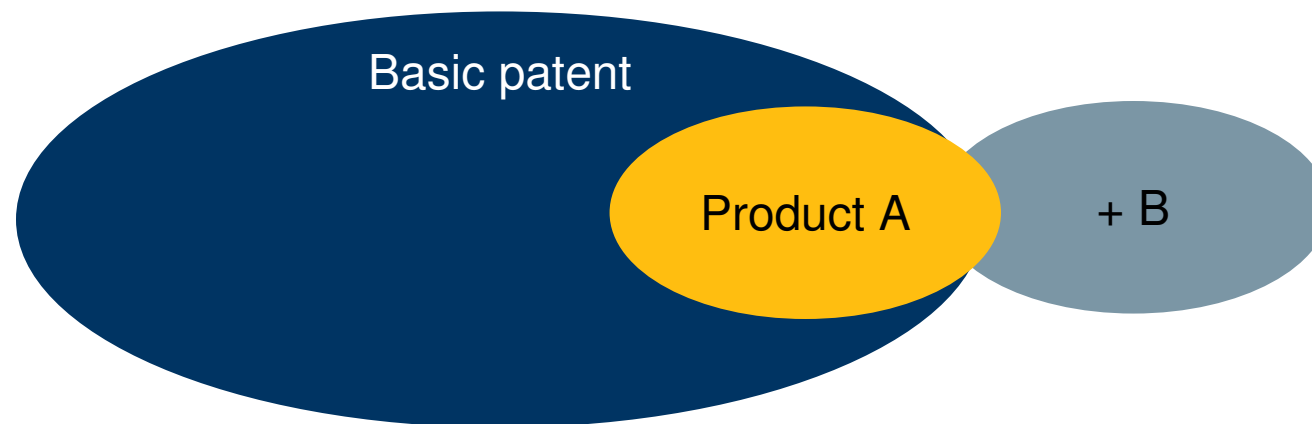


Administrative limitation of basic patent (DK)
Limitation procedure (EPO)

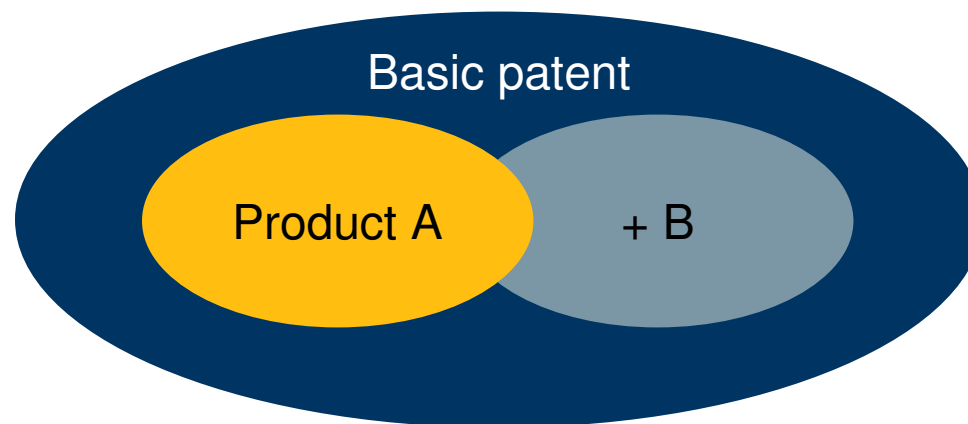
The "absurd" remedy – limitation of basic patent (if basis can be found)

- MA for Felodipin in combination with metoprolol
- "Product" for which protection was applied for "Combination of felodipin and metoprolol"
- Patent protection covering Felodipin – limited administratively (DK or EPO) to patent covering only Felodipin in combination with metoprolol
- Certificate should be granted!

