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# Lunes de Patentes - SPCs

Madrid, May 22, 2017

Klemens Stratmann, Gustavo Fuster



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# Supplementary protection certificates - Recent decisions, Biologics, UPC

Klemens Stratmann – Gustavo Fuster

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## 1 Introduction

2 SPCs based on 2<sup>nd</sup> medical use patents (CJEU Neurim)

3 What means “protected by the basic patent”

4 SPCs for Biologics

5 SPCs for a combination of actives

6 Further referrals pending before the CJEU

7 SPCs and UPCA - Proposal for a unitary SPC

8 SPC manufacturing waiver



## Requirements for granting SPCs

The conditions for obtaining an SPC are laid down in Art 3 of the SPC Regulation No. (EU) 469/09.

A certificate shall be granted if...

- 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 or plant protection product) has been granted;
- c)** the product has not already been the subject of a certificate;
- d)** the authorization referred to in point (b) is the first authorization to place the product on the market as a medicinal product.



## Art. 3 and its interpretation by the CJEU

**Art. 3a)** *the product is protected by a basic patent in force;*

must be interpreted as

*precluding the grant of SPCs relating to **active ingredients** which are not **specified / identified in the wording of the claims** of the basic patent*

(CJEU Medeva, C-322-10; CJEU Daiichi Sankyo, C-6/11)



## Art. 3 and its interpretation by the CJEU

**Art. 3b)** *a valid authorization to place the product on the market in accordance with Directive 2001/83/EC or Directive 2001/82/EC (as a medicinal product or plant protection product) has been granted;*

must be interpreted as

*not precluding the grant of **SPCs for an active ingredient** specified in the wording of the claims of the basic patent relied on, where the **medicinal product**, for which the **marketing authorisation** is submitted ....., contains **not only that active ingredient but also other active ingredients** (i.e. SPC for **A** if MA issued for **A + B**)*



## Art. 3 and its interpretation by the CJEU

**Art. 3c)** *the product has not already been the subject of a certificate*

must be interpreted as

*precluding, in circumstances, where, on the basis of a patent protecting an **innovative active ingredient (A)** and a MA for (A), the holder of that patent has already obtained an SPC for (A), the grant of further SPCs for (A+B), if (B) is not protected as such by patent*

(CJEU Actavis I, C-443/12)



## Art. 3 and its interpretation by the CJEU

**Art. 3d)** *the authorization referred to in point (b) is the first authorization to place the product on the market as a medicinal product*

must be interpreted as

*only the MA of the first medicinal product, comprising the product and **authorised for a therapeutic use corresponding to that protected by the patent** relied upon for the purposes of the application for the SPC, may be considered to be the first MA of ‘that product’*

→ SPCs for 2nd medical use patents (CJEU Neurim, C-130/11)





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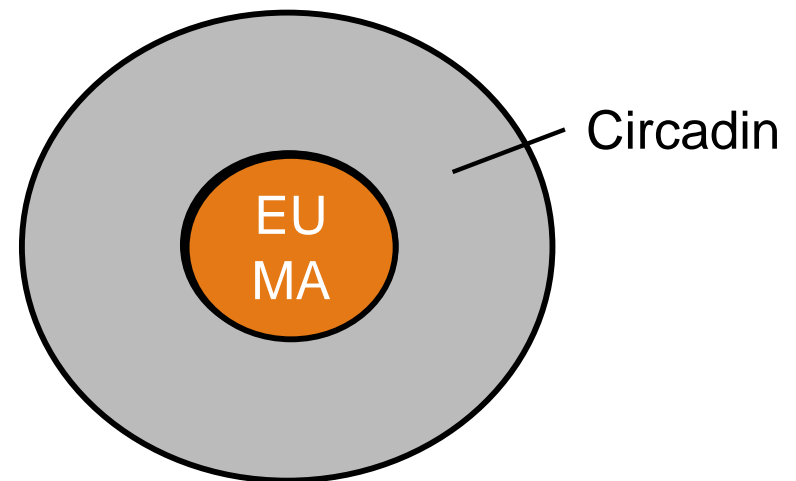
**Neurim – What is the „first“ MA (Art. 3(d)) for a 2nd medical use patent?**

Earlier MAs

1992   
Melatonin for enhancing  
fur growth in mink

1999   
Melatonin for initiating an  
early breeding season in  
sheep

Basis for Neurim SPC request



Neurim basic patent –  
melatonin for treating  
sleeping disorders



## The earlier case law of the CJEU

- **Pharmacia** C-31/03 – no difference whether first MA was for human or veterinary use
- **MIT** C-431/04 makes it clear that only the active ingredient is a “product” according to Art. 3(d), and not a specific use of the active ingredient
- **Yissum** C-202/05 emphasizes that the concept of “product” is to be strictly interpreted to mean active ingredient (no link to patented use)



## The Ruling of the CJEU (C-130/11), July 19, 2012

Ruling not limited to earlier veterinary MAs

• If a **patent protects a new therapeutic application** of a **known active ingredient** which has already been marketed as a medicinal product, **the MA for the new therapeutic application** of the same active ingredient may **enable its proprietor to obtain an SPC**,

- Irrelevant whether MA is for veterinary or human use, for other therapeutic indications
- Irrelevant whether active ingredient is protected by an earlier patent or not
- the scope of patent, in any event can not cover the active ingredient as such, but only the new use of that product (Art. 4)

New interpretation of Art. 3(d) – link between MA and protective scope

• **only the MA** of the first medicinal product, comprising the product and **authorised for a therapeutic use corresponding to that protected by the patent** relied upon for the purposes of the application for the SPC, may be considered to be the **first MA** of ‘that product’



## Outstanding issues

- Does Neurim overrule earlier decisions in Pharmacia Italia (C-31/03), MIT (C-431/04) and Yissum (C-202/05)?
- Does Neurim change the interpretation of Art. 3(c) that prevents the grant of more than one SPC for the same active ingredient being to the same applicant?
- Can a variation or extension to an MA amount to a new MA for the purposes of Art. 3(b) and 3(d)?
- How is “new use” in Neurim to be understood? Can CJEU Neurim be also applied to new formulations / new dosage regimes?



## Does Neurim overrule earlier decisions ?

- **Pharmacia** held a product patent and the CJEU decision concerned primarily the applicability of the transitional provision of Art. 19(1)
- **MIT** did also not rely on a 2nd medical use patent.
  - Innovative matrix polymer for the controlled release of toxic drugs (carmustine)
  - First MA was for the same indication (cancer) as the one relied upon for SPC application.
  - Question referred to the CJEU concerned the interpretation of Art. 1b (what means „*combination of active ingredients*“?)
- **Yissum** scenario similar to the one decided in Neurim:  
Patent and MA related to use of calcitriol for treatment of skin disorders.  
Earlier calcitriol MAs concerned different therapeutic applications.
  - However, the question put before the CJEU again focused on Art. 1(b): what is meant by “product” and in particular does the application of the therapeutic agent play any part in the definition of “product”



## Can a variation or extension to an MA amount to a new MA for the purposes of Art. 3(b) and 3(d)?

Art. 3 b) of the SPC regulation requires that:

- 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;
  - Art. 8(3) of Directive 2001/83/EC refers to the content of the MA application, including information on the name of the applicant, the name of the medicinal product, etc.
  - A request for a variation type II does not require a „full“ application as described in Art. 8(3) of Directive 2001/83/EC



## Can a variation or extension to an MA amount to a new MA for the purposes of Art. 3(b) and 3(d)?

Paragraph 33 of the Neurim decision:

• *Suffice it to note, first, that the provisions of Article 8(3) of Directive 2001/83 have a **purely procedural object**. Therefore, they cannot by themselves, in any event, have an effect on the assessment of the **substantive conditions** laid down in the SPC Regulation for determining, as regards that regulation, **which of the successive MAs it refers to**. Since the preceding questions concern the examination of those substantive conditions, the answers given to them do not depend on the provisions of Article 8(3) of Directive 2001/83.*



