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Patentanwälte

Supplementary Protection Certificate
- SPC -
- Questions and Answers -

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Outline – The Topics

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2. Types of Products available for an SPC
3. European Countries granting an SPC
4. Term of an SPC
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Outline – The Topics

II. Landmark Questions and Answers

1. Conditions of Product Protection by a Basic Patent
   Medeva / Eli Lilly v HGS

2. Marketing Authorisations for an SPC
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3. More than one SPC per Patent
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I.1 What are subject-matter and effect of an SPC?

Subject-matter of Protection of an SPC

No extension of the term of the whole patent

Protection conferred by an SPC
extends only to the product covered by the MA (Art. 4)

Example

Patent: protects A, B, C and D

SPC: protects only B

Effect of an SPC

For the product: confers the same rights as the basic patent (Art. 5 and Novartis v Actavis, C-442/11)

I.2 For what types of products is an SPC available?

Legal basis – „SPC Regulation“

- Medicinal products: Regulation (EC) No. 469/2009
- Plant protection products: Regulation (EC) No. 1610/96
- Germany: in conjunction with § 16a PatG

I.2 For what types of products is an SPC available?

SPC Regulation – an SPC is granted for

- An active ingredient or
  a combination of active ingredients
  of a medicinal or a plant protection product (Art. 1)

- Any product protected by a patent
  in the territory of an EU/EEA Member State (Art. 2)

- Any product for which a marketing authorisation (MA)
  is necessary to place the product on the market
  as a medicinal or a plant protection product (Art. 2)

I.2 For what types of products is an SPC available?

Practice 2014 – an SPC is granted for

- Medicinal products
- Veterinary medicinal products
- Plant protection products
- Safeners (with a toxic, phytotoxic or plant protection action, Bayer CropScience, C-11/13)

Practice 2014 – an SPC is <u>not</u> granted for

- Adjuvants (GSK Biologicals, C-210/13)
- Medical devices (Cerus Corporation, BL O/141/14)

I.3 Where in Europe is an SPC available?

In Europe – an SPC can be obtained

- In all Member States of the EU (currently: 28): Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom
- In all Member States of the European Economic Area (EEA) (currently: 3): Norway, Iceland, Liechtenstein
- In Switzerland: based on Swiss patent law

I.4 How long does an SPC last?

Purpose of an SPC

- Adequate effective protection of active ingredients
- Grant the holder of both a patent and an SPC
  a maximum term of exclusivity of 15 years
  from the grant of the first marketing authorisation
  (Merck Canada, C-555/13)

Term of an SPC

- Maximum term: **5 years** (Art. 13 No. 2)
- Extra 6 months (paediatric extension, Art. 13 No. 3)
- Minimum term: **Negative term** (Merck, C-125/10)

I.5 How is the term of an SPC calculated?

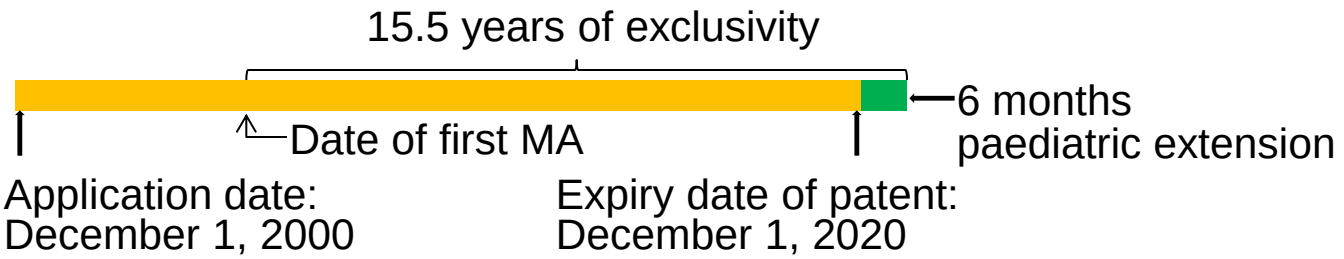
Term of an SPC (Art. 13 No. 1)

Period between application date of the patent and date of first MA in EU/EEA minus 5 years

Example 1

Application date of the patent: December 1, 2000
Date of first MA: December 1, 2005
Term of SPC: 0 days

} Period = 5 years



I.5 How is the term of an SPC calculated?

