

CASE COMMENTS

SUPPLEMENTARY PROTECTION CERTIFICATES: THE CJEU ISSUES ITS DECISION IN TWO SEMINAL CASES

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On 24 November 2011, the Court of Justice of the European Union issued decisions in two cases that will have important and far-reaching consequences for the application of the law relating to Supplementary Protection Certificates ('SPCs').

Some aspects of the decisions will have an immediate impact on the strategies of both innovator and generic companies in the pharmaceutical and agrochemical industries. However, other aspects of the decisions may require further judicial confirmation and/or interpretation before their commercial relevance becomes clear.

Background

SPCs are highly valuable IP rights that provide additional protection, beyond patent expiry, for newly authorised human or animal medicaments, and plant protection products.

SPCs are national rights, and must be applied for on a territory-by-territory basis. However, because the law governing SPCs is European legislation, it is supposed to be applied in a harmonised manner. That is, the provisions of the law should be interpreted consistently across all territories of the European Union (EU).

The first SPC law, Regulation (EEC) No 1768/92, came into force on 2 January 1993 and governed SPCs for the active ingredients present in human or animal medicaments. This has subsequently been codified as Regulation (EC) No 469/2009. Plant protection products may also be the subject of SPCs under Regulation (EC) No 1610/96. Subsequent to its introduction, the law has been subject to numerous judicial interpretations (including 15 separate clarifications of the law from the Court of Justice of the EU). Nevertheless, this has not prevented certain fundamental aspects of the law being afforded widely different interpretations in different EU territories.

In common with its predecessor, Regulation (EC) No 469/2009 focuses upon a 'product'. The definition of a 'product' makes it clear that supplementary protection is awarded to an active ingredient (or a combination of active ingredients), and not to a finished medicinal product (which may contain ingredients, such as excipients, that do not have a pharmacological effect on their own).

Article 3 of Regulation (EC) No 469/2009 sets out the primary conditions that must be met for an SPC for a human or animal medicament to be granted. These conditions are as follows, and must all be met in each territory where an SPC is sought.

- (a) The product in question must be protected by a basic patent in force in the territory.
- (b) There must be a valid authorisation in the territory (granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC) to place the product on the market as a medicinal product.
- (c) The product must not have already been the subject of a certificate in the territory.
- (d) The authorisation referred to in (b) must be the first authorisation to place the product on the market as a medicinal product in the territory.

The scope of protection afforded by an SPC is defined in Article 4 of Regulation (EC) No. 469/2009. The precise wording used in that Regulation is:

Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate.

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Surprisingly, and despite almost 18 years of the law being in force and the numerous clarifications of the law provided by the Court of Justice, the patent offices and courts of different EU territories have diverged in their interpretations of Article 3(a), Article 3(b) and Article 4. These differences have emerged particularly in connection with the handling of SPC applications relating to combination products and vaccines (that is, medicinal products that contain multiple active ingredients).

The specific points of divergence in practice in connection with combination products and vaccines related to:

- (1) the criteria that should be used to determine whether a product is protected by a basic patent (Article 3(a));
- (2) the definition of the product that is acceptable in the light of the multiple active ingredients present in the medicinal product (Article 3(b)); and
- (3) the scope of protection afforded to an SPC directed towards a single active ingredient (Article 4).

In the light of divergent practices (and a general lack of clarity), the UK courts have, in six recent cases, sought clarification on these points from the Court of Justice of the EU.¹

New Development

On 24 November 2011, the Court of Justice of the EU issued its decisions in respect of questions referred to it in the two earliest cases: C-322/10, *Medeva BV*, and C-422/10, *Georgetown University, University of Rochester and Loyola University*. Although these two cases only referred questions connected with points (1) and (2) above, the Court of Justice chose to comment upon all of points (1) to (3).

Since these seminal decisions, three further cases have been decided by way of reasoned orders, namely *Yeda* (C-518/10), *University of Queensland* (C-630/10) and *Daiichi* (C-6/11).

The essence of these decisions of the Court of Justice is as follows.

(A) For an SPC to be granted, the active ingredients representing the product must be specified (or identified) in the wording of the claims of the basic patent.

(B) The 'product' can be defined as a single active ingredient (or as a sub-combination of active ingredients) even when the medicinal product includes further active ingredients.

(C) An SPC provides the same protection as the basic patent against an unauthorised use of the product in the form of any medicinal product that contains that product (meaning that an SPC to 'product' A would be infringed, for example, by sale of a medicinal product containing active ingredients A + B).²

Commentary

With the possible exception of point (C) above, the decisions of the Court of Justice are binding upon all national patent offices and courts. Although, as discussed below, the decisions do not completely eliminate the possibility of diverging interpretations on some points of law, they will nevertheless have immediate and far-reaching consequences in connection with the supplementary protection afforded in general and, in particular, to combination products and vaccines.

