

Practical Issues related to Patent Term Extension in the European Union

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Patent Term Extension in the EU

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Introduction

The Legal Basis

- ♦ **EU Council Regulation 1768/92: Supplementary Protection Certificates (SPC) for medicinal products**
- ♦ **EU Council Regulation 1610/96: SPCs for plant protection products**
- ♦ **These Council Regulations represent directly applicable law in the EU member states!**
- ♦ **However, SPCs must be applied for and will be granted nationally!**
- ♦ **The European Court of Justice may provide guidance as to the interpretation of the Regulations!**

Introduction

Certificates can be granted for any product

- ♦ **being protected by a patent granted in the territory of an EC Member State, and**
- ♦ **being subject, prior to being placed on the market as a medicinal product or a plant protection product, to an administrative authorization procedure (Art. 2).**

A product is defined as the active substance or the combination of active substances of a medicinal product or a plant protection product (Art. 1).

Examination of SPCs

The application for a certificate shall be lodged with the competent industrial property office of the Member State which granted the basic patent or on whose behalf it was granted and in which the authorization referred to in Article 3(b) to place the product on the market was obtained, unless the Member State designates another authority for the purpose (Art. 9).

This authority shall reject the application if the application or the product to which it relates does not meet the conditions laid down in the Regulation (Art.10).

Examination of SPCs

The Conditions: Art. 3

At the date of filing the SPC request and in the member state in which the application is filed (Art. 3)

- ♦ the product is protected by a valid basic patent,
- (b) a valid authorization for placing the product on the market has been granted,
- (c) a certificate has not yet been issued for the product, and
- (d) the authorization under (b) is the first authorization for placing the product on the market.

Examination of SPCs

Appeals: Art. 17

The decisions of the authority ...shall be open to the same appeals as those provided for in national law against similar decisions taken in respect of national patents.

Examination of SPCs

The Judicial Authorities in SPC Proceedings in Germany:

- ◆ First instance: GPTO
- ◆ Appeal: Federal Patent Court
- ◆ Legal Appeal: Federal Supreme Court
- ◆ Possibility of reference to the ECJ for interpretation

Examination of SPCs

Invalidity: Art. 15

Any person may submit an action for declaration of invalidity before the body responsible under national law for the revocation of the corresponding basic patent.

Invalidity grounds:

- ♦ **Grant contrary to Article 3**
- ♦ **Basic patent lapsed prematurely**
- ♦ **Basic patent revoked or no longer covers product**

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The Idarubicin Case

The Idarubicin Case

- ◆ **medical authorization: Idarubicin hydrochloride**
- ◆ **claims of basic patent: Idarubicin**
- ◆ **description of basic patent: only Idarubicin hydrochloride**
- ◆ **request for the grant of the SPC: Idarubicin and salts thereof, including Idarubicin hydrochloride**

The Idarubicin Case

SPC-request rejected by the GPTO and the Federal Patents Court: protected technical teaching does not include other salts than hydrochloride.

Allowance of legal appeal at the Federal Supreme Court .

Decision of the Federal Supreme Court („Idarubicin I“): preliminary ruling of the ECJ regarding the legal question:

“What are the criteria to evaluate whether the product is protected by a basic patent in the sense of Art. 3, lit. (a)? Is the wording of the claims of the basic patent or the scope of protection of the basic patent decisive?”

The Idarubicin Case

**Decision of the ECJ (C-392/97 – Farmitalia Carlo Erba Srl),
September 16, 1999**

**“In the frame work of applying the Council Regulation No. 1768/92,
and especially Art. 3, lit. (a) thereof, it is determined by the
Regulations being applicable to the basic patent whether a product
is protected by this basic patent.”**

The Idarubicin Case

**Decision of the Federal Supreme Court of February 15, 2000
(„Idarubicin II“)**

- ♦ **Art. 3(a) fulfilled for Idarubicin being directly included in the patent claims**
- ♦ **The product in the form cited in the authorization (Idarubicin hydrochloride) must be protected by the basic patent.
The protection is not restricted to the wording of the claims, but also extends to equivalent modifications.**
- ♦ **The grant of a certificate including all salts of Idarubicin not justified.
Definition of the product would extend beyond the wording of the granted patent.**

The Idarubicin Case

Conclusions from the Idarubicin case:

- Specific form of the product as included in the marketing authorization must be covered by the **protective scope** of the basic patent, which does not include only the literal wording of the claims, but also equivalents thereof.
- **Definition of the product** for which the SPC is to be granted has to be covered by the literal wording of the claims.

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The Definition of the Product for the SPC

Narrow or broad definition allowable?

- ◆ **SPC granted only for the specific active ingredient named in the medical authorization?**
- ◆ **SPC granted on the basis of a broader and more general definition of this active ingredient?**

The Definition of the Product for the SPC

The Federal Supreme Court submitted the following question for preliminary ruling to the European Court of Justice:

„Is there a request in Art. 3, lit. (b), that the product for which the grant of an SPC is requested is indicated as active ingredient in the medical authorization?

Is Art. 3, lit. (b), not fulfilled when in the medical authorization as active ingredient a single specific salt of the product is indicated, the issuance of an SPC, however, is claimed for the free base and/or for other salts of the product?”

The Definition of the Product for the SPC

Decision of the European Court of Justice:

“A supplementary protection certificate, in line with Council Regulation (EC) No. 1768/92 dated June 18, 1992 regarding the creation of supplementary protection certificates for medicinal products, and in particular with reference to Art. 3 lit. (b), can cover a product as a medicinal product in all the forms protected by the basic patent, when the product in the form as indicated in the medical authorization is protected by a valid basic patent.”

The Definition of the Product for the SPC

The Sumatriptan Case

- ♦ Medical authorization: Sumatriptan hydrogen succinate
- ♦ Patent claims: compounds of a chemical formula (covering Sumatriptan), as well as physiologically acceptable salts and solvates, thereof
- ♦ SPC request: Sumatriptan as well as physiologically acceptable salts and solvates thereof including Sumatriptan hydrogen succinate

The Definition of the Product for the SPC

„Sumatriptan“ Decision of the Federal Patents Court of November 2, 2000

- ♦ **No problem with regard to Art. 3(a) of the Council Regulation.**
- ♦ **No right for the Applicant to formulate protective claims in the request for the grant of the SPC.**
- ♦ **SPC granted for “the active ingredient of the medicinal products Imigran and Avessa in all the forms underlying the scope of the basic patent.”**
- ♦ **Legal appeal to the Federal Supreme Court was allowed:**
“Is the Applicant entitled to define the subject matter to be protected and for which the certificate is to be granted, and which criteria are to be considered for the definition of this subject matter?”

The Definition of the Product for the SPC

Decision of the Federal Supreme Court (X ZB 12/01) of January 29, 2002

- ♦ The product for the SPC has to be indicated in an exact way.
- ♦ The request cannot be rejected when the necessary conditions of the Council Regulation are fulfilled.
- ♦ The Applicant must have the possibility to request the SPC for the active ingredient in said forms which fulfil the granting proceedings even in the case when in the medical authorization the product is defined in only one specific embodiment (form).
- ♦ All embodiments must represent different forms of the same active ingredient, i.e. the same therapy or preventive effect in the sense of Art. 1 of the Council Regulation must be achieved.

The Definition of the Product for the SPC

The Federal Patents Court granted the SPC for „Sumatriptan and physiologically acceptable salts and solvates thereof, including Sumatriptan hydrogen succinate“.

The Court did not doubt that Sumatriptan as well as its salts and solvates represent the same active ingredient, i.e. have the same healing or preventive effect which is described in the basic patent and the medical authorization documents.

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Protection of the Product by the Basic Patent

The „Custodiol“ Case

- ♦ Authorization: Custodiol (4 mmol/l MgCl_2)
- ♦ Claims of the basic patent: protective solution containing 10 +/- 2 mmol/l MgCl_2
- ♦ SPC request: Custodiol

Protection of the Product by the Basic Patent

Decision of the Federal Patents Court: Art. 3(a) not fulfilled since the product given in the authorization is not protected by the basic patent

Determination of the Protective Scope (Section 14 of the German Patents Act, Art. 69 EPC and the Protocol on Interpretation)

- ♦ **Protective scope not only determined by the exact wording of the patent claims**
- ♦ **Wording of the claims not only simple guideline**
- ♦ **Reasonable Protection for patent proprietor with sufficient legal certainty for third parties**

Protection of the Product by the Basic Patent

Decision of the Federal Patents Court:

Difference of the amounts of MgCl_2 considerable: amount in authorized product (4mmol) corresponds to only 50% of the minimum amount (8mmol/l) or 40% of the average amount (10mmol/l) of the basic patent.