The "absurd" remedy – limitation of basic patent

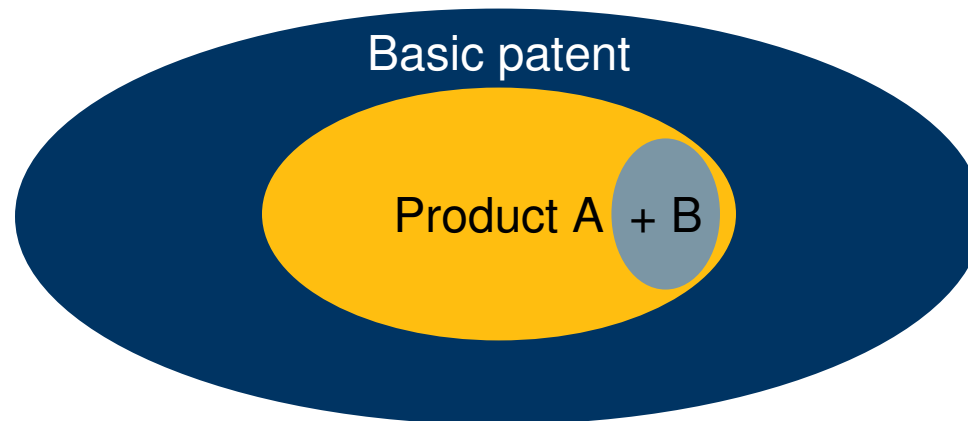


The "absurd" remedy – limitation of basic patent

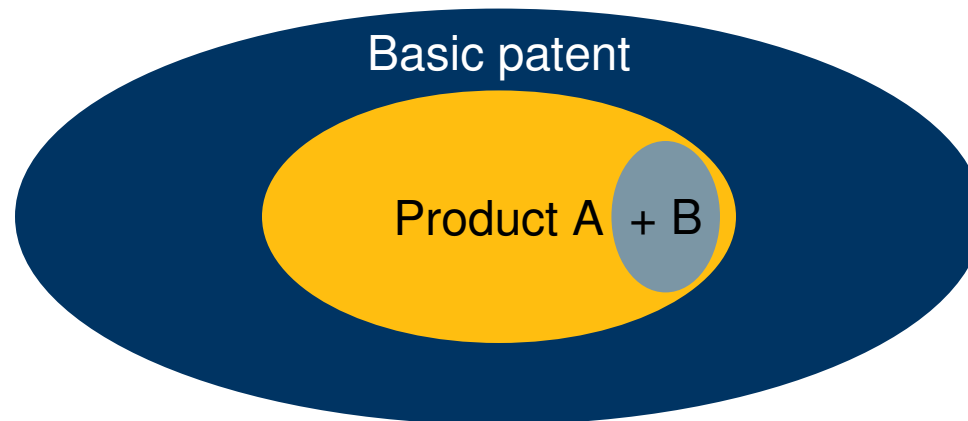


DKPTO : Limitation results in an unallowable extension of scope of claims

The "absurd" remedy – limitation of basic patent



The "absurd" remedy – limitation of basic patent



No extension of scope!!

Combination products

- Reference to ECJ needed?
- Until then - patent applications for medicinal products should be drafted comprising each and every possibly relevant combination product

Art 3(b). The "Product" and marketing authorisation

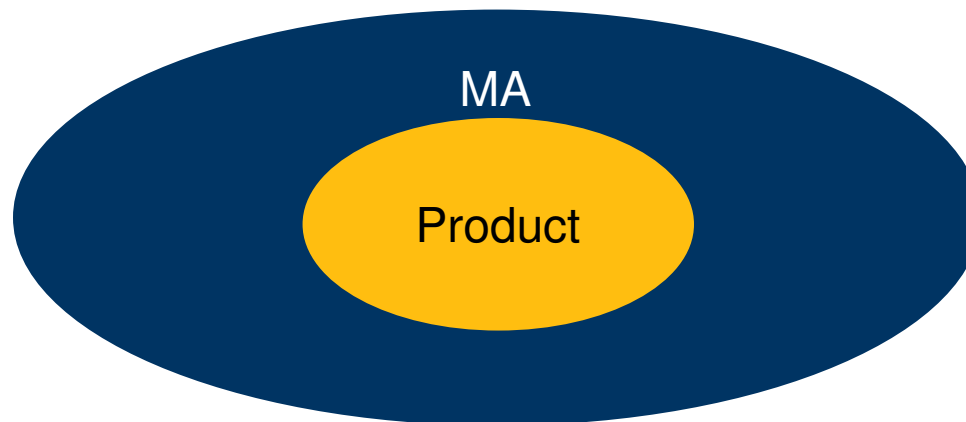
- Does Art. 3(b) require the product for which protection is sought and the active substance(s) referred to in MA to be identical?
- Or does Art. 3(b) only require that a MA for a medicinal product comprising the "Product" exist?

