

Advocate General's opinion concerning the EU harmonised test for granting an extension of the term of a patent for medicinal products

The Advocate General has delivered her advisory opinion on questions referred to the European Court of Justice seeking clarification on the conditions for obtaining supplementary protection certificates (“SPCs”) for medicinal products marketed in EU Member States. The references are from the following UK proceedings: *Medeva BV v Comptroller-General of Patents, Designs and Trade Marks* (case C-322-10) and *Georgetown University, University of Rochester, Loyola University of Chicago v Comptroller-General of Patents, Designs and Trade Marks* (Case C-422/10).

The questions referred to the ECJ consider the conditions for the grant of an SPC set out under Articles 3(a) and 3(b) of Council Regulation (EC) No. 469/2009 concerning the supplementary protection certificate for medicinal products (the “**SPC Regulation**”). The key question on which EU harmonisation is sought, is whether Articles 3(a) and 3(b) allow the grant of an SPC for medicinal products comprising active ingredients that are only partially disclosed or claimed in the patent whose term is effectively sought to be extended through the SPC framework.

The reference also asked the ECJ to consider the conditions governing the grant of an SPC for a multi-disease vaccine comprising multiple antigens, including where only one antigen is protected by the patent of interest. The questions relating to vaccines stem from a background where vaccine manufacturers are effectively required by government policy to aim towards large combinations of vaccines wherever possible. The concern by relevant vaccine manufacturers is that, on the application of the narrow test that has been applied to date in the UK to determine whether relevant conditions for the grant of an SPC have been satisfied, no SPC can ever be granted for multi-disease vaccines even though such vaccines require costly investment before marketing authorisation for these vaccines is obtained.

The Advocate General's opinion in effect dismisses the broader “infringement test” argued by the vaccine manufacturer claimant in the underlying *Medeva* proceedings. Her approach regarding whether relevant conditions for the grant of an SPC have been met supports the narrow test that has been applied to date in the UK. In addition to the specific concerns raised by vaccine manufacturers, it has been argued more generally, that the application of such a test is less favourable to an SPC applicant whose medicinal products comprise active ingredients that are only partially disclosed or claimed in the patent whose term is sought to be extended through the SPC framework. The opinion of the Advocate General is advisory only and the ECJ will not necessarily follow the Advocate General's opinion. The ECJ will now deliberate and deliver its ruling, which may take several weeks. The ECJ's ruling will clearly be of great importance to both drug companies facing much publicised patent expiries for blockbuster drugs, and their competitors keen to enter the market.

For further information on the SPC framework and the Advocate General's opinion, please see below.

The SPC system

The SPC Regulation establishes for the EU a system for effectively extending the patent term of a national patent or European patent for medicinal products through the grant of SPCs. The system recognises that a patentee loses significant periods of its 20 year patent term due to the time it takes to obtain marketing authorisation for a new medicinal product and an extension is justified in the interests of facilitating effective patent protection sufficient to cover the investment made in developing such product.

The SPC Regulation provides that SPCs are to be granted for a product protected under patent law and an SPC confers the same rights as conferred by the “basic patent” protecting the product. The duration of the protection granted by an SPC is such that the holder of both such a basic patent and an SPC is entitled to an overall maximum of 15 years of protection from the time the medicinal product in question first obtains authorisation to be placed on the market in the EU. An SPC, however, cannot be granted for a period exceeding 5 years from the date on which the SPC takes effect¹. This 5 year period can be extended for a further period of 6 months where a medicinal product has been tested for paediatric use².

Articles 3(a) and 3(b) of the SPC Regulation

Article 3 of the SPC Regulation sets out the conditions for obtaining an SPC and the reference to the ECJ concerns two of these conditions, namely the conditions set out in Articles 3(a) and 3(b) of the SPC Regulation. Under these conditions, an SPC can only be granted if in the Member State in which the SPC application is made and at the date of the SPC application:

- the product for which the SPC is sought (the “**SPC Product**”) is protected by a “basic patent” in force (Article 3(a)); and
- a valid authorisation to place the SPC Product on the market as a medicinal product has been granted (Article 3(b)).

Determining whether an SPC application satisfies these conditions requires identifying the following: (i) the SPC Product; (ii) the basic patent as required by Article 3(a); and (iii) the medicinal product covered by the valid authorisation as required by Article 3(b).

The questions referred to the ECJ and the Advocate General’s opinion

Question 1 - What is meant in Article 3(a) of the SPC Regulation by “the product is protected by a basic patent in force” and what are the criteria for deciding this?