Description of the patent does not allow conclusion that the values given in the claims are meant only exemplarily.

Authorized product not comprised by scope of protection.

Protection of the Product by the Basic Patent

Decision of the Federal Patents Court:

Legal Appeal allowed:

“Would a product within the meaning of the EC Council Regulation not be protected by the basic patent, if the amount of an active ingredient contained in the product identified by the authorization deviates considerably from the amount given in the patent claims of the basic patent for this active ingredient, and if no indication can be taken from the description that the values regarding the amounts given in the patent claims may be left out of consideration or are meant only exemplarily?”

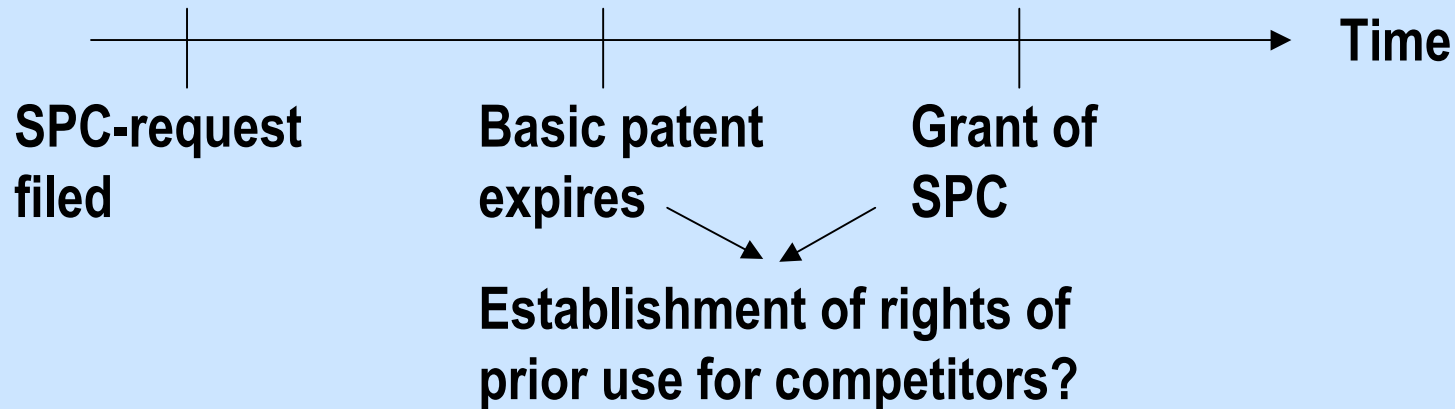
Protection of the Product by the Basic Patent

The Federal Supreme Court decision (X ZB 12/00) – March 12, 2002

- ◆ Custodiol does not fall under the protective scope of the basic patent
- ◆ Custodiol does not make use of important features of the claims of the basic patent, and the composition of Custodiol therefore is not within the meaning of the patent claims
- ◆ legal certainty for third parties: only small deviations from the limits of the claims may be included in the protective scope

Protection of the Product by the Basic Patent

Expiration of the Patent Before the Grant of the SPC

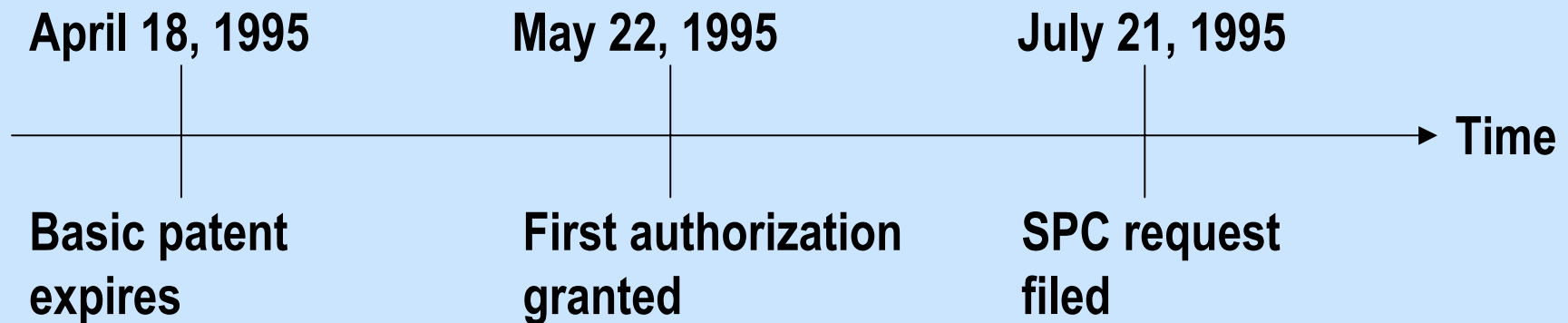


- File the SPC-request as soon as possible.
- File an acceleration request for the grant of the SPC.
- File the request to introduce the information about the pending SPC application in the official Register of the Patent Office.

Protection of the Product by the Basic Patent

Expiration of the Patent Before the Grant of Authorization

“Abamektin” Decision of the German Federal Patents Court



Art. 3(a) not fulfilled: at the time of application of the certificate no valid patent exists.

Protection of the Product by the Basic Patent

- ♦ Reinstatement not possible
- ♦ Filing the request for the grant of an SPC before expiration of the basic patent not helpful: Art. 3(b) not fulfilled (no authorization available)
- ♦ Amendment to the Council Regulation would be helpful

Protection of the Product by the Basic Patent

- **Ensure that authorization proceedings are finalized before expiration of the patent**
- **Properly select the basic patent**

Protection of the Product by the Basic Patent

Selection of the Basic Patent: Product, Method, Use Patents

- ◆ **Selection of the youngest patent: protection period for the product extended as far as possible**
- ◆ **Selection in view of protective scope: protection of the product within the limits of the patent**

Broadest protection offered by product patent.

Method patent covers product only when being produced by the claimed method.

Use patent covers product only when being used in the claimed way.

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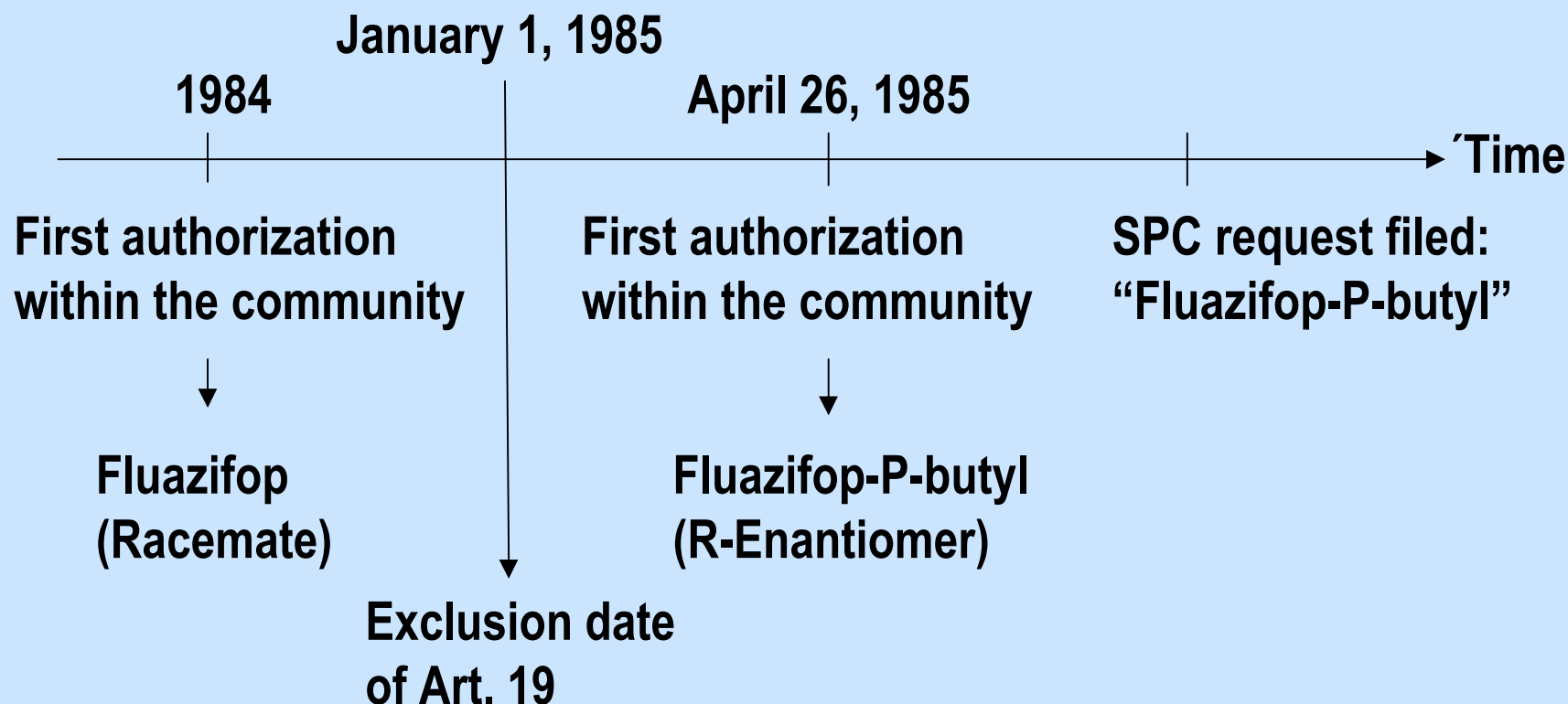
Article 3 (d)