Art. 3(b) a valid authorization to place the product on the market as a medicinal product has been granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC, as appropriate;

Art 3(b). The "Product" and marketing authorisation

- DKPTO – Art. 3(b) **requires** that the product for which protection is sought and the active substance(s) referred to in MA are identical? (pers. comm.)
- PRV – Art. 3(b) **does not necessarily require** that the product for which protection is sought and the active substance(s) referred to in MA are identical? (pers. comm.)

May the MA be broader than the "Product"?



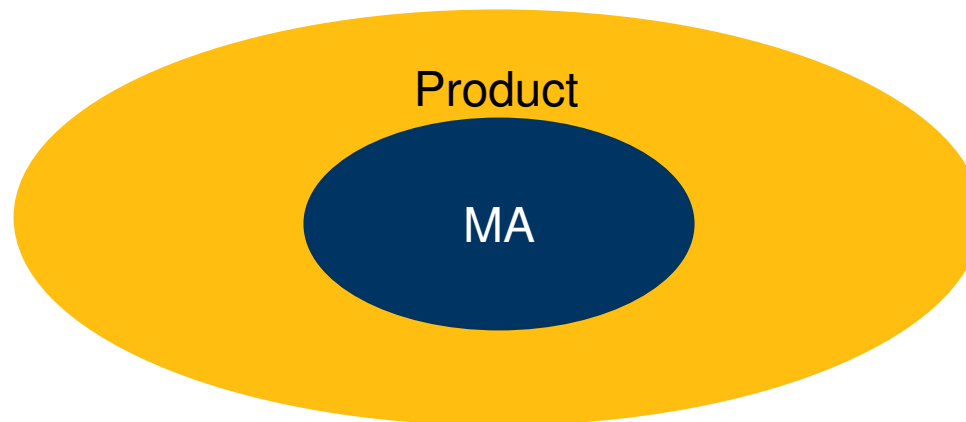
DKPTO - No

PRV –Yes (a known example)

Example I - polymorph

- MA covering substance X
- Patent covering polymorph X'
- SPC application for product = polymorph X'?
- PRV - grant (known example)
- DKPTO – reject (pers. comm.)

May the "product" be broader than the MA?



DKPTO - No

PRV –Yes (a known example)

Example II – combination product

- MA covering medicinal product comprising substances X and Y
- Patent covering only substance X
- SPC application for product = substance X + Y – not in accordance with Art 3(a)
- SPC application for product = substance X?
- PRV - grant (known example)
- DKPTO and UKPTO - reject (known example)

Art. 3(c). More than one certificate per product?

- *Art. 3(c) the product has not already been the subject of a certificate;*
- May different patent proprietors each obtain certificates on the same product?
- Yes (ECJ C-181/95).

Art. 3(c). More than one certificate per product?

- ECJ C-181/95

*“Where a medicinal product is covered by several basic patents, Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products does not preclude the grant of a supplementary protection certificate **to each holder** of a basic patent”*

Art. 3(c). More than one certificate per product?

- May the same patent "holder" obtain more than one certificate for the same product?
- If the answer is "no", what are the requirements for being the "same patent holder"? Same company? Same family of companies? Licensee?
- Current practice at DKPTO seems to be to grant more than one certificate to the same proprietor.
- However, corresponding regulation for plant protection products (Art. 3.2) indicates "no".

Art. 3(c). More than one certificate per product?

- Regulation (EC) No 1610/96, Art. 3.2.

The holder of more than one patent for the same product shall not be granted more than one certificate for that product. However, where two or more applications concerning the same product and emanating from two or more holders of different patents are pending, one certificate for this product may be issued to each of these holders.

Conclusions

- Art 3(a). Current practice seems to be **questionable** at least in relation to combination products.
- Art 3(b). Current practice is **not consistent** among member states.
- Art 3(c). Current practice seems to be **contradictory**.
- Do we need references to ECJ?

Thank you for your attention!