

# **SUPPLEMENTARY PROTECTION CERTIFICATES**

## **VALIDITY ISSUES AND SCOPE OF PROTECTION<sup>1</sup>**

### I – INTRODUCTION

#### 1. DEFINITION AND RATIO OF SUPPLEMENTARY PROTECTION CERTIFICATES

Supplementary Protection Certificates for medicinal products (hereinafter certificates or SPCs) are intellectual property rights extending pharmaceutical patents term of protection.<sup>2</sup>

SPCs have been introduced by the Council Regulation 1768/92, several times amended and finally codified by Council Regulation 469/2009 (hereinafter referred to as the Regulation). The Regulation provides an European system for the extension of patent terms for medicinal products that have been granted an authorization to be placed on the market.

SPCs are intended to compensate the patentee for the time spent in obtaining the marketability of the patented product, when according to the law the product cannot be placed on the market before having obtained an administrative authorization pursuant to Directive 2001/83/EC 6.11.2001 (or Directive 2001/82/EC 6.11.2001).

#### 2. DEFINITIONS IN THE REGULATION

A primary role in the framework of the Regulation is played by the concept of “product” and “medicinal product”. They are defined by article 1.

According to article 1(a), a “medicinal product” is a substance or combination of substances presented for treating or preventing diseases in human beings or animals, or for administration to human beings or animals to make medical diagnosis or influence physiological functions.

According to article 1(b) the “product” is the active ingredient or combination of active ingredients of a “medicinal product”.

Article 1(c) defines the “basic patent” as the patent designated by the SPCs’ holder for the purpose of the procedure for grant of the certificate. The patent may cover a product, a process to obtain a product, an application of a product.

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<sup>2</sup> Although the rights conferred by the certificate are not entirely comparable to the rights conferred by the patent as explained in this short brief.

### 3. SCOPE OF THE REGULATION

According to article 2 of the Regulation, SPCs may be granted with reference to any product that is (i) protected by a patent (in the territory of a member State) and is subject, prior to being placed on the market, to an administrative authorization procedure (as laid down in Directive 2001/83 or 2001/82, as appropriate).

#### II. THE SPCs SCOPE OF PROTECTION

The scope of protection provided by SPCs is defined by article 5 of the Regulation, as limited by article 4.

Article 5 of the Regulation, under the title “effects of the certificate”, provides that (within the limits provided by article 4) the certificate confers the same rights as conferred by the basic patent, subject to the same obligations and limitations.

Therefore, likewise the basic patent, the SPC provides a monopoly on the product and the exclusive right, to its owner, to manufacture, market, offer for sale the subject matter of the monopoly.

Under the title “subject matter of protection”, the article 4 of the Regulation specifies the limits of the scope of protection conferred by the certificate. According to this provision the certificate shall extend:

- i. “within the limits of the protection conferred by the basic patent”,
- ii. “only to the product covered by the authorization to place the corresponding medicinal product on the market”
- iii. “and for any use of the product as a medicinal product that has been authorized before the expiration of the certificate”.

The point sub i. provides the external limits of the protection provided by the SPC, by stating that the SPC shall not have a wider scope than the one provided by the basic patent. It has the same content as article 5, but from a negative standpoint.

The point sub ii. implies that the scope of protection, already limited within the scope of protection conferred by the patent, shall be further restricted to the “product” of the “medicinal product” which obtained the authorization to enter the market (hereinafter also MA). Recital 10 of the Regulation seems to suggest a narrow interpretation of this provision: *“the protection granted should furthermore be strictly confined to the product which obtained authorization to be placed on the market as a medicinal product”*.

Therefore, it was questioned whether the scope of protection of an SPC covering an active ingredient could extend to a medicinal product consisting of that active ingredient plus other

actives. Moreover it was questioned whether “*the certificate can protect the product only in the specific form stated in the marketing authorization*”.

Irrespective of the apparently strict meaning of article 4, especially if interpreted in the light of recital 10, it seems that the first point raised above should be answered positively and that the second point should be answered negatively.

As for the first point (whether the scope of protection of an SPC covering an active ingredient could extend to a medicinal product consisting of that active ingredient plus other active ingredients) it has been argued<sup>3</sup> that the positive answer is forced by the last part of article 4, indicated above sub iii..