At the date of filing the SPC request and in the member state in which the application is filed (Art. 3)

- ♦ **the product is protected by a valid basic patent,**
- (b) a valid authorization for placing the product on the market has been granted,**
- (c) a certificate has not yet been issued for the product, and**
- (d) the authorization under (b) is the first authorization for placing the product on the market.**

New Products by a Specific Stereochemistry?

“Fusilade” Decision of the German Federal Patents Court



New Products by a Specific Stereochemistry?

- ♦ Different compositions of active ingredients
 - Fluazifop: R:S=50:50
 - Fluazifop-P-butyl: R:S=91:9
- ♦ Different common names in the Pesticide Manual
- ♦ Different marketing authorizations
- ♦ Different properties with regard to post-emergence and pre-emergence activity
- ♦ EPO decisions (EPC): disclosure of Racemate does not destroy novelty of single Enantiomer

New Products by a Specific Stereochemistry?

- ♦ **“Farmitalia” decision of the ECJ: SPC covers all forms of the active ingredient, even when authorization includes only one specific form.
Conclusion: authorization of the Racemate represents the basis for the grant of an SPC also for the Enantiomer included in the Racemate**
- ♦ **Post-emergence activity in the Racemate stems exclusively from R-Enantiomer**
- ♦ **Difference only with regard to ratio of R- and S-Enantiomer**
- ♦ **Standard of authorization procedure cannot be transferred to the definition of the “product” as used in the granting proceedings for SPCs**
- ♦ **Grant of SPC for Enantiomer could be possible, if it were the subject of a patent where it would be specifically claimed.**

New Products by a Specific Stereochemistry?

Conclusion from the „Fusilade“ Decision

- ◆ When filing an SPC request for a „new“ product, the Applicant should be in a position to demonstrate that this „new“ product in comparison to earlier authorized products represents a „new“ active ingredient or composition of active ingredients.
- ◆ It is not sufficient that different authorizations were granted for the old and new product .
- ◆ Evidence is necessary showing that both products are active in a different way regarding their pharmaceutical or agricultural behaviour.
- ◆ Helpful for demonstrating „novelty“ of the product is the grant of a separate patent for the „new“ product.

A New Product due to New Additives?

„Clarithromycin“ decision of the Federal Patents Court

SPC request: Clarithromycin + potassium sorbate

Authorization for: “Klacid Ped” (October 31, 1991)

clarithromycin 125.0mg

potassium sorbate 20.0mg

SPC granted for: Clarithromycin (November 3, 1994)

Authorized product: “Klacid 250” (October 31, 1990)

A New Product due to New Additives?

„Clarithromycin“ decision of the Federal Patents Court

Potassium sorbate is not considered as a pharmaceutically active substance, but only as a preservative.

Art. 3(d) not fulfilled since authorization for “Klacid Ped” is not the first authorization for the same product.

A New Product due to New Additives?

Conclusions to be drawn from the „Clarithromycin“ decision

- ◆ **The basis for an SPC is only provided by a product as defined in Art. 1 of the Council Regulation (active ingredient or combination of active ingredients).**
- ◆ **It is not possible to obtain an SPC on the basis of a new galenic formulation (new, but non-active additives), in the case when for the active ingredient included in the formulation an SPC had already been granted.**

A New Product due to New Additives?

„Carmustin“ decision of the Federal Patents Court

- ◆ **SPC request: „Carmustin in combination with Polifeprosan“**
- ◆ **Medical authorization: Gliadel 7,7 mg**
Active ingredient: Carmustin 7,7 mg
Further ingredient: Polifeprosan 20 192,3 mg
- ◆ **Medical authorization for Carmustin (alone) was granted before.**

A New Product due to New Additives?

„Carmustin“ decision of the Federal Patents Court

Polifeprosan does not represent an active ingredient in the sense of Art. 1 of the EC Council Regulation;

Polifeprosan does not have disease healing or preventing effects by itself, but only improves the effect of the active ingredient Carmustin (controlled release)

Art. 3(d) not fulfilled, since Gliadel is not the first marketing authorization for the product „Carmustin“

A New Product due to New Additives?

„Carmustin“ decision of the Federal Patents Court

Legal appeal allowed:

„Do the terms „active ingredient“ and „active ingredient compositions“ in the sense of Art. 1(b) and Art. 3 of the EC Council Regulation only comprise pharmaceutically active ingredients?“

A New Product due to New Additives?

„Carmustin“ decision of the Federal Patents Court

The outcome of the legal appeal should have an important influence on the question of whether an SPC is allowable for the combination of a pharmaceutically active substance with an additive in the case where the additive has a strong influence on the effect of the pharmaceutically active ingredient, but does not represent a pharmaceutically active ingredient by itself.

A New Product due to a New Preparation Process?

The „Pyramin“ case

Marketing authorization of February 27, 1967 granted for “Pyramin” (<80% of active isomer 1 and >20% of inactive isomer 2 of chloridazon).

Marketing authorization of January 19, 1987 granted for “Pyramin DF” (>90% of active isomer 1 and <10% of inactive isomer 2 of chloridazon).

Basic patent for a process for the preparation of chloridazon with the higher concentration of active substance.

SPC request filed on the basis of the authorization of January 19, 1987.

A New Product due to a New Preparation Process?

The „Pyramin“ case – Decision of the Federal Patents Court

The SPC request was rejected in view of Art. 3(d) EC Council Regulation.

The plant protection products „Pyramin“ and „Pyramin DF“ are identical products in the sense of Art. 1(b) and Art. 3 EC Council Regulation, so that in view of Art. 3(d) EC Council Regulation the authorization of January 19, 1987 is not the first marketing authorization.

A New Product due to a New Preparation Process?

The „Pyramin“ case – Decision of the ECJ (C258/99)

- ◆ The concept of a product within the meaning of Art. 3 of the EC Council Regulation covers chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing process.
- ◆ Two products, which differ only in the proportion of the active chemical compound to the impurity they contain must be regarded as the same product within the meaning of Art. 3 of the EC Council Regulation.
- ◆ The fact of different marketing authorizations for the two products is not relevant for the purposes of establishing whether or not the constituent products of the two plant protection agents are the same.

A New Product due to a New Preparation Process?