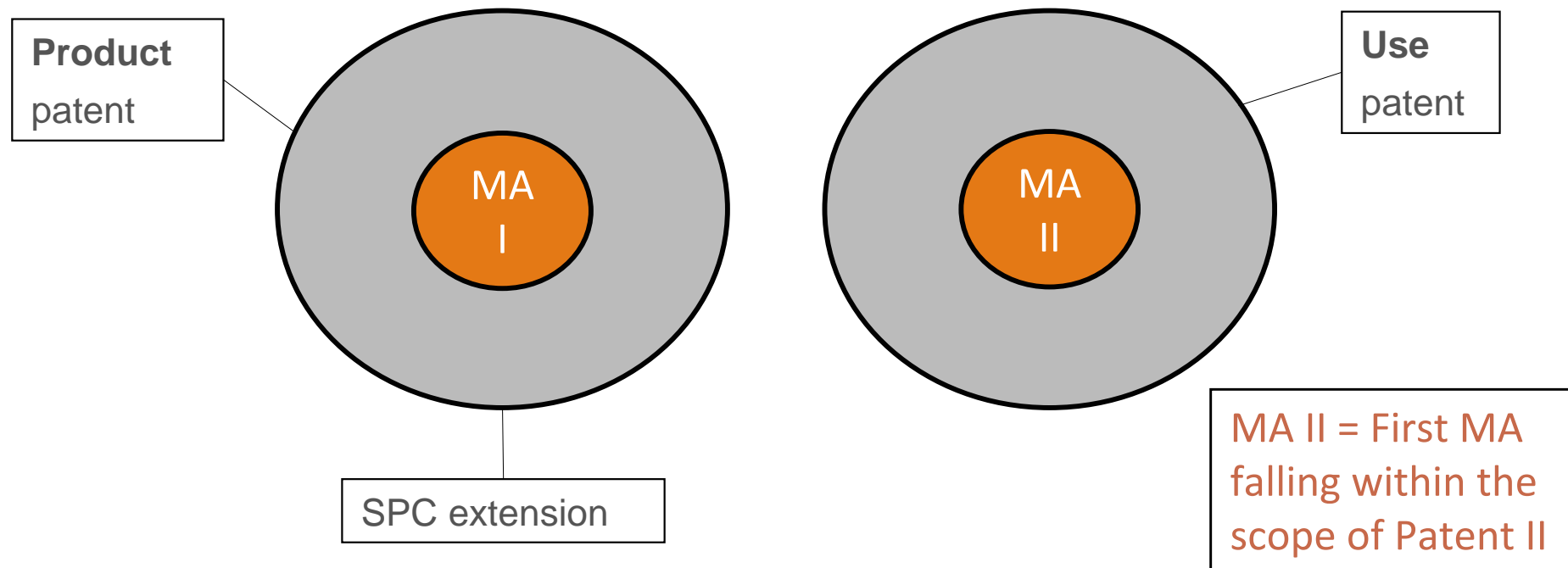


Decision by the Higher Regional Court of Vienna, Austria,  
(34 R 104/15):

- A marketing authorization as amended by a **Type II variation** can be considered as a **valid marketing authorization** in the sense of Art. 3(b) of Regulation 469/2009.
- The earlier authorizations do not deprive the more recent authorization of a patented use from being the “first authorization” pursuant to Art. 3(d) of Regulation 469/2009, if the earlier authorizations refers to areas not protected by the basic patent.
- Congruence in content between the basic patent and the marketing authorization is essential

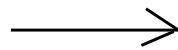


## Art. 3(c) - how broadly is the Ruling to be applied ?



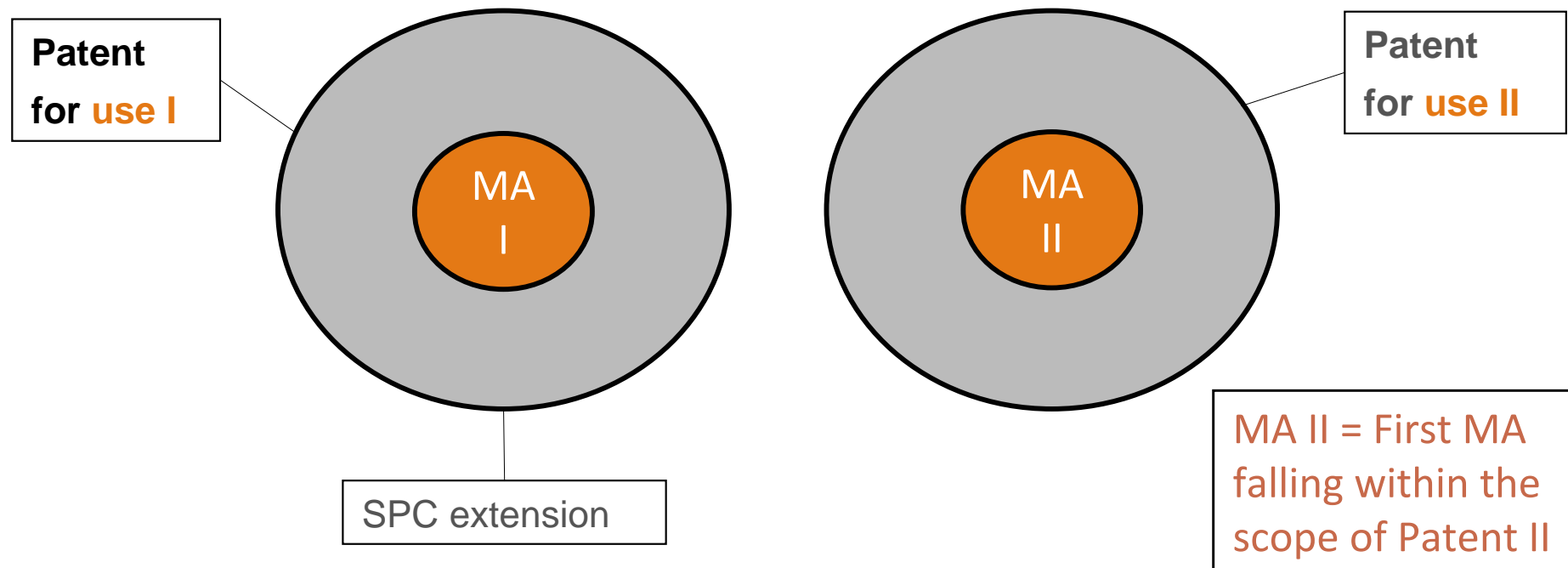
Same patent owners /same active ingredient

SPC for Patent I



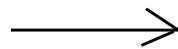
SPC for Patent II? (Art. 3(c))?

## Art. 3(c) - how broadly is the Ruling to be applied?



Same patent owners / same active ingredient

SPC for Patent I



SPC for Patent II? (Art. 3(c))?

## Art. 3(c) - how broadly is the Ruling to be applied?

- Neurim has created, for the purpose of Art. 3(d), a link between the understanding of „product“ and its therapeutic application.
- Does this link also apply for the purpose of Art. 3(c)?  
With the consequence that earlier SPCs of the same holder are only to be considered as far as they concern the same therapeutic application?
- No case law for SPCs on 2nd medical use patents
- Practice of national offices:
  - 1st scenario - seemingly hesitant to grant further SPCs over SPCs extending a product patent (one reason: Art. 4)
  - 2nd scenario – examples known from CH, DE, DK and GB for the grant of one further SPC for a 2nd medical use patent if the earlier SPC extended a patent for a different therapeutic use



Can CJEU Neurim be also applied to new formulations / new dosage regimes?

How broadly is the term “different application of the same product” to be interpreted?

- New indications (new diseases) only?
- New therapeutic dosage regimens such as once monthly administration instead of once daily?
- New patient groups?
- New formulations?



Can CJEU Neurim be also applied to new formulations / new dosage regimes?

The practice of the Spanish PTO and the Spanish Courts: No

Madrid High Court 45/2016 of January 2016

Alkermes v. SPTO

SPC application for polymer-based sustained release device containing exenatide as active ingredient:

Alkermes:

-EU MA for Bydureon/exenatide first MA within basic patent



## Alkermes v. SPTO (continued)

### SPTO:

- Earliest MA for Byetta – First MA (Art. 3d)
- Earlier SPC for exenatide opposes grant of further SPCs (Art. 3c)

### Madrid High Court:

- New dosage form ≠ „new therapeutic application“ in the sense of CJEU Neurim
- Treatment of same disease (Diabetes mellitus type 2)
- Art. 3(c) and 3(d) not fulfilled



# Madrid High Court 630/2016 of September 2016

## GSK Biologicals v. SPTO

SPC application REBIF™ (HSA-free interferon beta 1a) based on corresponding basic patent („ES 761“)

### GSK:

- EU-MA of 2007 for REBIF (amendment of MA from 1998) „first MA“ (Art. 3d)
- Major innovation – new way to stabilize interferon beta, dispensing with HSA and associated health risks

### SPTO:

- Earlier MA by Avonex for human interferon beta from 1997 is „first MA“





## Madrid High Court 630/2016 of September 2016 GSK Biologicals v. SPTO (continued)

- Relied on CJEU MIT – „*not any patented medicinal product justifies grant of SPC*“
  - Earlier MAs from 1997/1998 and amended REBIF MA (2007) concern same therapeutic indication (MS)
  - CJEU Neurim „*limited to **new** therapeutic applications*“ = *treatment of „new diseases*“
- Art. 3(d) not fulfilled



Can CJEU Neurim be also applied to new formulation of known actives?