In particular, the decisions pave the way for useful supplementary protection to be granted in situations where a basic patent protects at least one (but not all) of the active ingredients present in a medicinal product that is the first authorised medicament to contain those patented active(s).

Further, whilst the scope of some granted SPCs to single active ingredients appears to have now been confirmed as being appropriately broad (see point (C) above), the validity of other granted SPCs (especially those in which the 'product' is defined as comprising multiple active ingredients) will now be subject to great scrutiny. This could result in a flurry of challenges to the validity of certain SPCs (e.g. those for combination products) and/or to earlier than expected launches of generic versions of combination products that are the subject of such SPCs.

Point (A)

In connection with point (A) above, the decisions of the Court of Justice effectively clarify that, for SPCs, it is *not* appropriate to assess the 'protection' afforded by a basic patent by using the kind of infringement test that would usually be employed in patent enforcement/validity proceedings.

1) References from the UK courts have been made in the following cases: C-322/10 (*Medeva*, relating to vaccines); C-422/10 (*Georgetown University, University of Rochester and Loyola University*, relating to vaccines); C-518/10 (*Yeda Research and Development Company Ltd, Aventis Holdings Inc.*, relating to a medicinal product for use in a combination treatment); C-630/10 (*University of Queensland, CSL Ltd*, relating to vaccines); C-6/11 (*Daiichi*

Sankyo Co. Ltd, relating to a combination product); and C-442/11 (*Novartis AG v Actavis UK Ltd*, relating to a combination product).

2) As discussed below, this issue did not form part of the questions referred, and so, formally, the Court of Justice has not (yet) given a binding ruling on this point.

However, there remains some uncertainty with regard to the criterion that the Court of Justice has indicated should be used instead. That is, it is not yet entirely clear what degree of ‘specification’ of each active is required. Various different interpretations may, therefore, be applied by the national patent offices and courts on this point.

Patent offices and courts may choose to adopt a broad interpretation, requiring merely a positive recitation of claim features that read on each active ingredient mentioned in the definition of the ‘product’ for the SPC application in question. This could perhaps accord with the approach adopted in the *Gilead Sciences, Inc.* Case at the UK High Court.³

In the *Gilead* Case, claim 27 of the basic patent⁴ related to a pharmaceutical formulation comprising, as essential active ingredient, a compound that could be tenofovir disoproxil. The UK Patents Court found that the recitation in claim 27 of ‘optionally other therapeutic ingredients’ meant that the patent ‘protected’ the combination of tenofovir disoproxil and a structurally unrelated active ingredient (emtricitabine).

However, it seems more likely to us that patent offices and courts may adopt a narrower interpretation, requiring either unambiguous individualisation of each active ingredient, or at least something more specific than just ‘therapeutic ingredient(s)’.

In the light of the uncertainties remaining, it is possible that one or more further references to the Court of Justice will be required in order to determine the level of specificity in the wording of the claims that is required for a patent to protect a ‘product’.

Points (B) and (C)

Although points (B) and (C) are probably the clearest aspects of the court’s decisions, they are also the most unexpected.

Prior to the arguments advanced in the *Georgetown et al.* case, it was very uncertain whether an active ingredient authorised for the first time in a combination product or vaccine could be the subject of its own SPC. Indeed, a literal interpretation of the legislation could lead to the conclusion that it is not permissible to define a product as anything other than the precise (combination of) active ingredient(s) present in the authorised medicinal product.

However, as is usual for EU legislation, the court interpreted the law by determining the original purpose behind the SPC legislation (that is, it applied a teleological interpretation).⁵ As a result, the court held that the original aims and objectives of the legislation would only be met if it were permissible to define a product as one or more (but not necessarily all) of the active ingredients present in an authorised medicinal product.

Going hand-in-hand with this conclusion was the court’s observation that an SPC provides a patent-like right, and therefore allows its owner to prevent the marketing by others of any medicaments containing the product defined in the SPC (even if other active ingredients are also present in those medicaments).

It was not necessarily expected that the court would comment on this point. This is because it was not at issue in either of Cases C-322/10 and C-422/10, and is in fact the subject of a separate reference to the court (Case C-442/11). Indeed, the existence of a separate, pending case on this point means that, in theory, the court’s comments on point (C) above are not (yet) binding on any national patent offices or courts. However, it is difficult to see how the Court of Justice can reach a different conclusion in Case C-442/11 without creating irreconcilable differences from the court’s reasoning for providing its decision on point (B) above.