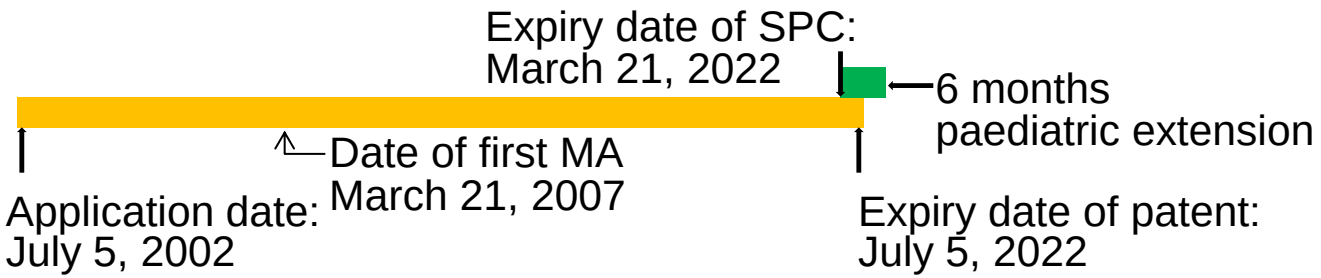
Term of an SPC (Art. 13 No. 1)

Period between application date of the patent and date of first MA in EU/EEA minus 5 years

Example 2

Application date of the patent: July 5, 2002
Date of first MA: March 21, 2007
Term of SPC: minus 3 m 14 d

} Period = 4 y 8 m 16 d



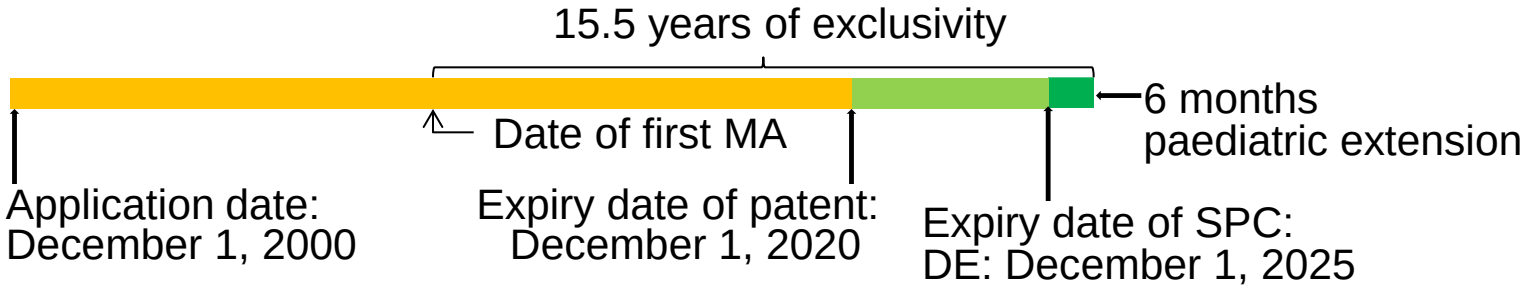
I.5 How is the term of an SPC calculated?

Term of an SPC (Art. 13 No. 1)

Period between application date of the patent and date of first MA in EU/EEA minus 5 years

Example 3

Application date of the patent: December 1, 2000
Date of grant of first MA: December 1, 2010
} Period = 10 years
Term of SPC: 5 years
Start of SPC protection: December 1, 2020



I.5 How is the term of an SPC calculated?

Practice 2014 – Date of first MA

- UK: uses date of notification of first MA (Genzyme, BL O/418/13)
- DE: uses date of grant of first MA
- **Seattle Genetics, C-471/14**, referral to the CJEU:

  Is the date of first MA to be determined according to Community law or according to the date on which MA comes into effect according to the law of the EU Member State?

  Is the relevant date the date of grant of the authorisation or the date of notification of the authorisation?

I.6 What are the conditions for obtaining an SPC?

An SPC shall be granted if at the filing date of the SPC application and in the Member State, in which the application is filed (Art. 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/plant protection product has been granted;

(c) an SPC has not yet been granted for the product;

(d) the authorisation under (b) is the first authorisation for placing the product on the market.

II.1 When is a product protected by a basic patent?

An SPC shall be granted if at the filing date of the SPC application and in the Member State, in which the application is filed (Art. 3):

(a) the product is protected by a basic patent in force;

(b) …; (c) …; (d)… .

Medeva (C-322/10)

A product is protected by the basic patent if it is **„specified in the wording of a claim“**

What is understood by „specified“ in the case of Markush structures, functionally defined active ingredients?

II.1 When is a product protected by a basic patent?