**CJEU referral by the UK High Court of Justice  
[2017] EWHC 14(Pat) dated January 13, 2017  
(Abraxis Bioscience LLC v. Comptroller):**

*Is Article 3(d) of the SPC Regulation to be interpreted as permitting the grant of an SPC where the marketing authorisation referred to in article 3(b) is the first authorisation within the scope of the basic patent to place the product on the market as a medicinal product and where **the product is a new formulation of an old active ingredient?***



## CJEU referral in Abraxis Bioscience LLC:

### Background:

Claim 1. A composition comprising **particles** of a [...] pharmacologically **active agent, coated with protein**, wherein the average diameter of said particles is less than 200 nm [..].

Claim 23. A composition according to any one of claims 1 to 22 **for use in eliminating cancer cells**, wherein [...] said pharmacologically active agent is an antineoplastic.

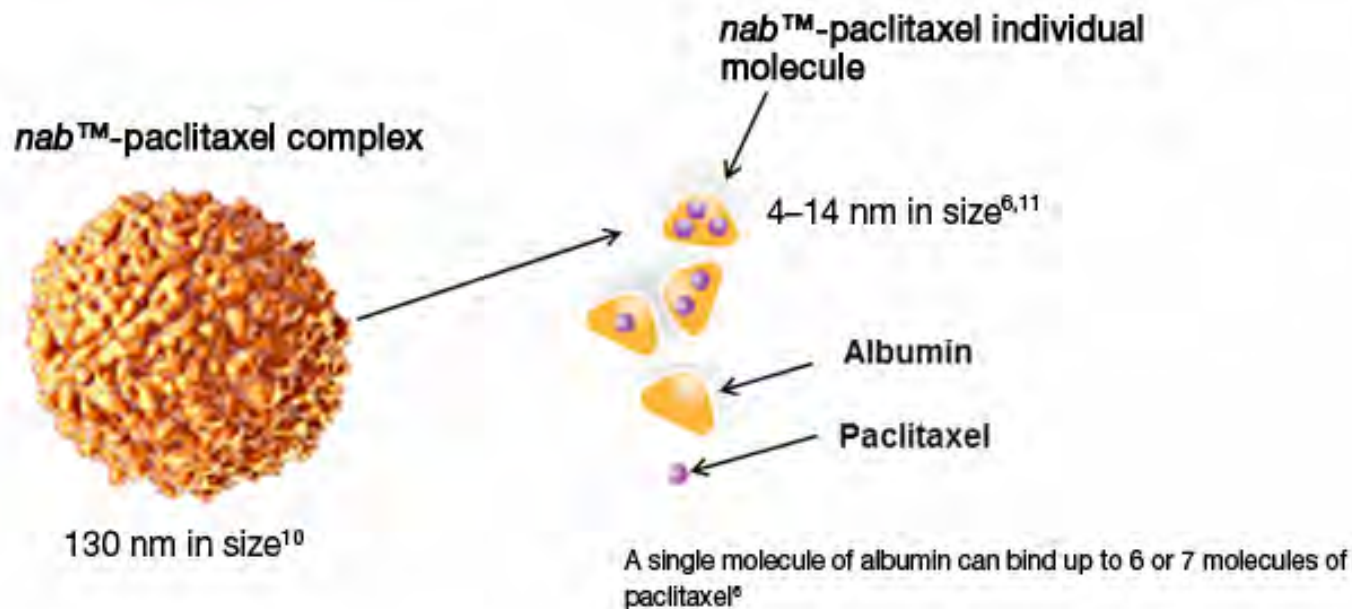
Claim 33. A composition according to claim 32, wherein said antineoplastic is **paclitaxel** and said protein is **albumin**.



## CJEU referral in Abraxis Bioscience LLC

### Background (cont.):

MA for Abraxane containing nab™ – paclitaxel (nab: nanoparticle albumin bound paclitaxel)



(see [http://www.abraxane.eu/wp-content/uploads/2013/05/nano\\_2.jpg](http://www.abraxane.eu/wp-content/uploads/2013/05/nano_2.jpg))

## CJEU referral in Abraxis Bioscience LLC

### Background (cont.):

- There exist **earlier MAs** for Taxol and Paxene containing the active ingredient paclitaxel



- Paxene is a concentrated **solution** for infusion containing **paclitaxel in a co-solvent system** (50:50 ethanol and polyoxyl castor oil, stabilised by anhydrous citric acid)

## CJEU referral in Abraxis Bioscience LLC

### Background (cont.):

“Old” Paxene MA:

- Paclitaxel in solution
- Indication: Anticancer medicine, including metastatic breast cancer

Abraxane MA relied upon by Abraxis:

- Nanoparticles of Paclitaxel bound with albumin
- Indication: Metastatic breast cancer



## CJEU referral in Abraxis Bioscience LLC

### Opinion of Justice Arnold:

- SPCs should be available for new applications (i.e. new therapeutic uses) of old active ingredients, but **not for new formulations**

### Reasoning:

- SPC Regulation was intended to provide a simple and predictable system
- SPC Regulation aims to balance the interest of patentees with those of other stakeholders



## Arguments in favor of a broad interpretation of the term “application” including formulations

- Excluding new formulations does not make the granting of SPCs more simple and predictable
  - Example CJEU Neurim - What counts as a formulation invention, what represents a new therapeutic application?
- SPC Regulation aims to balance the interest of Patentees with those of other stakeholders:
  - *“The same applies to state health systems in general which, in addition, have a particular interest in preventing old active ingredients from being brought onto the market in **slightly modified** form under the protection of certificates but without **genuine** innovation and thereby artificially driving up expenditure in the health section.”* Citation from the Opinion of the Advocate General on Neurim (Paragraph 41)
- Patented new formulations can represent genuine innovations!





## Arguments in favor of a broad interpretation of the term “application” including formulations

### Example Abraxane

- Distinct pharmacological activity compared to paclitaxel (cf. UKIPO decision BL O/410/16, section 96):
  - More effective in the treatment of metastatic breast cancer
  - Shows effectiveness in treating other tumors albeit in combination therapy
  - Better safety profile
- Supporting MA (EU/1/107/428/001) based on full application and full set of clinical studies



## Arguments for a broad interpretation of the term “application” including formulations

- *The fundamental objective of the SPC Regulation is to ensure sufficient protection to encourage pharmaceutical research (paragraph 22 of Neurim).*
- *All research, whatever the strategy or final result, must be given sufficient protection (paragraph 29 of the explanatory memorandum to the proposal for a council regulation concerning the creation of an SPC for medicinal products (COM(90) 101 final) mentioned in paragraph 24 of Neurim). The proposal is not confined to new products only.*



## C-130/11 – Neurim

### Summary

- Neurim creates for the first time a **link between the scope of protection** of the selected **basic patent and the authorized [medicinal] product**
- SPCs may be granted on the basis of a patent protecting the **new therapeutic application of a known active ingredient** and the **first MA** approving the new application
- The approval may be issued as a **variation type II** of an existing global MA (national court decision in AT)



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**Art. 3a)** *the product is protected by a basic patent in force;*

CJEU in *Farmitalia* (C-392/97): *can be determined only in the light of the non-European Union rules governing patents*

The practice of many PTOs:

- if the product directly infringes a claim, the product is “protected”

Recent fundamental changes in case law

- **Medeva**, C-322/10
- **Georgetown University**, C-422/10
- **Daiichi Sankyo**, C-6/11
- **Eli Lilly**, C-493/12
- **New Referral: Teva v Gilead**



## The Medeva dilemma Multivalent vaccine

Patent protects

- Pertactin
- Filamentous Haemagglutinin
- 8 / 11 further active agents

Active agents  
according to  
MAs



## CJEU on the interpretation of Art. 3(a) and Art. 3(b):

### Medeva, (C-322/10) and Georgetown I (C-422/10) on Art. 3(a):

- An SPC cannot be granted for active ingredients which are not **specified in the wording of the claims** of the basic patent
- Medeva patent **protects only** the combination of **pertactin and haemagglutinin** but not a product with all 10 or 13 actives
  - although such product would infringe the combination claim

### CJEU seems to reject **infringement test!**

### Medeva, (C-322/10) and Georgetown I (C-422/10) on Art. 3(b):

- SPC can be granted for A if MA relates to A+ further actives
- SPC can be granted for **A+B** if MA is for **A+B+C+D+etc.**
- **SPC grant for combination of pertactin and filamentous haemagglutinin**



CJEU rulings raise many new questions:

- Is it permissible after issuance of an SPC to amend/limit a granted patent to make my claims compliant with *Medeva*?
  - cf. “Actavis II”, C-577/13
- What means “specified” or “identified” (C-6/11, Daiichi)?
- Required degree of specification /identification?