The „Pyramin“ case

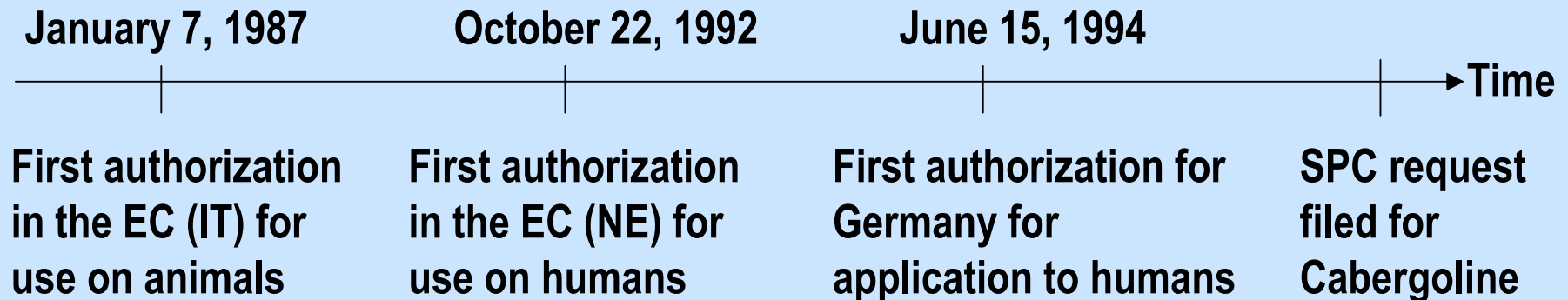
Conclusion:

- ◆ The „product“ is understood in a broad way so that a modification in the formulation of the pharmaceutical or agricultural composition with regard to the additive (impurity) is not suitable to establish a „new“ product.
- ◆ It is necessary to show that the changes in the formulation refer to the active ingredient or the combination of active ingredients. The modified product must be a new active ingredient or combination of active ingredients in the sense of Art. 1(b) of the EC Council Regulation.

Differentiation Between Products as Pharmaceuticals for Humans and for Animals?

The “Cabergoline” case

Can an SPC be granted on the basis of an authorization for human medicinal purposes being obtained after an authorization for the same product but for veterinary purposes?



Differentiation Between Products as Pharmaceuticals for Humans and for Animals?

GPTO:

Art. 19 does not make a difference between pharmaceuticals for humans and animals.

First authorization in the EC dates June 7, 1987.

Grant of SPC excluded, since first authorization is before January 1, 1988.

Differentiation Between Products as Pharmaceuticals for Humans and for Animals?

The Federal Patents Court rejected the appeal, but allowed the legal appeal with regard to the question:

“In the case where the request for a grant of a supplementary protection certificate for pharmaceuticals refers to a medicinal product, where the medical authorization is directed to the application of this product to human beings, is then as the first authorization in the Community only the first authorization for the application of the product for human beings to be considered, or also an earlier first authorization of the same product for the application to animals?”

The Federal Supreme Court submitted this question to the European Court of Justice.

Differentiation Between Products as Pharmaceuticals for Humans and for Animals?

Differentiation of products as pharmaceuticals for humans and for animals?

Arguments supporting the differentiation of products as pharmaceutical for humans and for animals:

- ◆ **The wording of the Council Regulation**

With the reference to authorizations according to the Guideline 65/65/EEC (for humans and for animals) and according to the Guideline 81/851/EEC (for animals) a differentiation is made between authorizations for applications to humans and to animals. This differentiation is implicitly applicable to all Articles of the Regulation.

Differentiation Between Products as Pharmaceuticals for Humans and for Animals?

Arguments supporting the differentiation of products as pharmaceuticals for humans and for animals:

- ◆ **The meaning and the sense of the Council Regulation.**

The differentiation between pharmaceuticals for humans and for animals is justified since the authorization proceedings for pharmaceuticals for humans cover a more difficult and a more time-consuming frame in comparison to those for pharmaceuticals for animals (analytical, pharmacological- toxicological, clinical tests).

It is not justified to prevent a compensation for the development of a product as a pharmaceutical for humans, due to the development of the same product as a pharmaceutical for animals, which regularly is much easier and less time-consuming.

Differentiation Between Products as Pharmaceuticals for Humans and for Animals?

Arguments supporting the differentiation of products as pharmaceuticals for humans and for animals:

- ◆ Systematical connection of the Articles of the Council Regulation.

No contradictions exist when a general differentiation between pharmaceuticals for humans and for animals is made and therefore SPCs for the same product are granted depending on different medical authorizations for humans and for animals.

Art. 4: the scope of the SPC only refers to uses of the product as a pharmaceutical for humans, when the SPC is granted on the basis of a medical authorization for human uses and *vice versa*.

Art. 13: the running times of the SPCs are different depending on whether they were granted on the basis of a medical authorization for application for humans or for animals.

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Several Certificates for Different Patent Owners for the Same Product?

Paragraph (c) of Art. 3: grant of an SPC only possible when for the same product a certificate has not yet been issued.

Is only the patent owner entitled to the SPC who filed or obtained first an SPC for the relevant product?

Several Certificates for Different Patent Owners for the Same Product?

Owner of patents referring to medicinal products against hepatitis (Biogen)



Applying for an SPC without authorization copies



Suit filed against SmithKline

Proprietor of authorizations for placing medicinal products against hepatitis on the market (SmithKline)



Authorization copy given to Institute Pasteur: Owner of a basic patent



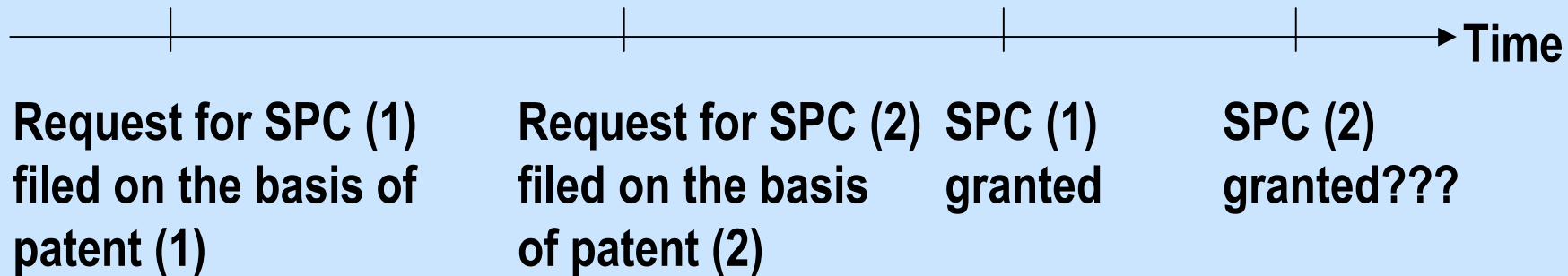
SPC granted

- ◆ ECJ (C-181/85 – Biogen vs. SmithKline): Grant of an SPC to each proprietor of a basic patent for the same authorized product
- ◆ No obligation of the proprietor of the authorization to make available copies thereof to the patent proprietor

Several Certificates for Different Patent Owners for the Same Product?

- ◆ Patent proprietor not in a position to present to the national authority (Patent Office) a copy of the authorization:
Rejection of the application not justified.
- File a request for the grant of an SPC even if for the same product an SPC was already granted to a different patent owner of a different basic patent.
- File the request to obtain a copy of the relevant authorization by the National Authority (Patent Office).

Several Certificates for the Same Patent Owner for the Same Product?



Art. 3 of the Council Regulations requires only that at the date of filing the SPC an earlier SPC has not yet been granted

Several Certificates for the Same Patent Owner for the Same Product?

**Art. 3(2) of the EC Council Regulation 1610/96
(also applicable to the EEC Council Regulation 1768/92)**

“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 enumerating from two or more holders of different patents are pending, one certificate for this product may be issued to each of these holders.”

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The First Authorization in the Community

Art. 13: Duration of the certificate

1. The certificate shall take effect at the end of the lawful terms of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and **the date of the first authorization to place the product on the market in the Community** reduced by a period of five years.

The First Authorization in the Community

Art. 19: Transitional provisions

Any product which, on 2 January 1993, is protected by a valid basic patent and for which **the first authorization to place the product on the market as a medicinal product in the Community** was obtained after 1 January 1985 may be granted a certificate.

- ♦ For Denmark, Germany, Finland and Norway: 1 January 1988
- ♦ For Belgium, Italy and Austria: 1 January 1982
- ♦ Art. 19 not applicable in Member States whose national law did not on 1 January 1990 provide for the patentability of pharmaceutical products

The First Authorization in the Community

Which requirements an authorization according to Art. 3(d) or Art. 19 of the Council Regulations has to fulfil in order to represent a relevant first authorization?