This question arises where there is mismatch between the SPC Product and the nominated “basic patent”. In particular, where the SPC Product contains active ingredients not described or claimed in the nominated basic patent, can such a patent be the basic patent for the purposes of Article 3(a) and enjoy the benefit of patent term extension offered by the SPC system? By way of example, the particular mismatch that has arisen in the Medeva proceedings is as follows:

- The basic patent that Medeva relies on discloses a method for preparing a vaccine by mixing an antigen referred to as pertactin with another antigen, the filamentous haemagglutinin antigen. In general terms, antigens mimic the disease-causing agent of interest and induce the immune response critical to the mechanism by which vaccines improve immunity.
- Medeva is seeking SPCs to cover vaccine products aimed at the following 5 diseases: diphtheria, tetanus, pertussis, polio and haemophilus influenza type B (a cause of meningitis).
- In certain of the SPC applications made by Medeva, the relevant SPC Product contains active substances in addition to those described in the subject matter of the Medeva patent. For example, one such SPC Product (SPC1 09/015) is a vaccine that contains the following additional antigens: diphtheria toxoid, tetanus toxoid, pertussis toxoid, inactivated poliovirus type 1, inactivated poliovirus type 2, inactivated poliovirus type 3, haemophilus influenza type b capsular polysaccharide, pertussis fimbrial agglutinogens 2 and 3, and haemophilus influenza type B polyribosylribitol phosphate.

The general issue, as has been considered in the UK, is whether the words “protected by a basic patent in force” in Article 3(a) mean that (i) the SPC Product is disclosed and claimed by the basic patent or (ii) the manufacture or supply of the product would infringe the basic patent ((ii) is known as the “**Infringement Test**”). Of these tests, the Infringement Test is more favourable to an SPC applicant whose basic patent covers only part of the underlying active ingredients of the SPC Product because such a basic patent, by virtue of claiming only part of the active ingredients (or in the case of a vaccine, only part of the antigens), could prevent the sale of a product that uses a combination of active ingredients (or a vaccine that includes other antigens), even though not the subject-matter of the basic patent.

¹ Articles 13(1) and 13(2) of the SPC Regulation

² Article 36 of Regulation (EC) No. 1901/2006

The Advocate General's opinion dismisses the application of the Infringement Test. She partly arrives at this view on the basis of her interpretation of the terms "product" and "basic patent" as defined in the SPC Regulation. The SPC Regulation provides that SPCs are granted for a product protected under patent law. A product is defined as "the" active ingredient or combination of active ingredients of a medicinal product. The Advocate General considers this definition to encompass the whole active or effective part of the medicinal product and, in the case of a medicinal product with multiple active ingredients, the combination of all the active ingredients constitute the "product" and for the grant of an SPC, a product must form the subject matter of a "basic patent".

Although not phrasing the distinction between the 2 tests in the same way as described above, the Advocate General considers that the correct test should be to establish which active ingredients are protected by a patent under national law (i.e. asking the question what is the subject matter of the patent) and not which forms of commercial activity the patent proprietor can prohibit third parties from engaging in (i.e. asking the question what is the protective effect of the patent). The question of whether a medicinal product forms the subject matter of a national or European patent must be answered on the basis of the national rules governing that patent.

Questions 2 and 3 - Should a different test be applied in cases where the product is a medicinal product comprising multiple active ingredients or where the product is a multi-disease vaccine?

The Advocate General's opinion is that there are no further or different criteria in the case of a medicinal product comprising more than one active ingredient or, where the product is a multi-disease vaccine, for the purposes of Article 3(a).

Questions 4 and 5 - 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"? 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"?

The Advocate General's opinion is that these questions must be answered according to the rules governing the basic patent. However, the protective effect of the basic patent must not be used as a criterion for the purposes of answering the question of whether a product within the meaning of Article 3(a) exists.

Question 6 - Does the SPC Regulation and, in particular, Article 3(b), permit the grant of an SPC 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 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 which is the first marketing authorisation that places the single active ingredient or combination of active ingredients on the market?*

This question stems from the scenario where the marketing authorisation sought to be relied on for the purposes of Article 3(b) is for a medicinal product that contains active ingredients in addition to the single active ingredient or combination of active ingredients comprising the SPC Product, resulting in a mismatch between the SPC Product and the medicinal product covered by the nominated marketing authorisation. The Advocate General's opinion is that a valid authorisation for the SPC Product exists for the purposes of Article 3(b) where the active ingredient or combination of active ingredients comprising the SPC Product is contained together with one or more other active ingredients in a medicinal product which was the subject of a valid marketing authorisation.

For a complete copy of the opinion, [click here](#).

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