## C-493/12 Eli Lilly - Background

- The basic patent (by HGS) relates to a new protein – Neutrokin alpha
- Claim 13 of the patent claims very broadly antibodies that “bind specifically” to Neutrokin alpha
- No specific antibody is identified in the patent
- Eli Lilly developed Tabalumab that binds to Neutrokin alpha and requested MA
  - ➔ sought declaration that HGS SPC relying on Tabalumab MA would be invalid in view of Art. 3a



## C-493/12 Eli Lilly (continued)

### UK High Court - Questions referred to the CJEU:

1) What are the criteria for deciding whether “the product is protected by a basic patent in force” in Art. 3(a) of the Regulation?

2)[...]

3) In the case of a claimed antibody or a class of antibodies, is it [...] necessary to provide a structural definition of the antibody or the antibodies [...]?



## C-493/12 Eli Lilly (continued)

### Decision of the CJEU:

- Article 3(a) does not require that the active ingredient is defined in the claims of the patent by a structural formula.
- Where the active ingredient is covered by a functional formula, the claims must relate, **implicitly but necessarily and specifically**, to the active ingredient in question, which is a matter to be determined by the referring court.



## C-493/12 Eli Lilly

### Reasons for the decision (continued):

- The Patentee has failed to take any steps to carry out more in-depth research and **identify** the antibody **specifically**.
  - Does CJEU suggest here the application of a **disclosure test** for the purposes of Art. 3a?
- If an SPC were granted to the patent holder - who was not the holder of the MA – even though he had not made any investment in research, that would undermine the objective of the SPC regulation.

(“Third party issue” – “SPC squatting”)



## The application of C-493/12 by UK High Court Eli Lilly v. HGS - Decision of July 18, 2014

UK High Court (J Warren) on “*third party issue*”:

- An approach which discriminated between different stages of the research leading to an MA would be almost impossible to implement practically
  - Answer given by CJEU does not depend on who invested in what research
  - Lilly relied on HGS’ work in developing tabalumab
  - In the real world, subsequent research often conducted by third party (licensee)
- „*third party issue*“ **abandoned**



## Eli Lilly v. HGS - UK High Court Decision

UK High Court on **the test for determining whether a product is *protected*** in the sense of Art. 3a:

- *Medeva* rejected infringement test in its broadest sense [62]

UK High Court interprets CJEU *Medeva* (and CJEU *Eli Lilly*) as follows:

- **If the product falls within the claims, it will be *protected* within Art. 3(a), subject to the following **proviso** [65]**



## Eli Lilly v. HGS - UK High Court (continued)

- The **proviso** relates to combination products and claims containing general wording, e.g. “*comprises*”, which extends the scope
- Example: claim reading “*composition comprising A + B*”
  - **Product P** comprising A, B, X, Y and Z **infringes** this claim
  - However, product P is **not “protected”** by this claim in the sense of Art. 3a because the claim does not relate *implicitly, necessarily and specifically* to the active ingredients X, Y and Z
- However, an “individualized” description of the active ingredient(s) is not required [70-74]



## Eli Lilly v. HGS - UK High Court (continued)

### Art. 3a test proposed by J Warren:

The product is protected, if

1. it falls within the **extent of protection** provided by the claims, **and**
2. represents **the focus of the claims** (as opposed to falling within the scope of the claims merely due to the use of extending, general words)  
– modified “**extent of protection test**”

... and the practical consequences of the UK judgment?

- HGS patent “protects” tabalumab
- HGS can use Eli Lilly’s MA for tabalumab to request an SPC for its own patent (and claim royalties/damages from Eli Lilly for extended period of time)





## UK High Court (J Arnold)

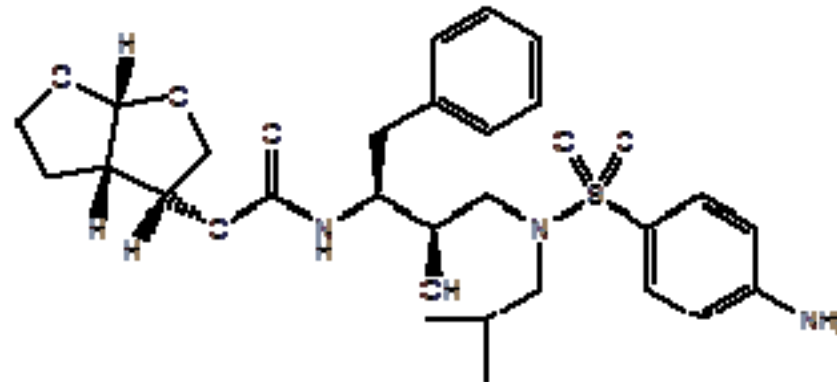
### Sandoz et al. v Searle et al. of May 3, 2017

MA (Janssen):

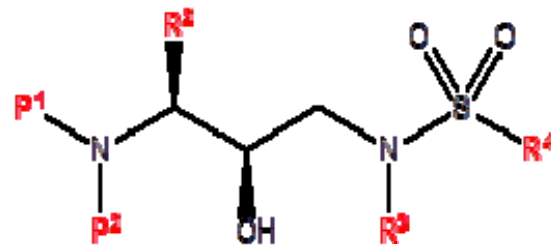
- Prezista (darunavir) – HIV treatment

SPC (held by Searle):

- Darunavir (..and salts thereof)



Patent – claim 1:



## Sandoz et al. v Searle et al. (continued)

**Patent** did not concretely disclose darunavir

### Claimants

- Darunavir differs from examples in nature of substituent P1 (according to claim 1 “heterocycloxy carbonyl”):  
fused bis-THF substituent instead of benzyloxycarbonyl -  
one of at least  $8 \times 10^{36}$  possibilities

### Justice Arnold

- Clear from CJEU Eli Lilly (*“relate implicitly..”*) that identification by means of structural formula is permissible
- Markush claim embodies inventive advance
- Claimant’s objection as to excessive breadth is an objection to the validity of the patent (insufficiency, Agrevo)
- Not the function of IPO to assess claim breadth in SPC cases
- Darunavir is protected (Art. 3(a))



## **New Referral: UK High Court (Justice Arnold)**

### ***Teva et. al v Gilead* - Decision of January 13, 2017**

#### **MA (Gilead):**

- Truvada (Tenofovir disoproxil (TD) and Emtricitabine)

#### **Patent:**

- Claim 25 = compound claim to TD
- Claim 27 = Pharmaceutical composition comprising TD *together with optionally other therapeutic agents*
- Emtricitabine not mentioned in patent

#### **SPC:**

- Composition containing both Tenofovir disoproxil, optionally .... together with Emtricitabine



## Teva v Gilead referral (continued)

### J Arnold struggles with CJEU Eli Lilly:

- The Court of justice has “once again” (sic) failed to give national authorities clear guidance as to the proper interpretation of Art. 3a
- What does “*relate implicitly but necessarily and specifically*” mean?
- Asks the same question again (as put before CJEU in Actavis I)

### Referred question:

- What are the criteria for deciding whether “the product is protected by a basic patent in force” in Article 3(a) of the SPC Regulation?***



## Art. 3a - Resolved and open issues

### Resolved

- **Not sufficient** for a product to be “protected” that dealings in the product would **infringe** a claim

### Open

- How a proper test is to be phrased

- **Proposal by J Arnold in Sandoz et al. v. Searle et al:** the product is "protected" by the basic patent if **(i)** the product falls within the scope of the claim when interpreted in accordance with the **Extent of Protection Rules** and **(ii) the product does so because it** contains an active ingredient, or a combination of active ingredients, which **embodies the inventive advance (or technical contribution) of the patent.**

- Applies to Markush formulae
- General applicability? To use claims, claims for combination of new active and functionally defined active (e.g. diuretic)?



## Art. 3a - Resolved and open issues

### Open (continued)

- **Is the test proposed by J Warren in Eli Lilly better suited?** ...the product is "protected" by the basic patent if
  - (i) the product falls within the scope of the claim when interpreted in accordance with the **Extent of Protection Rules** and
  - (ii) the product represent **the focus of the claims**
- Can the patent be amended/limited after filing the SPC, or even its grant, to comply with Art. 3a?