The last part of article 4 provides that the scope of protection of the SPC extends to “any use of the product as a medicinal product that has been authorized before the expiration of the certificate”. According to the author quoted above, there is no reason in the Regulation implying that the new use of the product should be necessarily a new use of the product as such: therefore the use of the product together with a further active ingredient should be considered a new use of the product as well. For example: given a product X, the medicinal product comprising the active ingredients X and Y implies a new use of the product X (namely, the use with the active Y). Therefore the medicinal product comprising X and Y falls under the scope of protection of the SPC granted for product X.

The second point, if I understand it properly, has been dealt with by the European Court of Justice (hereinafter ECJ) in the *Farmitalia* decision (C-392/97, held in September 16, 1999). For sake of clarity, in this case the ECJ had been asked to answer whether article 3(b) of the Regulation requires that “the product in respect of which the grant of a protection certificate is sought is described as an active ingredient in the medicinal authorization” and whether, consequently, the requirements of article 3(b) of the Regulation are met “where only one individual salt of a substance is stated in the notice of authorisation to be an active ingredient, but the grant of a protection certificate is sought for the free basis and/or for other salts of the active ingredient”.

Therefore, the question submitted by the Bundesgerichtshof referred to a matter of validity of the SPC (consisting in the relationship between the product and the MA, as required by article 3b).

In spite of that, when dealing with this question, the ECJ summarized it as follows: “*whether, on a proper construction of Regulation N. 1768/92, the certificate can protect the product only in the specific form stated in the marketing authorization*”. Therefore, a question of infringement (consisting in the assessment whether the product is protected by the certificate).

Consistently, the ECJ provided a guide for assessing infringement by stating that “where the basic patent covers an active substance and its various derivatives (salts and esters), the certificate

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<sup>3</sup> Philippe de Jong, *SPCs and combination products – Infringement issues*, published on [www.eplawpatentblog.com](http://www.eplawpatentblog.com).

confers the same protection” and that “where an active ingredient [...] is referred to in the marketing authorization concerned and is protected by a basic patent in force, the certificate is capable of covering the active ingredient as such and also its various derived forms such as salts and esters, as medicinal products, in so far as they are covered by the protection of the basic patent”.

It has been noticed that the difference between the rights conferred by the patent and the rights conferred by the SPC to their owners lies in this: whilst the patent owner is awarded an absolute protection against any use of the patented compound, the proprietor of the SPC is provided a protection limited to the uses of the compound which have been authorized and that fall within the pharmaceutical field.<sup>4</sup>

Some decisions have been rendered in Italy with regard to the scope of protection of SPCs and their infringement.

The Court of Roma in the *Beecham vs. Biochemie* decision rendered on July 4, 2003 stated that the scope of protection conferred by the certificate encompasses the product claimed by the patent and that the reference to the “product covered by the authorization” is only intended to exclude from the certificate’s scope of protection the active ingredients claimed by the patent which are different from those used in the authorized medicinal product. In the case brought to the attention of the Court, the basic patent claimed *clavulanic acid* whilst the authorized medicinal product (“Augmentin”) comprised *clavulanic acid* and a further active ingredient, *amoxicillin* (therefore, in principle, implying a narrower scope of protection). According to the Court, the related certificate covers also medicinal products comprising *clavulanic acid* only, irrespective of the fact that the marketing authorization had been granted for *clavulanic acid* plus another active ingredient. The decision quoted the former ruling of the Court of Milan *Vis vs. Istituto Scientifico delle Venezie* September 17, 1998 where it is explained that the provision according to which the scope of protection of a certificate is limited to the product covered by the authorization means that the certificate’s scope of protection is limited within the sole claims that have been actuated by manufacturing and/or marketing the authorized medicinal product.

### III – VALIDITY ISSUES

#### 1. REQUIREMENTS FOR SPCs TO BE GRANTED

According to article 3 of the Regulation SPCs may be granted provided that, in the member state where the SPC is applied for,

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<sup>4</sup> Philippe de Jong, quoted above.

- (a) “The product is protected by a basic patent in force”;
- (b) “a valid authorization to place the product on the market as a medicinal product” has been granted;
- (c) the product has not been already the subject of a certificate;
- (d) the authorization referred to sub b is the first authorization to place the product on the market as a medicinal product.