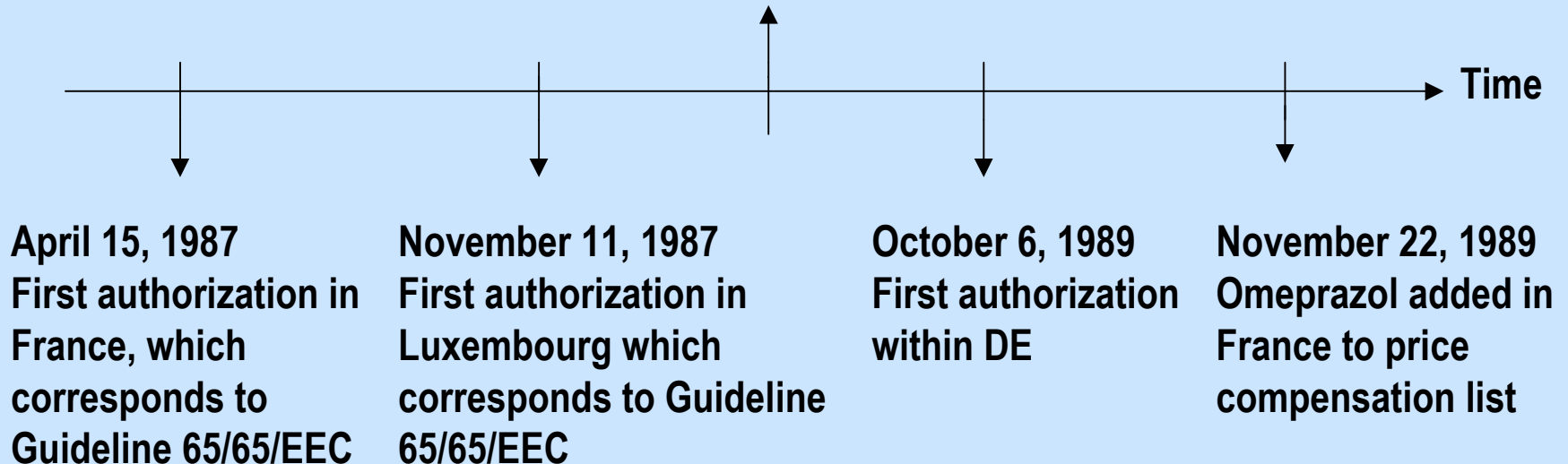
Is it sufficient, that the authorization is in line with the Guidelines 65/65/EEC and 81/851/EEC, respectively, or is it necessary that the relevant marketing authorization allows a real entering of the market by the product (due to price fixing)?

The First Authorization in the Community

“Omeprazol” Decision of the Federal Supreme Court

March 21, 1988

Omeprazol taken up in list of pharmaceuticals authorized for distribution in LU (price fixing)



The First Authorization in the Community

Granted SPC: first authorization within the Community indicated, March 1988, Luxembourg.

Nullity suit: SPC revoked, since first authorization within the Community issued before cut-off date of January 1, 1988.

Appeal at the Federal Supreme Court: questions for preliminary ruling submitted to ECJ:

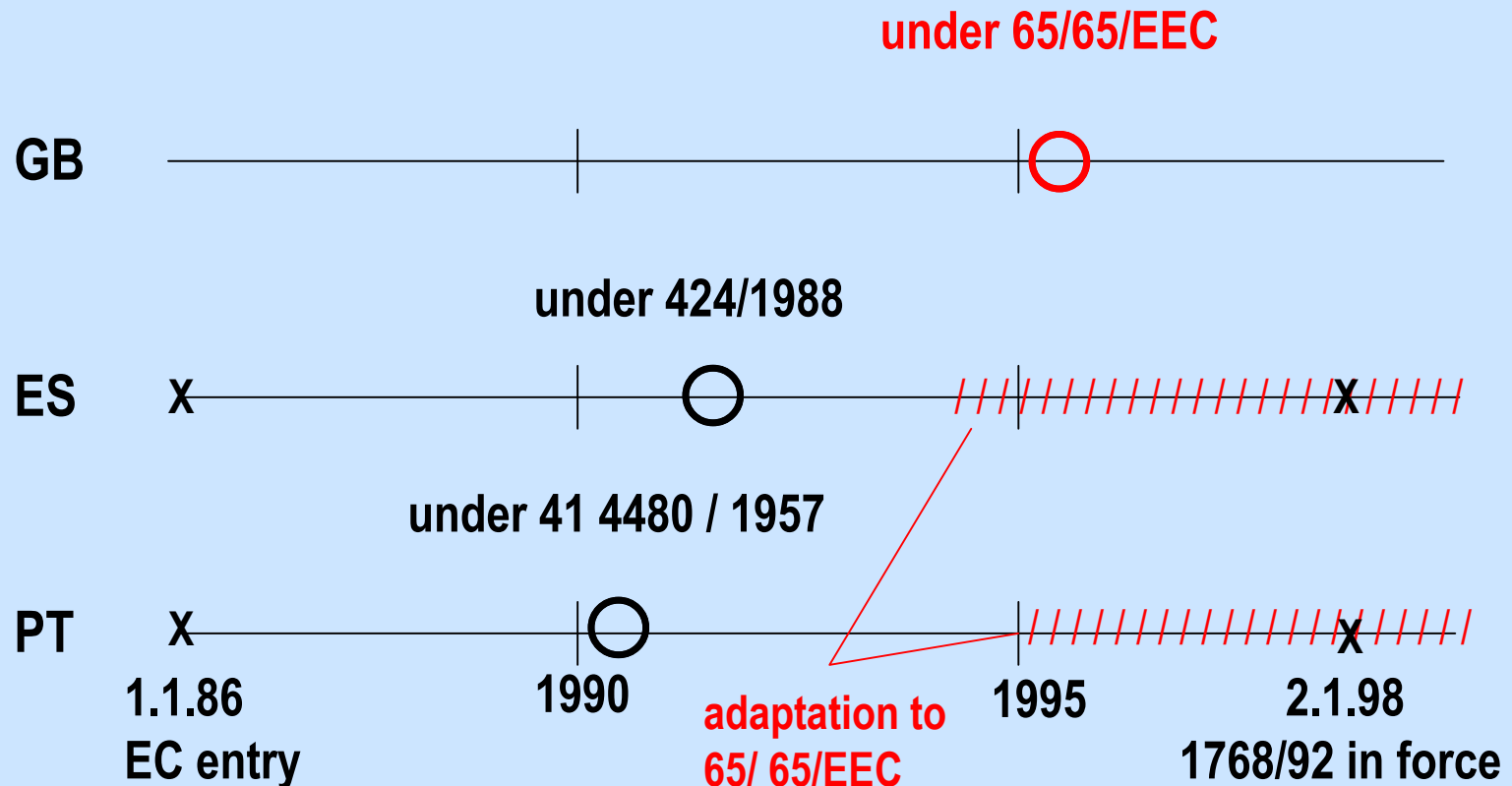
The First Authorization in the Community

- 1a) Is it only significant for application of the transitional Regulation of Art. 19 that the first authorization in the Community is an authorization within the meaning of Guidelines 65/65/EEC or 85/851/EEC or can also another authorization granted later, after the cut-off date, pertaining in particular to the price fixing of the pharmaceutical, be relevant?**

- 1b) Is a first authorization granted in any member state of the Community (as in Arts. 8 and 13 of the Regulation) of significance or is the first authorization in the member state of significance for which grant of the supplementary protection certificate was requested?**

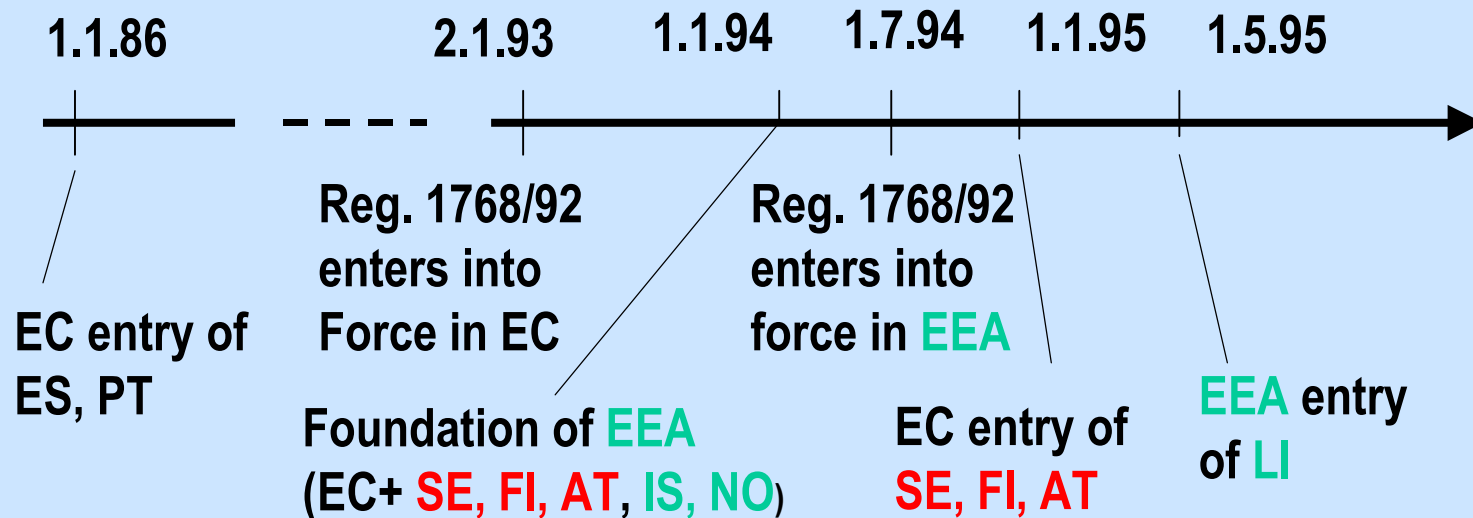
The First Authorization in the Community