## Consequences resulting from Medeva and Eli Lilly decisions (in light of UK judgments)

Product claims in the basic patent	Product of the SPC application	Protection by the basic patent
Markush formula that comprises A	A	yes
Pharmaceutical composition comprising A	A + B	no
Pharmaceutical composition comprising A and a <i>“further active substance”</i>	A + B	Depends on circumstances
Pharmaceutical composition comprising A and a further <i>functionally defined active substance</i> (e.g. diuretic)	A + B (B is a diuretic)	probably yes (if J. Warren test is used)
Pharmaceutical composition comprising A + B	A + B	yes



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SPCs are also available for biological products (e.g. blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins, antibodies, vaccines)

• **Can a MA for a *similar or new form* of a known biological product be relied upon for obtaining SPC protection?**

### Regulatory perspective

- EMA definition: a “*biosimilar*” is a biological medicine highly similar to another already approved biological medicine (the ‘reference medicine’).
- Developers of biosimilars are required to demonstrate through comprehensive **comparability studies** with the ‘reference’ biological medicine that:
  - their biological medicine is highly similar to the reference medicine notwithstanding natural variability inherent to all biological medicines;
  - there are **no clinically meaningful differences** between the biosimilar and the reference medicine in terms of safety, quality and efficacy.



## Regulatory perspective (continued)

By demonstrating biosimilarity, a **biosimilar** can rely on the safety and efficacy experience gained with the reference medicine.

- From a regulatory standpoint: a biosimilar is **not** a “**new**” active ingredient

By contrast, a **new form** of a known biological product, e.g. a new glycoform or a new recombinant form, **may be** considered a “**new**” **product**

## Patent and SPC perspective?

SPCs can only be granted if a patent exists for the similar or new form of a biological active

- Less likely in the case of “**biosimilar**”
- Likely if **new form** shows benefits, e.g. clinically meaningful difference



## Patent and SPC perspective (continued)

Assuming that a patent has been granted for a new form of a known biological product, SPC applicants may face the following **problem**:

- in the jurisprudence for small molecules, derivatives such as salts or esters are, as a rule, considered the same product
- CJEU in Farmitalia (C-392/97): *the SPC is capable of covering the product, as a medicinal product, in any of the forms enjoying the protection of the basic patent such as salts or esters*



...and **possible solutions** to this problem:

If the patent for the known biological form is held by company A and company B holds a separate patent for the new biological form:

- Company B can rely on its own patent to obtain an SPC (CJEU *Biogen* C-181/95) and Art. 3(2) of Regulation for plant protection products (PPP-Reg): **one SPC per product per patent holder**

If company A develops a new biological form:

- Recital 14 of PPP-Reg (applicable to medicinal products as well): *the issuance of a certificate for a product consisting of an active substance **does not prejudice** the issue of other certificates for derivatives (salts and esters) of the substances, **provided that the derivatives are the subject of patents specifically covering them.***



## Biologics – different glycosylation = “new product” ?

### UK Decision (UKIPO): 2014 BL O/552/14 (SPC-GB13-069), Icahn School of Medicine

- Icahn holds basic patent directed to methods for producing “secreted human  $\alpha$ -Galactosidase A enzyme” in **CHO** cells (claim 1)
- Icahn applied for SPC for “Agalsidase-**beta**” (active ingredient in Fabrazyme, Genzyme) – **CHO** cells
- Icahn holds SPC for Replagade (Agalsidase-**alpha**, produced in **human** cells)



## Background:

-**CHO** and **human** cells differ in glycosylation machinery (e.g. human cells have  $\alpha$ -2,6-sialyltransferase; CHO cells do not)

-**Agalsidase- $\alpha$**  (human cells) and **Agalsidase- $\beta$**  (CHO cells) differ in their glycosylation patterns

-Sugars are relevant:

- Level of mannose-6-phosphate relevant for uptake of enzyme by cells
- Sialic acid affects bioavailability and clearance by liver



## Key Questions:

1. Is Agalsidase-beta “identified/specified” in the basic patent, Art 3(a)?  
[Medeva, Queensland, Eli Lilly]

2. Does the application meet Art 3(c) over Replagade (containing Agalsidase-alpha)?

[3(c): the product has not already been the subject of a certificate;]



# 1. Is Agalsidase-beta “identified” in the basic patent, Art 3(a)?

- Claim 1 of basis patent referred to a method of using **CHO** cells to express **human  $\alpha$ -Galactosidase A enzyme** (not Agalsidase-beta *per se*)
- [67] of the decision:  
*“The CJEU’s decision in C-630/10 **Queensland** merely requires that the product of the SPC application is **identified in the wording of the claims of the basic patent as the product deriving from the process in question.**”*





## 1. Is Agalsidase-beta “identified” in the basic patent, Art 3(a)? (continued)

- [78] “The CJEU’s recent decision in C-493/12 (**Eli Lilly**) stated that a functional definition may suffice for a product to be protected by a basic patent (for the purposes of Article 3(a)) if “the claims relate, **implicitly** but necessarily and specifically to the active ingredient in question”. As such, I believe that the CJEU’s decision in C-493/12 provides a clear indication that it is **not necessary** for the claim of the basic **patent to use identical wording** to the marketing authorisation when specifying/ identifying the product for which an SPC is sought.”

**Art 3(a) held to be met**



## 2. *Does the application meet Art 3(c) over Replagade (Agalsidase-alpha)?*

[87] of the decision:

*“...I am content that these active ingredients are different products for the purposes of the SPC Regulation because of the differing characteristic glycosylation profiles on the enzyme when it is produced in the different cell types. I am therefore of the opinion that each product can be the subject of a separate SPC, and that the requirements of Article 3(c) are satisfied.”*



## SPCs for Biologics

### appropriate product definition & scope of protection

#### **A fundamental question for SPCs for biologics**

- Narrow product definition (e.g. specific viral strain) in MA
- Frequently broad functional language in patent
  - What is the appropriate product definition between these extremes?
  - What is the protective scope of the resulting SPC?

#### ***Pharmac vs Intervet (EFTA court judgment E-16/14 and decisions of Norwegian Courts)***

- Norway as EEA member has harmonised SPC provisions with EU law



## Background

- **Basic patent (Intervet)** is a Norwegian patent covering any **SAV** virus strain that causes pancreatic disease (“PD”) in salmonid fish (and vaccine)
- **MA** for the product “Norvax Compact PD” based on **SAV1**. SAV1 belongs to one of six subtypes of Salmonid Alpha Virus (“SAV”)
- **SPC** granted to Intervet for **SAV1 or closely related strains** which share similar genotypic and/or phenotypic characteristics

## Pharmaq

- had developed a vaccine based on **SAV3**, a virus strain which belongs to one of the six subtypes of SAV
- sought declaration that Intervet’s SPC is invalid or that its scope is deemed not to include Pharmaq’s vaccine (**SAV3**)



## E-16/14 – Pharmaq v Intervet

### Questions 5 and 6 (Excerpt)

- Can the scope of protection under the SPC cover **not only the specific strain of the virus that is included in the medicinal product** and covered by the basic patent, **but also other strains** of the virus that are covered by the basic patent?
- If the product definition of the SPC is not strictly limited to the specific strain of the authorised virus,
  - (a) will such an SPC be valid, or
  - (b) will the SPC be valid but the scope pursuant to Art. 4 will not extend beyond the specific virus strain [here: SAV1]?



## Decision - Second Headnote

SPC extends to a specific strain of a virus covered by the basic patent, but not referred to in the MA **only** if

- the specific strain constitutes the **same active ingredient** as the authorized medicinal product and (cf. CJEU – Farmitalia)
- has therapeutic effects falling within the therapeutic indications** for which the MA was granted(cf. CJEU – Forsgren)

It is not relevant whether a medicinal product based on such other strain would require a separate MA.

A supplementary protection certificate is invalid to the extent it is granted a wider scope than that set out in the relevant MA.



## Do SAV1 and SAV3 represent different forms of the same active ingredient?

Determination of whether SAV3 constitutes the same active ingredient as SAV1 has been **left to the national court**



## **Borgarting Court of Appeal** (15-170539ASD-BORG/01)

- In the Court of Appeal's opinion it was not clear how the limits on the scope of protection for biological medicinal products ought to be established.
- The Court of Appeal held that Pharmaq's vaccine is systematically, consistently and significantly **more efficacious** against SAV 3 infection than Intervet's vaccine.
- Thus, the two strains could **not** be considered **the same active ingredient** in the meaning of the SPC regulation.