Eli Lilly v HGS (C-493/12)

The dispute:

- **HGS** is the holder of a patent (expiry date:10-25-2016) relating to a new protein, Neutrokine-α, and antibodies binding thereto
- HGS's patent contains antibody and composition claims which define the antibody functionally
- **Eli Lilly** wanted to market a composition comprising antibody Tabalumab specifically binding to Neutrokine-α
- **Eli Lilly's risk:** is Tabalumab protected by HGS's patent and may HGS obtain a valid SPC for Tabalumab?

II.1 When is a product protected by a basic patent?

Eli Lilly v HGS (C-493/12)

Landmark questions referred to the CJEU:

1. What are the criteria for deciding whether "the product is protected by a basic patent in force"?
3. In the case of a claim to an antibody …, is it sufficient that the antibody … is defined in terms of its binding characteristics to a target protein, or is it necessary to provide a structural definition for the antibody …, and if so, how much?

II.1 When is a product protected by a basic patent?

Eli Lilly v HGS (C-493/12)

„Answers“ of the CJEU:

A product is protected by a basic patent
if the active ingredient is identified in the claims
by means of a structural or a functional definition

In the case of a functional definition in the claims
the product may be regarded as protected by the patent,
if it is possible to reach the conclusion on the basis
of the claims, interpreted in the light of the description,
that the claims relate, implicitly but necessarily and
specifically, to the active ingredient

II.1 When is a product protected by a basic patent?

Eli Lilly v HGS (C-493/12) – Impacts on Practice 2014

Product not identified in the claims of the basic patent

→ **SPC** is invalid (Art. 15(1)(a))

→ **SPC application** will not be granted (Art. 3(a))

Remedies:

- Limitation of the basic patent
  before EPO or national patent offices
- Request for revocation of SPC/withdrawal of SPC request;
  filing of a new SPC application based on another patent?

II.2 On which MA must an SPC be based?

An SPC shall be granted if at the filing date of the SPC application and in the Member State, in which the application is filed (Art. 3):

(a) …;

(b) a valid authorisation to place the product on the market as a medicinal/plant protection product has been granted;

(c) …;

(d) the authorisation under (b) is the first authorisation for placing the product on the market.

II.2 On which MA must an SPC be based?

An SPC application must be based

- on the first marketing authorisation (MA) in the country, in which the SPC application is filed
- on a marketing authorisation for the product, which covers the active ingredient or the combination of active ingredients of the product

Landmark question relating to MAs:

Can the MA contain further active ingredients beyond the active ingredients in the SPC application?
Georgetown I (C-422/10)

Answer: Yes

II.3 Can more than one SPC be granted per patent?

SPC shall be granted if at the filing date of the SPC application and in the Member State, in which the application is filed (Art. 3):

(a) …;

(b) … ;

(c) an SPC has not yet been granted for the product;

(d) … .

II.3 Can more than one SPC be granted per patent?

Georgetown II (C-482/12)/Actavis v Sanofi (C-443/12)

It is possible to obtain more than one SPC per patent
if the same patent protects several different active ingredients „as such“.

Protection „as such“ means:

the active ingredient, for which protection is sought constitutes the „**core inventive advance**“ of that patent

II.3 Can more than one SPC be granted per patent?

Georgetown II (C-482/12)/Actavis v Sanofi (C-443/12) – Impacts on Practice 2014

A second SPC for a combination of
an active ingredient protected „as such“ by a basic patent
plus a further long known active ingredient is invalid,
if for the active ingredient alone a first SPC has already been granted

Reasoning: The first SPC confers the owner already the same rights as the basic patent also for the use of the combination of the two active ingredients

II.3 Can more than one SPC be granted per patent?

Federal Patent Court, BPatG, Telmisartan, 3 Ni 5/13

The dispute:

- **1st SPC/2nd SPC:** granted based on the same patent
- **1st SPC:** Telmisartan alone (expiry date: 11-12-2013)
- **2nd SPC**: Telmisartan + HCTZ (expiry date: 01-31-2017)
  HCTZ is a long known active ingredient
- Actavis filed a nullity action against the 2nd SPC:
  2nd SPC is invalid as an SPC has already been granted for the same active ingredient

Decision of BPatG: 2nd SPC is invalid

III. Summary – Where are we in 2014?

1. **When is a product protected by a basic patent?**

   If active ingredient is identified in the claims by means of a structural or a functional definition in a specific manner

2. **What is a valid marketing authorisation?**

   A first MA covering the active ingredient of the product, and possibly further active ingredients

3. **Can more than one SPC be granted per basic patent?**

   Yes, if the patent protects different active ingredients as such, i.e. if the active ingredients constitute the "core inventive advance" of the basic patent

Thank you
for your attention!