Early ES and PT Authorizations



The First Authorization in the Community

EEA Treaty and SPCs



The First Authorization in the Community

EEA Treaty and SPCs

Duration of SPC according to Article 13 of EC Regulation 1768/92: period equal to period which elapsed between application date of basic patent and the date of “*the first authorization to place the product on the market in the Community*” reduced by a period of five years.

Protocol 1, item 8, horizontal adjustments of EEA treaty: references to territory of the “*Community*” found in EC legal acts annexed to EEA agreement are **deemed to be references to the sovereign territories of the EEA contracting state.**

The First Authorization in the Community

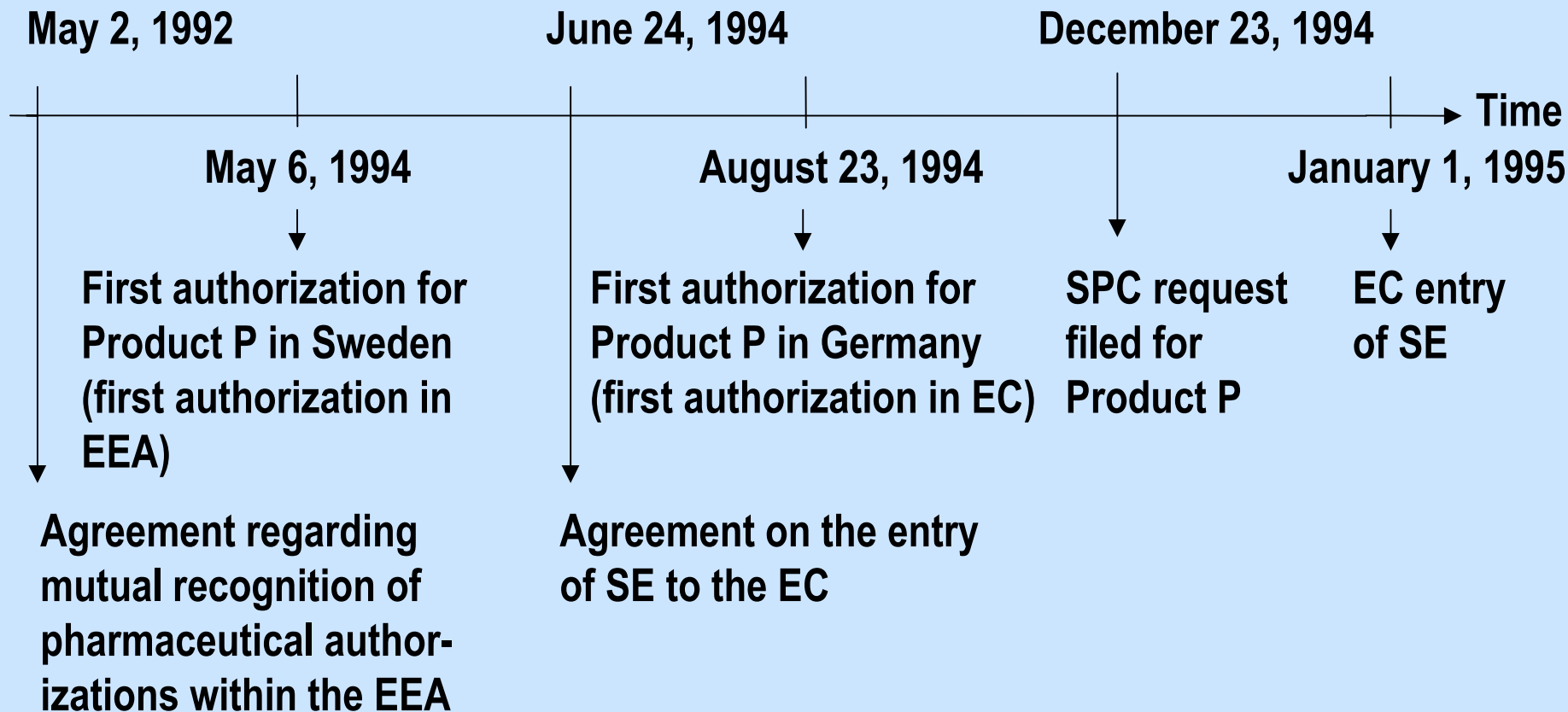
EEA Treaty and SPCs

- Marketing authorization issued in IS, NO, SE, FI and AT since July 1, 1994 are relevant when calculating the SPC duration

Unresolved issues for pharmaceutical SPCs:

- Marketing authorizations issued in IS, NO, SE, FI and AT prior to July 1, 1994
- The effect of Swiss authorization being automatically effective in Liechtenstein

The First Authorization in the Community



The First Authorization in the Community

Opinion of GPTO

Authorization of May 6, 1994 in SE is the first authorization within the EC

- ♦ Entry of SE to EC decided before the SPC request was filed
- ♦ Mutual recognition of authorizations within EEA acknowledged before the SPC request was filed

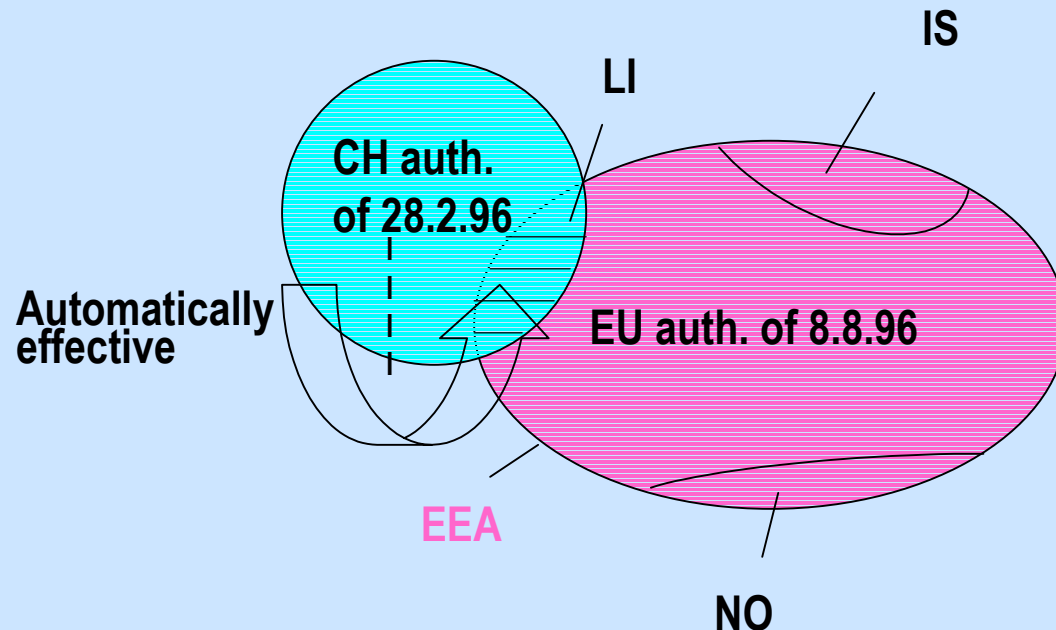
Opinion of Applicant

Authorization of May 6, 1994 in SE is not the first authorization within the EC

- ♦ Request for grant was filed before the date of entry of SE to the EC
- ♦ Explicit recognition of an EFTA State authorization as an EC authorization for Art. 3(b), but not Art. 13(1)
- ♦ Marketing authorization issued prior to July 1, 1994 (entry into force of 1768/ 92/ EEC in EEA state Sweden) is not retroactively to be taken into account