**In line with the guidance given by the EFTA Court, the consequence was that the SPC was found invalid.**

(Appeal to Norwegian Supreme Court?)

**Decision implies narrow protection for biotech products.**





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## CJEU - C-484/12 Georgetown University

### Background:

- Basic patent (Georgetown University, EP 0 647 140): claims for each of HPV (Human papilloma virus) 6, 11, 16 and 18 and their combination
- MA for Gardasil: HPV 6 + 11 + 16 + 18
- 1st SPC: granted for HPV 6 + 11 + 16 + 18
- 2nd SPC: granted for HPV 16 + 18
- 3rd SPC: requested for HPV 16; rejected by the Dutch Patent Office as contravening Art. 3(c) in view of *Medeva*



## C-484/12 Georgetown University

### Decision of the CJEU:

On the basis of the same basic patent, a patentee may obtain an SPC for a combination of several active ingredients as well as an SPC for each of those active ingredients provided that the active ingredients are protected as such by the basic patent.

- Patent with claims for A, B and A+B → **B protected as such**
- **SPC for A, B and A+B possible!**

To be distinguished from cases where the patent relates to new active A and protects in separate claim A + B

- Patent with claims for A and A+B → **B not protected as such**



## C-443/12 Actavis v Sanofi

Background:

- Basic patent
  - Claim 1 for Irbesartan (antihypertensive drug)
  - Claim 20 for a combination of Irbesartan + “diuretic”
- 1st SPC granted for Irbesartan
- 2<sup>nd</sup> SPC granted for Irbesartan + HCTZ (hydrochlorothiazide) on the basis of claim 20
  - HCTZ well known diuretic but not mentioned in patent
- Actavis challenged the grant of the 2nd SPC



## Question referred to the CJEU:

If a patent protects several products, does Art. 3(c) preclude the issuance of a certificate for each of the products?

## Reasoning of CJEU:

- HCTZ is not protected as such by the patent because
  - The “core inventive advance” was Irbesartan
  - The patentability of the claim to the combination of Irbesartan and a “diuretic” was acknowledged in view of the presence of Irbesartan (“piggyback claim”)
  - There was no claim to a diuretic/HCTZ as single active active
- Protective scope of first SPC for Irbesartan (A) alone extends to combination products (e.g. A+B, A+C, etc.) (cf. CJEU in C-442/11 and C-574/11 – Novartis).
  - First SPC already enabled Sanofi to oppose the marketing of such combination products
  - **Sanofi was already given sufficient reward by first SPC !!!**



## Decision of the CJEU:

If an SPC has been granted for an active ingredient (A) for a basic patent, Article 3(c) **precludes that an SPC is granted** on the basis of the same basic patent for the **combination** of the active ingredient (A) and **another active ingredient (B) which is not protected as such**.

- A is protected by the basic patent
- Claim to A+B does not protect B as such
- SPC for A+ B** on the basis of the same basic patent **not possible**

Are there any exceptions from this rule?



**Circumstances of *Actavis v. Sanofi* contrasted by the CJEU with following hypothetical scenario:**

- If single active ingredient (A) of earlier SPC is used for forming an **innovative combination** with another drug (C) not protected in earlier basic patent,
- and this combination (A + C) is the subject of **another basic patent,**
- **said another basic patent could form the basis for granting another SPC** because it pertains to a **different innovation.**

Is there any reason to limit this scenario only to later filed patents (“earlier basic patent”, “another basic patent”)?



## The “different innovation” test

### UK High Court in Teva et al. v MSD - March 21, 2017

#### MA:

- Atripla (efavirenz, emtricitabine and tenofovir disoproxil)

#### SPC:

- Composition of *efavirenz, emtricitabine and tenofovir* (..and salts thereof)

#### Patent:

- Focus on efavirenz
- emtricitabine and tenofovir are not mentioned
- Claim 16 = a combination of efavirenz .. *with a nucleoside analog having biological activity against HIV reverse transcriptase*

#### Earlier SPC (“035”) for efavirenz

#### Central question under Art. 3(c):

- Is the combination of claim 16 a “different innovation”?





## How is the test applied?

### J Arnold in *Teva et al. v MSD* [169]

*By the end of the trial, it was common ground between counsel that, given that*  
*(i) efavirenz was protected by the Patent and*  
*(ii) MSD had already obtained the 035 SPC in respect of efavirenz,*  
*then Article 3(c) precluded the grant of the SPC in respect of the Product*  
***unless claim 16 of the Patent was independently valid over the claims***  
***which protected efavirenz and thus represented a distinct invention from***  
***the invention protected by those claims.***



## How is the test applied?

### J Arnold in Teva et al. v MSD [170]

*Counsel for the Claimants submitted that it should be **assumed for this purpose** that the skilled person had **efavirenz and its activity against HIV reverse transcriptase disclosed to them at the priority date.***

*Although counsel for MSD took issue with this, I consider that it is correct. The question to be considered is not the conventional one of whether a claim is invalid over a particular item of prior art read in the light of the common general knowledge, but whether, given the invention of efavirenz, **claim 16 represents a distinct invention such that it could in principle form the subject-matter of a separate patent.***

→ In order to determine for a given **combination product** whether the requirements of **Art. 3 (c)** are met in view of CJEU Actavis I, the “**different innovation**” test needs to be applied by the IPOs !!!



## How is the test applied?

### UKIPO decision BL O/117/16 in MSD v Comptroller

#### MA and SPC:

- ATOZET – combination of ezetimibe and atorvastatin

#### Patent:

- Claim 1: Markush formula covering ezetimibe
- **Claim 16/17** = pharmaceutical composition for the treatment of atherosclerosis ...comprising **ezetimibe** *in combination with a cholesterol biosynthesis inhibitor* selected from **atorvastatin**

#### Earlier SPC (2003) for ezetimibe based on claim 1 of the patent

**Question under Art. 3(c):** Is the combination of ezetimibe and atorvastatin a “different innovation”?

- **UKIPO** based on witness statements: **yes**
  - Not well known to use statins in combination therapy
  - Combination represents a significant technical advance over claim 1



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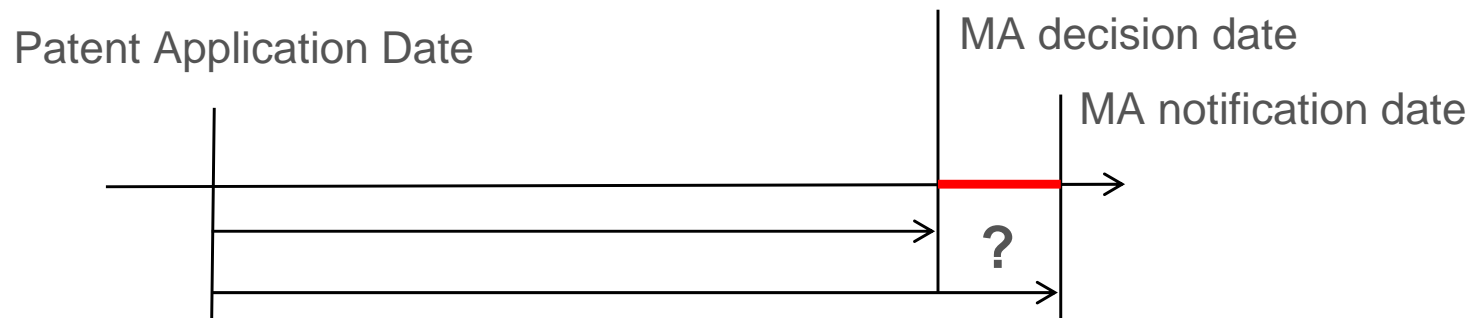


## New Referral: C-492/16

Incyte Corp v Szellemi Tulajdon Nemzeti Hivatala (Hungarian Court)  
as to the application of C-471/14 – Seattle Genetics

Background:

- SPC duration calculated according to Art. 13(1) = „Date“ of MA – Patent Application Date – 5 years (Max. 5 years)



Facts underlying C-471/14:

- EU Decision of 25 October 2012, granting a MA for ‘Adcetris — Brentuximab vedotin’
- Notification date 30 October 2012 (published in OJEU)

## C-471/14 – Seattle Genetics

### Decision of the CJEU

Article 13(1) is to be interpreted as meaning that **the date of the first authorisation** to place the product on the market in the EU within the meaning of that provision **is the date on which notification** of the decision granting marketing authorisation was given to the addressee of the decision.