Several problems arose in connection with the interpretation of article 3. Precondition for the application of article 3 (and many other provisions of the Regulation) is the correct understanding of the notion of “product”, as defined by article 1 (b).

## 2. THE INTERPRETATION OF ART. 1 (b) – The meaning of “product”

The notion of “product” has been construed narrowly by the Court of Justice in two decisions, namely the *Massachusetts Institute of Technology* decision, case C-431/04, issued on May 4, 2006 (addressed also as the *MIT* decision), and the *Yissum* decision, case C-202/05, issued on April 17, 2007.

*Gliadel* is a device to be implanted into the human body for the treatment of tumors. Its action is characterized by the *carmustine*, an active ingredient, being released gradually by means of *polifeprosan* which acts as a bioerodible matrix. *Carmustine* and *polifeprosan* were claimed, inter alia, by an European Patent owned by the MIT. *Gliadel* was granted a marketing authorization in Germany. The MIT applied for an SPC to be granted for *Gliadel*. The MIT requested, as main claim, an SPC to be granted with reference to *carmustine* combined with *polifeprosan* and, as alternative claim, an SPC to be granted for the sole *carmustine*.

The SPC application was rejected, with reference to both the main and the alternative claim. As per the main claim, the Patent Office found that *polifeprosan* could not be considered an active ingredient, pursuant to art. 1(b) of the Regulation. Regarding the alternative claim, it was objected that *carmustine* as such had already been granted a marketing authorization and therefore the requirement of article 3(d) of the Regulation was not met.

Following an appeal from the MIT, the Bundesgerichtshof decided to refer the following questions to the Court:

1. *Does the concept of “combination of active ingredients of a medicinal product” within the meaning of Article 1(b) of Regulation 1768/92 mean that the components of the combination must all be active ingredients with a therapeutic effect?*
2. *Is there a “combination of active ingredients of a medicinal product” also where a combination of substances comprises two components of which one component is a known substance with a therapeutic effect for a specific indication and the other component*

*renders possible a pharmaceutical form of the medicinal product that brings about a changed efficacy of the medicinal product for this indication?*

The Court observed that the Explanatory Memorandum to the Proposal for a Council Regulation of April 11 1990, concerning the creation of a supplementary protection certificate for medicinal products, at point 11 specifies that *“the proposal for a Regulation therefore concerns only new medicinal products. It does not involve granting a [SPC] for all medicinal products that are authorized to be placed on the market. Only one [SPC] may be granted for any one product, a product being understood to mean an active substance in the strict sense. Minor changes to the medicinal product such as a new dose, the use of a different salt or ester or a different pharmaceutical form will not lead to the issue of a new [SPC]”* (point 19).

The notion of “product”, according to the ECJ, shall be construed according to the directions referred to above.

Moreover, the Court, at point 23 of the decision, referred to point 68 of the Explanatory Memorandum to the Proposal for a Regulation, of December 9 1994, concerning the creation of a supplementary protection certificate for plant protection products, where it is stated that:

- *“it would not be acceptable, in view of the balance required between the interests concerned, for the total duration of protection granted by the SPC and the patent for one and the same product to be exceeded;*
- *that might be the case if one and the same product were able to be the subject of several successive SPCs;*
- *that calls for a strict definition of the product;*
- *if an SPC has already been granted for the active substance itself, a new SPC may not be granted for that substance, whatever changes may have been made regarding other features of the plant protection product (use of a different salt, different excipients, different presentation, etc.);*
- *in conclusion, it should be noted that, although one and the same substance may be the subject of several patents and several marketing authorizations in one and the same Member State, the SPC will be granted for that substance only on the basis of a single patent and a single authorization, namely the first granted in the Member State concerned.”*

Considered that, as set out in recital 17 of the preamble to that regulation, the rules in Article 3(2) thereof shall be deemed valid also for the interpretation of Article 3 of Regulation 1768/92, the ECJ concluded that *“a substance which does not have any therapeutic effect of its own and which is used to obtain a certain pharmaceutical form of the medicinal product is not covered by the concept of ‘active ingredient’, which in turn is used to define the term product”* (point 25) and that

*“the answer to the questions referred must be that Article 1(b) of Regulation No 1768/92 must be interpreted so as not to include in the concept of ‘combination of active ingredients of a medicinal product’ a combination of two substances, only one of which has therapeutic effects of its own for a specific indication, the other rendering possible a pharmaceutical form of the medicinal product which is necessary for the therapeutic efficacy of the first substance for that indication”* (point 31).

