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Patent Alert

SPC New Case Law of the Court of Justice of the EU

The Court of Justice of the European Union decisions in the Medeva (case C-322/10) and Georgetown (case C-422/10) matters issued on November 24, 2011, clarify the interpretation of Article 3 of the Regulation No. 469/2009 on the Supplementary Protection Certificate with respect to medicines comprising a combination of active substances.

MEDEVA case C-322/10

The question referred to the CJEU concerned two major points:

1. What is the criteria to be applied for defining the product subject matter of an SPC. Certain national courts applied the so called "infringement "test whereas others applied the "protection "test.

   The Court of Justice decided that the "protection" test should be applied. If a combination is to be protected, it should be specified in the claims.

   "Article 3(a) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products must be interpreted as precluding the competent industrial property office of a Member State from granting a supplementary protection certificate relating to active ingredients which are not specified in the wording of the claims of the basic patent relied on in support of the application for such a certificate."

2. Can a SPC be granted if the marketing authorisation relates to a combination of active substance if the patent protects only a single element of the combination or only the combination of some elements of the combination subject of the marketing authorisation. The Court of Justice authorises the grant of an SPC on a combination of active substances even if the medicinal product subject of the Marketing Authorisation contains additional active substances.

   "Article 3(b) of Regulation No 469/2009 must be interpreted as meaning that, provided the other requirements laid down in Article 3 are also met, that provision does not preclude the competent industrial property office of a Member State from granting a supplementary protection certificate for a combination of two active ingredients, corresponding to that specified in the wording of the claims of the basic patent relied on, where the medicinal product for which the marketing authorisation is submitted in support of the application for a special protection certificate contains not only that combination of the two active ingredients but also other active ingredients."

GEORGETOWN case C-422/10

The question raised was similar to that raised in the MEDEVA case and applies the rule for the case of a basic patent covering one active substance only.

"Article 3(b) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products must be interpreted as meaning that, provided the other requirements laid down in Article 3 are also met, that provision does not preclude the competent industrial property office of a Member State from granting a supplementary protection certificate 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 in support of the supplementary protection certificate application contains not only that active ingredient but also other active ingredients."

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UNIVERSITY OF QUEENSLAND case C-630/10 (Still pending)

The questions referred to the Court of Justice are the following:

1. *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 of 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?*

3. *Is one of these further or different criteria whether the active ingredients are admixed together rather than being delivered in separate formulations but at the same time?*

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. *In a case involving a medicinal product comprising more than one active ingredient, is it relevant to the assessment of whether or not "the product is protected by a basic patent" according to Article 3(a) that the basic patent is one of a family of patents based on the same original patent application and comprising a parent patent and two divisional patents which between them protect all the active ingredients in the medicinal product?*

6. *In a case like the present one involving a basic patent with claims to "a process to obtain a product" in the sense of Article l(c), does the "product" of Article 3(a) have to be obtained directly by means of that process?*

7. *Does the SPC Regulation and, in particular, Article 3(b), permit the grant of a Supplementary Protection Certificate for a single active ingredient where:*

   a) a basic patent in force protects the single active ingredient within the meaning of Article 3(a) of the SPC Regulation; and
   b) a medicinal product containing the single active ingredient together with one or more other active ingredients is the subject of a valid authorisation granted in accordance with Directive 2001/83/EC or 2001/82/EC which is the first marketing authorization that places the single active ingredient on the market?

8. *Does the answer to Question 7 differ depending on whether the authorisation is for the single active ingredient admixed with the one or more other active ingredients rather than being delivered in separate formulations but at the same time?*

The MEDEVA decision partially answers to some of the questions referred to in C-630/10:

- by applying the "protection" test to determine the subject matter of a basic patent (question 1 and 2) i.e the wording of the claims will be the basis.

The MEDEVA and the GEORGETOWN decision answer to question 3 i.e it is sufficient that one or several active substance of the medicine subject of the Marketing authorisation be claimed. Regulation (EC) No 469/2009 does not require that all the active substances of the Medicine on the market be claimed.

THE DAIICHI SANKYO case C- 6/11 (still pending)

The questions referred to the Court of Justice are the following:

1. *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 Art 3(a) of the Regulation and, if so, what are those further or different criteria?*

3. *In order for a combination of active ingredients cited in an authorisation for placing a medicinal product on the market to be the subject of an SPC, and having regard to the wording to Article 4 of the Regulation, is the condition that the product be "protected by a basic patent" within the meaning of Articles 1 and 3 of the Regulation satisfied if the product infringes the basic patent under national law?*

4. *In order for a combination of active ingredients cited in an authorisation for placing a medicinal product on the market to be the subject of an SPC, and having regard to the wording to Article 4 of the Regulation, does satisfaction of the condition that the product be "protected by a basic patent" within the meaning of Articles 1 and 3 of the Regulation depend upon whether the basic patent contains one (or more) claims which specifically mention a combination of (1) a class of compounds which includes one of the active ingredients in the said product and (2) a class of further active ingredients which may be unspecified but which includes the other active ingredient in the said product; or is it sufficient that the basic patent contains one (or more) claims which (1) claim a class of compounds which includes one of the active ingredients in the said product and (2) use specific language which as a matter of national law extends the scope of protection to include the presence of further other unspecified active ingredients including the other active ingredient in the said product?*

The answers of the CJEU in the MEDEVA and GEORGETOWN decisions of November 24, 2001should apply here, as they applied the "protection "test and not the "infringement" test for determining what is covered by the term "product" in the basic patent.

NOVARTIS v ACTAVIS case C- 442/11 (still pending)

This decision of the Court of Justice does not solve the question pending before the Court of Justice on the interpretation of Articles 4 and 5 of the Regulation on the SPC under N°C-442/11.

"Where a supplementary protection certificate has been granted for a product as defined by Regulation (EC) No 469/2009 for an active ingredient, are the rights conferred by that certificate pursuant to Article 5 of the Regulation in respect of the subject matter as defined in Article 4 of the Regulation infringed:

- *by a medicinal product that contains that active ingredient (in this case valsartan) in combination with one or more other active ingredients (in this case hydrochlorothiazide); or*

- *only by a medicinal product that contains that active ingredient (in this case valsartan) as the sole active ingredient?"*

If in the light of the above referred decisions the "protection test" applies in order to define the product covered by the basic patent which might be protected by an SPC, the logical consequence should be to apply the "infringement" test to determine the scope of SPC.

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