### Reasons:

*..... it cannot be accepted that procedural steps carried out between the decision granting marketing authorisation and the notification of that decision — the duration of which is not within the control of the SPC holder — reduce the period of validity of an SPC.*



# Application of CJEU Seattle Genetics

Diverging national practice

	Pending SPC application	Also for national MA	Granted SPC	Correction of granted SPCs of its own motion
DE	+	+	+	-
FR	+	?	- *	-
GB	+	?	+	-
ES	+	?	-	-
IE	+	+	+	-
IT	+	?	- *	-
NL	+	+	+	-

\* recommendation - request for public file



## New Referral: C-492/16

Incyte Corp v Szellemi Tulajdon Nemzeti Hivatala (Hungarian Court)

Questions referred:

1....appropriate to rectify the date of expiry of the supplementary protection certificate even if the **decision to grant** that certificate was made **prior to Seattle Genetics judgment** (C-471/14) and the time limit for appealing against that decision has already expired?

2.Is the industrial property authority... required to rectify, **of its own motion** the date of expiry of that certificate...?





## New Referral C-567/16

### Merck Sharp and Dohme Corporation v UKIPO

#### Background:

- MA for ATOZET requested by MSD according to DCP
  - RMS records the agreement of all parties, closes the procedure and informs the applicant by means of “end-of-procedure” communication
  - Each Member State has 30 days from the closure of the procedure to adopt a decision (i.e. grant a marketing authorisation) in conformity with the approved assessment report, approved SmPC and approved labelling and packaging (see Article 28(5) of Reg 726/2004/EC).
- MSD received “end-of-procedure” communication (“EoP”) from German NHA three days before patent expiry
- SPC application filed one day before patent expiry in UK in the absence of MA (with copy of EoP Notice)



## Problem

- EoP has no legal effect
- Valid MA on the date of application is mandatory condition for the grant of SPC pursuant to Art. 3b

Can absence of MA be regarded as an *irregularity* which could be cured under Art. 10(3)?

- Considerations
  - Legal certainty for third parties v. obligation of NHA to grant MA within 30 days
  - How to deal with cases where delay is beyond control of MA applicant
- UK High Court (J Arnold) doubts that absence of MA is “*irregularity*” but does not consider this to be *Acte claire* Referral >

Note: the NL-IPO in parallel proceedings ruled that MSD’s application satisfied Art. 3b



## The questions referred to the CJEU are:

- Is an **End of Procedure Notice** issued by the reference member state under Article 28(4) of European Parliament and Council Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use before expiry of the basic patent to be treated as **equivalent to a granted marketing authorisation** for the purposes of Article 3(b) of European Parliament and Council Regulation 469/2009/EC of 6 May 2009 concerning the supplementary protection certificate for medicinal products (codified version) (the “SPC Regulation”), such that an applicant for an SPC in the Member State in question is entitled to apply for and be granted an SPC on the basis of the End of Procedure Notice?
- If the answer to question (1) is no; in the circumstances in question 1, is the absence of a granted marketing authorisation in the Member State in question at the date of the application for an SPC in that member state an **irregularity** that can be cured under Article 10(3) of the SPC Regulation once the marketing authorisation has been granted?



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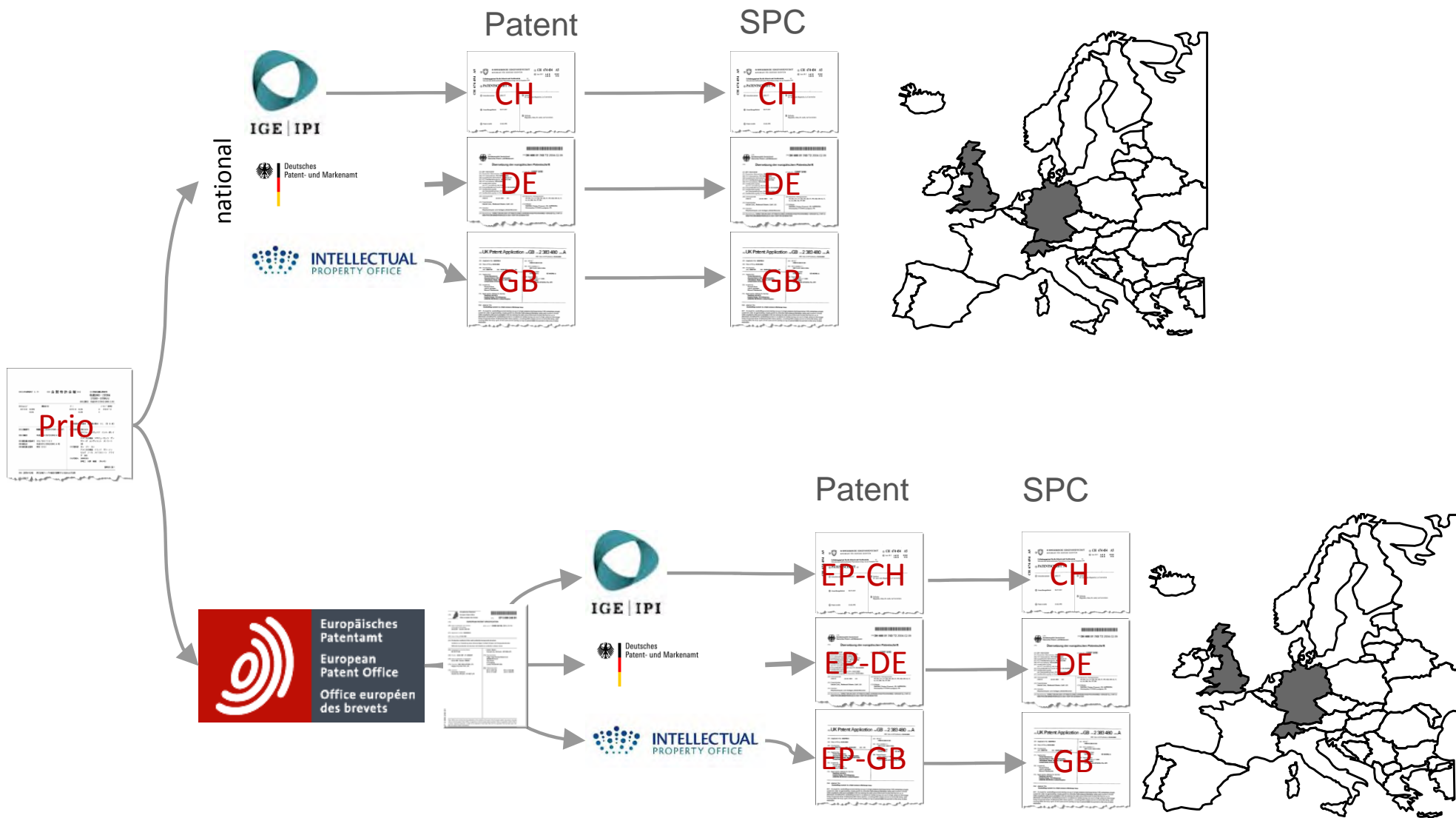
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# SPC GRANT – THE STATUS QUO



## The status quo

National SPC filings for

- National patents
- EP - national parts

## The near (?) future (after entry into force of UPCA)

National SPC filings

- National patents
- EP – national parts (whether or not opted out)
- EPUE ?

Jurisdiction of UPC: “*the SPC follows the basic patent*”

- Basic patent = EP (only if **not** opted out)
- Basic patent = EPUE



## Will it indeed be possible to obtain **national** SPCs based on a **unitary** title (EPUE)?

### Provided in UPCA

- Art. 3 UPCA refers to SPCs issued “*for a product protected by a patent*”  
Art. 2(g) UPCA: “*a patent*” = EP and/or EPUE
- Rule 5.2(e) RoP of UPC (18<sup>th</sup> draft): *For the avoidance of doubt, it is **not possible to opt out SPCs** (whether **granted by the authorities of a Contracting Member state** or otherwise) **based on a Unitary Patent**.*