In the Yissum decision, the ECJ dealt with a case where an SPC, sought for the product *calcitriol*, had been refused on the ground that other medicinal products consisting of *calcitriol* had been granted authorization to be placed on the market.<sup>5</sup>

On appeal, Yissum argued that its SPC application had to be admitted since it referred to *calcitriol* for a particular therapeutic use different to that of the products previously authorized.

The High Court of Justice (England & Wales), Chancery Division, decided to refer the following question to the ECJ: *“in a case in which the basic patent protects a second medical application of a therapeutic agent what is meant by “product” in Article 1(b) of the Regulation [No 1768/92] and in particular does the application of the therapeutic agent play any part in the definition of “product” for the purpose of the Regulation?”*<sup>6</sup>

The Court mentioned the MIT decision and the Pharmacia decision (case C-31/03 October 19, 2004) where it was highlighted that *“the concept of product referred to in Article 1(b) of Regulation 1768/92 must be interpreted strictly to mean active substance or active ingredient”* (point 17) and that *“the decisive factor for the grant of the certificate is not the intended use of the medicinal product and [...] the purpose of the protection conferred by the certificate relates to any use of the product as a medicinal product without any distinction between use of the product as a medicinal product for human use and as a veterinary medicinal product”* (point 19).

In consideration of the above the Court held that *“the answer to the question referred must be that Article 1(b) of Regulation 1768/92 is to be interpreted as meaning that, in a case where a basic patent protects a second medical use of an active ingredient, that use does not form an integral part of the definition of the product”* (point 20).

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<sup>5</sup> And on the basis that an ointment base could not be considered to be an active ingredient (*calcitriol* was combined with an ointment in the medicinal product which had been authorized).

<sup>6</sup> The following further questions had been submitted to the Court:

- does the term “combination of active ingredients of a medicinal product” within the meaning of Article 1(b) of the Regulation 1768/92 mean that each component of the combination must have therapeutic activity?
- is there a “combination of active ingredients of a medicinal product” where a combination of substances comprising two components of which one component is a substance with a therapeutic effect for a specific indication and the other component renders possible a form of the medicinal product that brings about efficacy of the medicinal product for that indication?

These questions, nevertheless, were renounced by the national court after having been informed by the Registrar of the ECJ of the MIT decision.

### 3. THE INTERPRETATION OF ART.3 (a) – The meaning of “protected by a basic patent”

Various theories have been formulated with regard to the interpretation of the provision at issue.

Several tests have been developed in order to assess whether an active ingredient or a combination of active ingredients of a medicinal product may be considered as “protected” by the basic patent.

The **infringement test** implies that a product is considered as “protected by the basic patent” if, in case of manufacture or sale of the product by a third party without the consent of the patentee, it results in a violation of the patent. The infringement test is applied by the German Courts and by some Dutch decisions. In assessing infringement the doctrine of equivalence is applied. Indirect infringement, on the contrary, is disregarded.<sup>7</sup>

The **identification test (or Takeda test or express disclosure test)** and the **clear pointer test** are applied in UK.

The “identification test” was developed by Jacob J in the Takeda case.<sup>8</sup> In that case the owner of a patent claiming *lansoprazole* sought an SPC for a combination product comprising *lansoprazole*. On appeal the Court stated that, although the combination product could be considered infringing the basic patent owing to the presence of *lansoprazole*, the combination as such was not “protected” by the patent. Jacob J observed that Takeda had a monopoly on *lansoprazole* and that they were seeking to obtain, by means of the SPC application, a monopoly on the combination of *lansoprazole* and an antibiotic. This, according to the Court, would be not in line with the SPC system since “*it is not a system for providing protection for different monopolies*”. Assessing whether the requirement of article 3(a) of the Regulation is met, according to this opinion, requires that the subject of the application for the SPC is “*identifiable with the invention*” of the basic patent. In other words it implies to “*identify the active ingredients of the product that are relevant to a consideration of whether the product falls within the scope of protection of the patent. Only those ingredients can be said to be protected by the patent within the meaning of the Regulation*”.