The First Authorization in the Community

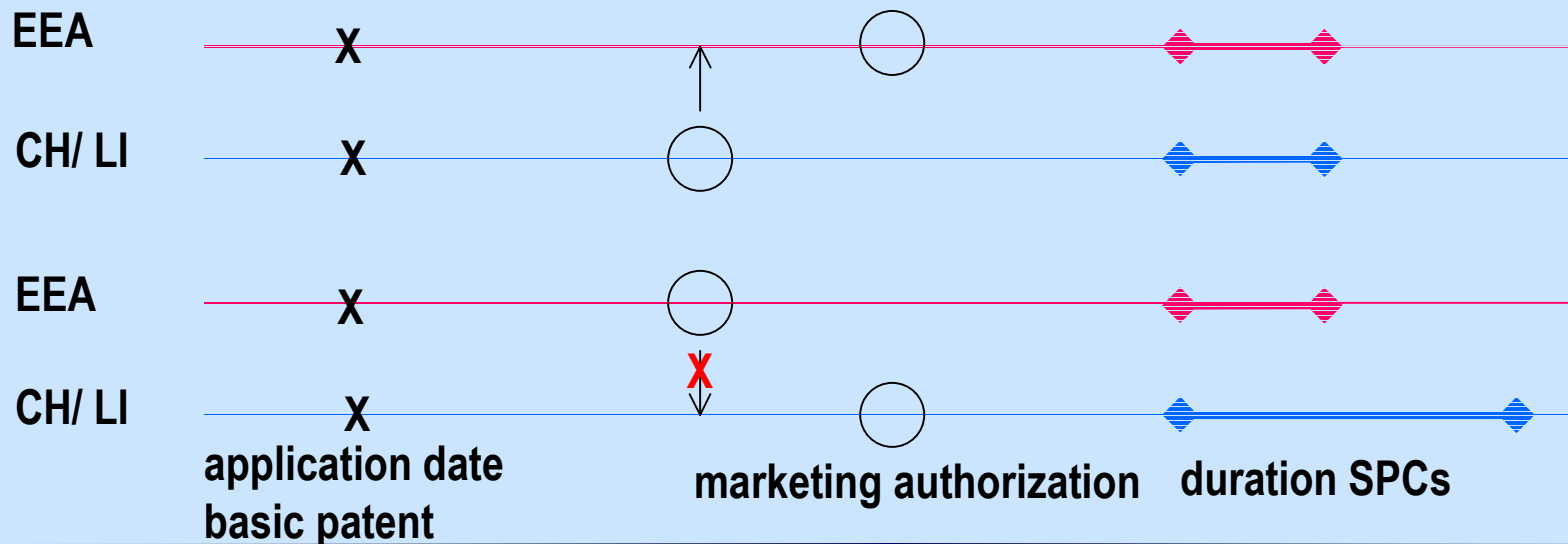
The Possible Effect of Swiss Marketing Authorizations in the EEA



The First Authorization in the Community

UK and German Patent Offices:

Swiss authorization is to be taken into account → paradox situation

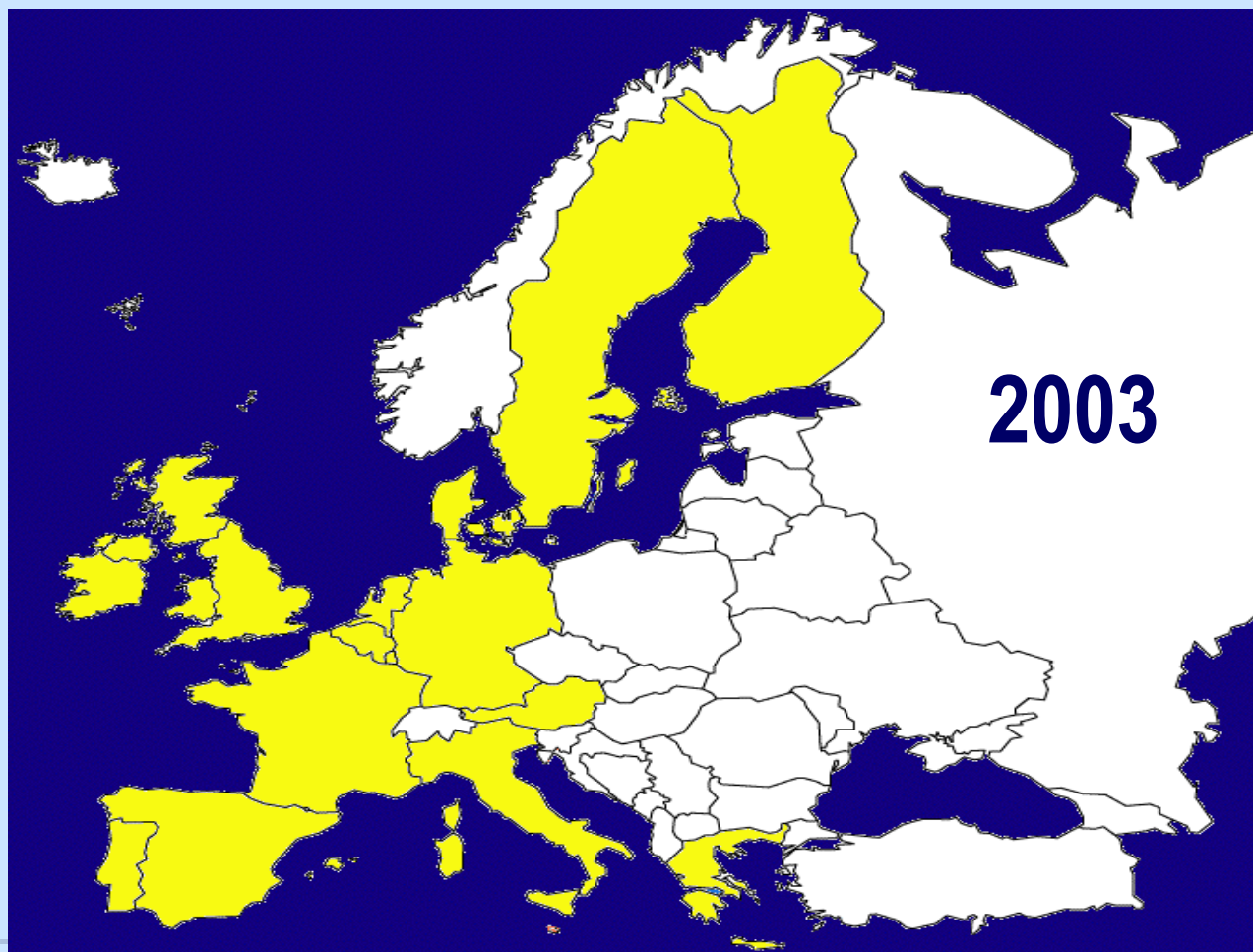


Patent Term Extension in the EU

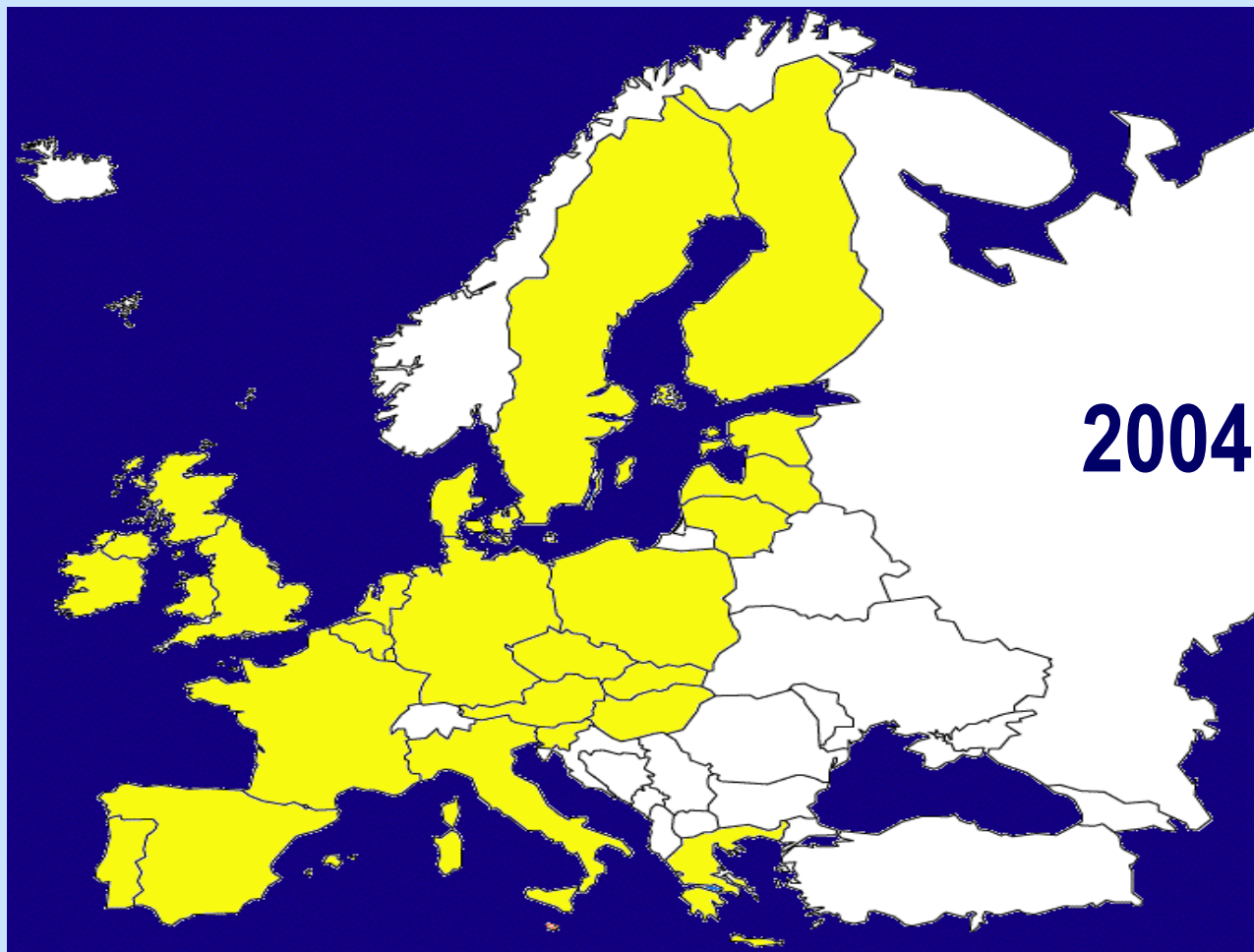
Contents

- ◆ Introduction
- ◆ Examination of SPCs
- ◆ The Idarubicin Case
- ◆ The Definition of the Product for the SPC
- ◆ Protection of the Product by the Basic Patent
- ◆ What is a “New Product”?
- ◆ Several Certificates for the Same Product
- ◆ The First Authorization in the Community
- ◆ **SPCs and EU Enlargement**

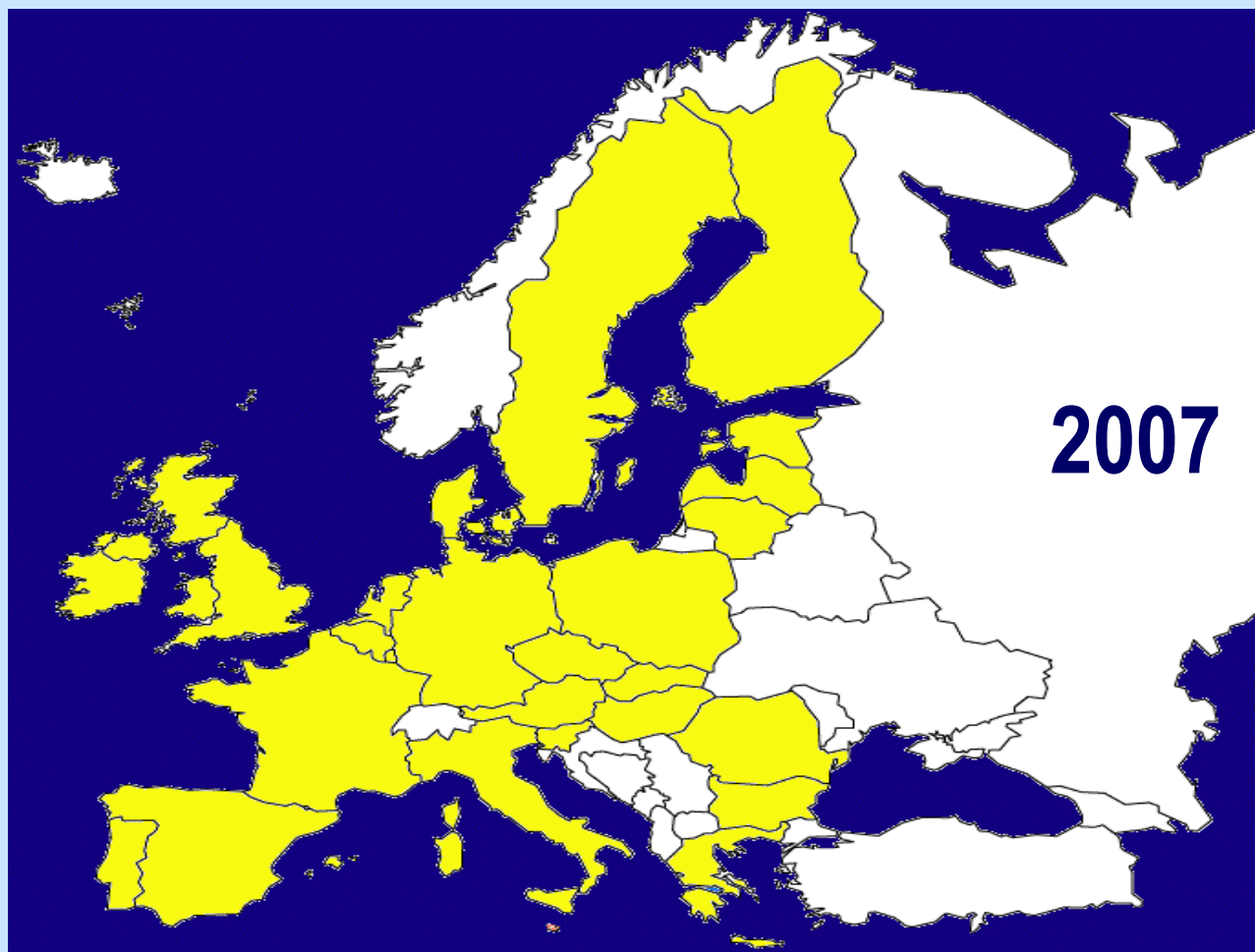
SPCs and EU Enlargement



SPCs and EU Enlargement



SPCs and EU Enlargement



SPCs and EU Enlargement

- SPC Regulation 1768/92 is part of the *acquis communautaire*
- National pharmaceutical SPC's available since

■ EE	1 / 2000	■ CZ	4 / 2000
■ LV	1 / 1994 *	■ HU	not yet
■ LT	1 / 2002	■ SI	7 / 2002 *
■ PL	not yet	■ CY	4 / 1998
■ SK	2001	■ MT	1 / 2003

SPCs and EU Enlargement

- **SPC Regulation 1768/92 (medicinal products) provides that the proprietor can obtain an SPC in an accession state if he holds a valid basic patent and a marketing authorization in the accession state at stake.**
- **Partially supplementary protection is also allowed for medicaments approved a longer time ago.**
- **This is regulated by cut-off dates.**
- **Identical Regulations are found for SPC Regulation 1610/96 (plant protection products).**
- **Details are summarized in Act of Accession, Annex II, Section 4, Chapter C II, Article 1.**

SPCs and EU Enlargement

Poland – Annex II, Ch 4, CII, 1h of Act of June 6, 2002

- SPC may be granted for an active ingredient for which the first marketing authorisation has been obtained after January 1, 2000 in Poland
- SPC application must be filed **within 6 months of the accession date**

SPCs and EU Enlargement

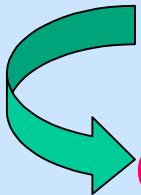
Cut-off Dates

- **CZ:** First marketing authorization in CZ after November 10, 1999 or first marketing authorization in the community not earlier than 6 months prior to accession date.
- **LT:** application date of basic patent after February 1, 1994.
- **HU, PL, SK:** First marketing authorization after January 1, 2000.

SPCs and EU Enlargement

Transition Deadlines for Filing an SPC Application

- LV, LT, HU, MT, PL, SI: within 6 months of accession
- CZ, EE, CY, SK: within 6 months of the date of the first marketing authorization



Care should be taken that especially in the latter countries no deadlines for filing SPCs are missed !

MUCHAS GRACIAS POR SU ATENCIÓN