But **no amendments to SPC Reg** (469/2009) planned

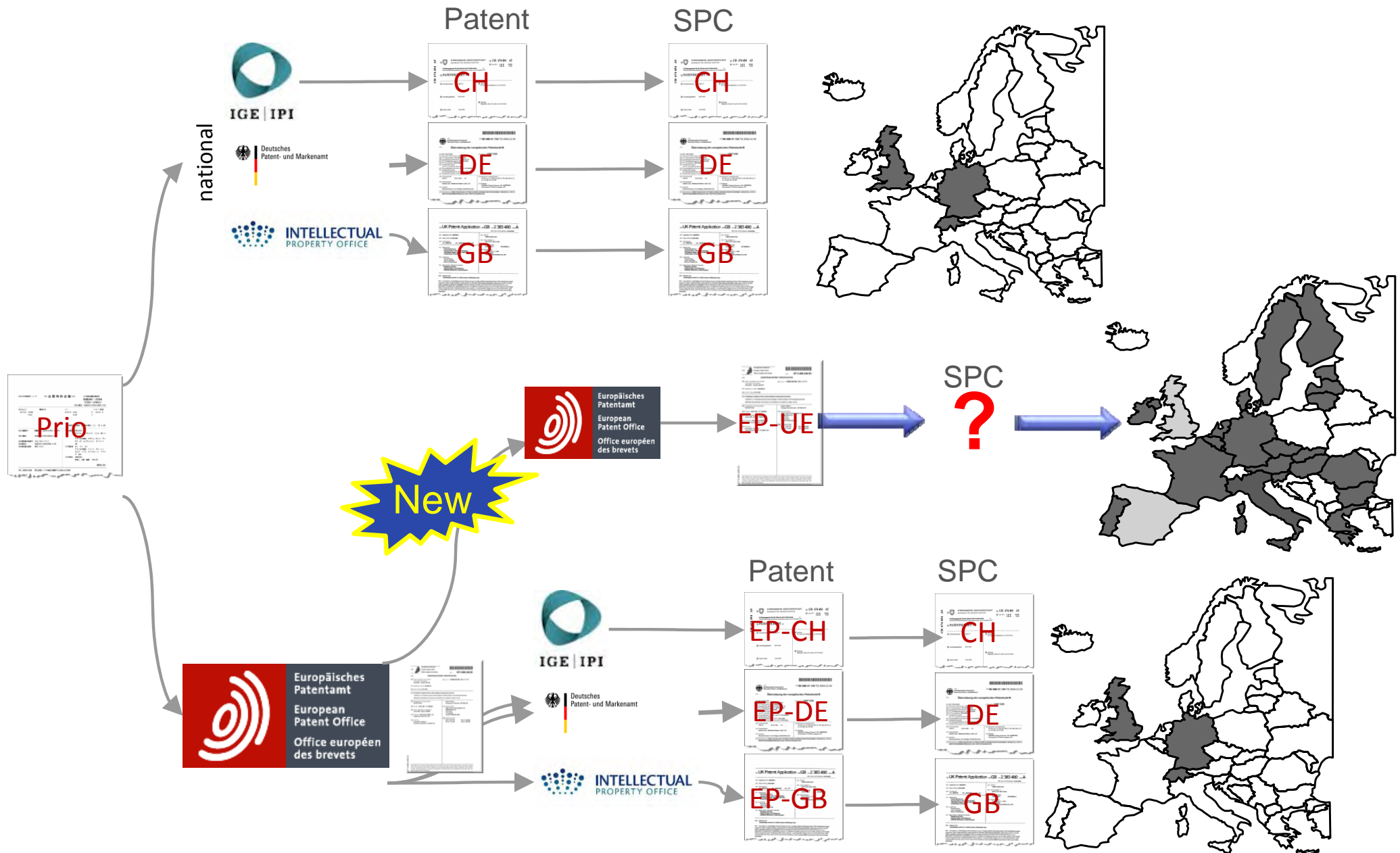
- Considered unnecessary by scholars and legislator
- Art. 3 of SPC Reg only requires a “basic patent” without specifying this patent

### Implementation at national and EU level

- Amended Patents Act (UK), planned amendment to application form (FR), statement of legislator (DE)
- Clarifying statement by EU Commission planned



# SPCs and UPCA – the Unitary SPC - a look into the future





So, will we soon have an SPC with Unitary Effect?





# But why not?

## What are the main issues?

1. Can U-SPCs be granted on national MAs, also if the MAs do not cover the entire EU territory?
2. Who should grant U-SPCs?
3. Competence for appeals?

## Re 1 – Should one allow **partly unitary** SPCs?

### Background

- Grant of SPC requires MA (1<sup>st</sup> MA → 6M filing term)
  - EU-MA (granted by Commission/EMA) → U-SPC
  - **How to deal with national MAs** (MRP / decentralized procedure)?



Proposal by von Renesse et al. (GRUR Int. 2016, 1129):

**Partly unitary SPC** - an SPC that can be enforced only at the territories of the member states which have issued a MA

- Grant of “uniform” SPC within 6 months from the date of the first national MA in the EU
- Obligation to update granting authority in respect of further MAs?
- Enforcement conditional on proof that MA exists for a particular state
- Proposal would keep application procedure simple
- **Very important for plant protection industry (no central MAs)**



## Re 2 & 3 – Who should grant unitary SPCs?

### The options

- A **virtual office** composed of experienced SPC examiners from the national IPOs
  - + experience / reduced costs
  - no institutional framework (EPO or even the EUIPO?)

### • The EPO

- + experience with patents
  - but not with SPCs
  - + can provide organisational framework, incl. register
  - no EU authority (SPC = EU law)
- Competence to grant U-SPC? Can Art. 142 EPC again help?  
Which body has the competence for judicial reviews?



## Summary

- National IPOs will allow the grant of national SPCs based on EPUEs
  - residual risk since SPC Reg has not been clarified in this respect?
- Creation of Unitary SPC is on the agenda of the Commission (“The Single Market Strategy”, COM(2015)550)
  - Does this also include the creation of a partly unitary SPC based on national MAs?
  - Could be a long way in view of various outstanding issues



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## Manufacturing waiver for SPCs in Europe Proposal by the EU Commission

The Single Market Strategy, adopted in October 2015 (COM(2015)550), announced that the Commission will explore a recalibration of certain aspects of patent and Supplementary Protection Certificate (SPC) protection, and announced that this could comprise the following three elements:

- (i) the creation of a European SPC title;
- (ii) an update of the scope of the EU patent research exemptions; and
- (iii) the introduction of an SPC manufacturing waiver.

### **Possible scope of waiver:**

- Manufacture of SPC-protected products within EU
- Export of products in non-EU countries for any purpose





## Political background (I)

### European Parliament

(Para 82, P8\_TA-PROV(2017(0061 Options for improving access to medicines [2 March 2017])

*Calls on the Commission to introduce an SPC manufacturing waiver to Regulation (EC) No 469/2009 allowing the **production** of generic and biosimilar medicines in Europe, **with the purpose of exporting them to countries without SPCs or where these have expired earlier**, without undermining the exclusivity granted under the SPC regime in protected markets; believes that such provisions could have a **positive impact** on access to high-quality medicines in developing countries and LDCs, and on **increasing manufacturing and R&D in the EU, creating new jobs and stimulating economic growth**;*



## Political background (II)

### EU Commission

Commission inception impact assessment published [15/2/17]

*Loss of export markets and lead-time to entry into Member State markets for EU-based generics and biosimilars, resulting in reliance on foreign based supplies of generics and active pharmaceutical ingredients (APIs)*

[...]

*EU reliance on foreign-manufactured medicines might be increasing, with the loss of high value jobs in the EU.*



## Is this expectation supported by evidence?

Assumption: SPC rights within the EU often expire after ex-EU rights

Vicente & Simoes, *J Generic Med*, 2014, Vol. 11, pp. 35-47: over 9 years considering 73 % EU and 11 % non-EU markets

- 3.3 billion Euros in business volume (ex-works)
- 8,890 direct jobs
- 35,560 indirect jobs
- 37 new medium-sized pharma enterprises

Sussell et al., *J Generic Med*, 2017: criticizes VS study

- 1,898 direct jobs
- 6,642 indirect jobs
- 14 new medium-sized pharma enterprises
- Using the V&S figures, **2,490 job losses** predicted **in originator businesses**



## Counterarguments / Concerns

- Is there an economic case in favor of the waiver?
- Erosion of SPC title? How to distinguish between manufacturing and stockpiling for export and for early entry in EU?
  - Waiver would introduce additional evidential and intent issues to infringement analysis and enforcement
  - Audit and disclosure provisions?
  - Will such a waiver make launch at risk easier?
- Could this waiver also lead to an erosion of patent protection?
- What is the impact on EU patentees in their **ex-EU** markets and is this measure proportionate?



## State of implementation

- Parliament has approved in committee and full session a report calling for this right to be created
- MEPs have addressed a series of questions to the Commission
- Parliament resolution „*Options for improving access to medicines*“ adopted on 2 March 2017
- Consultation process by EU Commission not yet completed
  - Currently ongoing studies on legal and economic aspects of SPCs





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