The “clear pointer test” was developed in the Gilead case.<sup>9</sup> In that case Gilead was the owner of a patent covering a class of antiretroviral compounds including *tenofovir*. The MA was granted with reference to a medicinal product comprising *tenofovir* and *emtricitabine*. The SPC was sought for the combination product. The application was rejected since the combination was not claimed as such. According to the decision, not everything that infringes may be considered to be “protected by the basic patent”: the patent’s specification should at least provide a “clear pointer” to the

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<sup>7</sup> See András Kupecz, *SPCs covering combination products – current validity issues across Europe?* published at [www.eplawpatentblog.com](http://www.eplawpatentblog.com).

<sup>8</sup> Takeda Chemical Industries Ltd’s SPC Applications [2004] RPC 1.

<sup>9</sup> Gilead Sciences Inc.’s SPC Application [2008] EWHC 1902 (Pat).

specific combination that was granted the authorization. The appeal in Gilead was decided by Kitchin J. The appeal was considered admissible, since it was found that the combination was covered by a subsidiary claim. The Judge had nevertheless the occasion to observe that, although “the infringement test would permit [...] evergreening”, there are “circumstances where the application of the Takeda test may produce a harsh result”.

Similar doubts have been raised by Arnold J in the Astellas case,<sup>10</sup> where he affirmed that, although he was not convinced that Takeda is wrong, he agreed with Kitchin J that there are arguments in favour of the infringement test that merit consideration by a higher court, and by Kitchin J in the first Medeva decision issued this year.<sup>11</sup> In this latter case the patent claimed a method for making a vaccine composition comprising *pertactin* and a further active ingredient. The marketing authorization had been granted with reference to the medicinal products *Infanrix*, *Pediacel*, *Repevax*, etc. composed of the ingredients described in the patent and several additional ingredients. SPCs were sought by Medeva with reference to the authorized products and they had been refused since the combination of ingredients was not found to be “protected by the basic patent”. On appeal Medeva did not argue that the Court had to refuse the Takeda or Gilead tests since they were wrong in the abstract. They argued that in the specific case of vaccines a different test had to be applied, since combined vaccines operate individually and separately and since it is not possible to avoid offering on the market combination products with ingredients additional to those claimed by the patent.

The Court rejected Medeva’s grounds of appeal by stating that there was no evidence that the combined vaccines effectively worked separately and that the result of the Takeda test may produce problems which are not peculiar to vaccines and that apply to all combination products.

The decision was challenged by Medeva. With decision held on June 23, 2010<sup>12</sup> the Court of Appeal decided to refer to the Court of Justice questions relating to the interpretation of articles 3(a) and (b) of the Regulation. The following questions have been referred to the ECJ on July 5, 2010:

1. In the absence of Community harmonisation of patent law, what is meant in Article 3(a) of the Regulation by "the product is protected by a basic patent in force" and what are the criteria for deciding this?
2. In a case like the present one involving a medicinal product comprising more than one active ingredient, are there further or different criteria for determining whether or not "the product is protected by a basic patent" according to Article 3(a) of the Regulation and, if so, what are those further or different criteria?

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<sup>10</sup> Astellas Pharma Inc.’s SPC Application [2009] EWHC (Pat).

<sup>11</sup> Medeva BV’s SPC Applications [2010] EWHC 68 (Pat).

<sup>12</sup> Medeva’s SPC Applications [2010] EWCA Civ 700.

3. In a case like the present one involving a multi-disease vaccine, are there further or different criteria for determining whether or not "the product is protected by a basic patent" according to Article 3(a) of the Regulation and, if so, what are those further or different criteria?
4. For the purposes of Article 3(a), is a multi-disease vaccine comprising multiple antigens "protected by a basic patent" if one antigen of the vaccine is "protected by the basic patent in force"?
5. For the purposes of Article 3(a), is a multi-disease vaccine comprising multiple antigens "protected by a basic patent" if all antigens directed against one disease are "protected by the basic patent in force"?
6. Does the SPC Regulation and, in particular, Article 3(b); permit the grant of a Supplementary Protection Certificate for a single active ingredient or combination of active ingredients where:
  - (a) a basic patent in force protects the single active ingredient or combination of active ingredients within the meaning of Article 3(a) of the SPC Regulation; and
  - (b) a medicinal product containing the single active Ingredient or combination of active Ingredients together with one or more other active ingredients is the subject of a valid authorisation granted in accordance with Directive 2001/83/EC<sup>2</sup> or 2001/82/EC<sup>3</sup> which is the first marketing authorization that places the single active Ingredient or combination of active ingredients on the market?

Before deciding to submit the above indicated questions to the ECJ, the Court of Appeal dealt with Medeva's remark according to which the questions regarding the interpretation of article 3(a) had already been decided by the ECJ in the *Farmitalia* decision. The Court of Appeal rejected this argument by stating that *"first, it is far from clear that [...] the Court addressed the issue arising in this case. Second, even if the Court intended to leave to the national courts the determination of the precise scope of the protection afforded by the patent [...] there must be a real question whether it is compatible with EU law to interpret the phrase "product protected by the basic patent" in article 3(a) as extending to any product with respect to which proceedings could be successfully brought in any national court for infringing the patent. Third, the very fact, as considered by the Court of Justice in paragraph 27 of its judgment, that there has been no EU harmonization of patent law indicates the need for the concept of "protection by a basic patent in force" in relation to a product as defined in Article 1(b) to reflect a European concept separate from its meaning in any particular system of national law"* (point 35).

Likewise the Court of Appeal, Arnold J in the *Astellas* decision (at point 34) stated *"as to Farmitalia, it is not clear to me that the ECJ either endorsed or rejected the infringement test"*.

Despite these opinions, in the *Farmitalia* ruling (C-392/97) held on September 16, 1999, the ECJ seems to have already given its interpretation of article 3(a). Indeed, if points 23 and 27 of the *Farmitalia* decision are read together, it appears clear that, according to the Court, “for determining whether or not a product is protected by a basic patent” the “extent of the patent protection” has to be assessed. Given that, the Court further explains that “accordingly, in the absence of Community harmonization of patent law, the extent of patent protection can be determined only in the light of the non-Community rules which governs patents” (point 27). “The answer to be given to the second question must therefore be that, in order to determine [...] whether a product is protected by a basic patent, reference must be made to the rules which govern that patent” (point 29).

The arguments put forward by the English Court of Appeal, therefore, seem to miss the target. Indeed, provided that the Court has interpreted the requirement “protected by a basic patent” as “encompassed by the basic patent’s scope of protection”, providing an “European concept” to assess this requirement, since to exceed the Court’s function. Without considering that the non-Community law referred to by the Court are, in principle, art. 69 of the European Patent Convention and art. 8 of the Strasbourg Convention, which already provide a substantial European concept of “patent scope of protection”.

If this is correct, then it is possible to say that according to the ECJ, the requirement of article 3(a) may be assessed by means of an infringement test that could take into consideration also indirect infringement.

#### 4. THE INTERPRETATION OF ART. 3 (b)

In the *Farmitalia* decision the ECJ had been addressed a further question regarding the interpretation of the term “product” on a proper construction of art. 3(b), namely whether the product in respect of which the grant of the SPC is sought has to be described as an “active constituent” in the MA (and therefore, whether it is possible or not to obtain an SPC for the free base of the active ingredient when the MA stated a single individual salt of the active ingredient to be an “active constituent”). According to my opinion, the ECJ did not answer this question clearly. According to the Court “where a product in the form referred to in the marketing authorization is protected by a basic patent in force, the certificate is capable of covering that product, as a medicinal product, in any of the forms enjoying the protection of the basic patent”. The answer seems to address to scope of protection instead than to validity issues. Moreover the Court argues that “where the basic patent covers an active substance and its various derivatives (salts and esters), the certificate confers the same protection” and “where an active ingredient in the form of a salt is referred to in the marketing authorisation concerned and is protected by a basic patent in force, the certificate is capable of covering the active ingredient as such and also its various derived forms such as salts and esters, as medicinal products, in so far as they are covered by the protection of the basic patent”.

The answer of the court seems to consider interpretation of article 4 and 5 of the regulation, instead than interpretation of article 3(b).

To this purpose the UK Medeva first decision should be mentioned. The judge on that occasion stated that the condition set forth by art. 3(b) was not met since the SPC application did not make reference to all the active ingredients that had been the subject of the MA. As already said, the Medeva case was challenged before the Court of appeal which decided to submit to the ECJ the question indicated above sub point 6 of paragraph 3.