Assuming that the court’s comments are confirmed in Case C-442/11, points (B) and (C) together should pave the way for innovators to gain appropriately broad and useful supplementary protection for their active ingredients (whether those actives are authorised for the first time in combination with other actives, or as a monotherapy). The court has noted that this is required to ensure that the fundamental objective of the Regulation, which is to ensure sufficient protection to encourage pharmaceutical research and play a decisive role in the continuing improvement in public health, is not undermined.⁶

How Many SPCs per Patent?

A curious aspect of the decisions in the *Medeva* and *Georgetown et al.* Cases is that the Court of Justice decided to state the following:

*where a patent protects a product, in accordance with Article 3(c) of Regulation No 469/2009, only one certificate may be granted for that basic patent.*⁷

3) [2008] EWHC 1902 (Pat).

4) EP 0 915 894 B1.

5) See, for example, Case C-482/07 (*AHP Manufacturing BV v Bureau voor de Industriële Eigendom*), where a teleological interpretation was used to arrive at a result contrary to a literal reading of the legislation.

6) Paragraph 34 in C-322/10 and paragraph 28 in C-422/10.

7) Paragraph 41 of the decision in C-322/10 and paragraph 34 of the decision in C-422/10.

Taken solely in the context of final decisions of the Court of Justice, this statement could be viewed as merely reiterating what the court has previously ruled in the case of *Biogen Inc. v SmithKline Beecham Biologicals SA*.⁸ In that case, the following was stated:

*Under Article 3(c) of the Regulation, only one certificate may be granted for each basic patent.*⁹

This statement in the *Biogen* decision had been widely interpreted by national patent offices and courts as meaning that only one SPC *per product* may be granted for each basic patent. This may well be because Article 3(c) only prevents multiple SPCs being awarded in respect of a single product.¹⁰ Indeed, it would seem that the wording of Article 3(c), at least if interpreted literally, does *not* prevent multiple SPCs being granted in respect of patents that protect multiple products.

Thus, the court's comments on this point could easily be interpreted as merely confirming the established law (in a manner that should not have any impact on the previously established practices of national patent offices and courts).

Nevertheless, it is not entirely clear whether the court's observations on this point in the *Medeva* and *Georgetown et al.* decisions are intended to alter the status quo. This point will no doubt be the subject of further judicial interpretation in the near future.

Practical Consequences of the Decisions

Short to Medium Term

The decisions will be most straightforward to implement in connection with the points where there is no room for doubt. Thus, likely consequences in the short to medium term will include the following.

- National courts will invalidate SPCs to combination products that have been granted on the basis of the 'infringement test' but where the active ingredient(s) are not specified in the wording of the claims of the basic patent.
- More SPC applications will be filed in which the product is defined as one or more (but not all) of the active ingredients present in the authorised medicinal product.

- Subject to confirmation in Case C-442/11 of the Court of Justice's comments on point (C) above, national courts will enforce SPCs to single active ingredients against the manufacturers of generic versions of combination products containing a protected active.

- Generic manufacturers will delay launch of combination products until SPCs to the individual actives have expired (or have been invalidated).

Further, although it is a point of view that may not be shared by all practitioners, the authors believe that the decisions may not lead to any changes in established practices with regard to the numbers of SPCs granted for basic patents that protect more than one product.

The Longer Term

The greatest area of uncertainty relates to the degree of 'specification' of each active in the wording of the claims that will be required to meet the test set by the court for determining whether a patent protects a product.

As mentioned above, it is possible that one or more further references to the Court of Justice will be required to resolve the uncertainty (in connection with specific factual scenarios). Nevertheless, the authors believe that two observations on the current decisions provide hints as to how the Court of Justice may ultimately rule on the level of specificity required.

Firstly, assuming that the court confirms point (C) above in Case C-442/11, the decisions allow for the owner of an SPC to a single active agent to prevent, during the lifetime of the SPC, the launch of *any* medicinal products containing that active agent.

Secondly, the *Medeva* decision points to a recital in related SPC legislation¹¹ that allows for 'derivatives (salts and esters)' of active ingredients to be defined as the product in an SPC application (as a different product from the active ingredient *per se*), but only if the derivatives are 'the subject of patents specifically covering them'.

Thirdly, in paragraph 33 of the *Yeda* case (C-518/10), it appears that the Court of Justice may have implicitly accepted that the definition "*a monoclonal antibody which inhibits the growth of human tumor cells by said antibody binding to the*

8) Case C-181/95.

9) Paragraph 28 of Case C-181/95.

10) Article 3(c) is actually interpreted more permissively than the literal wording, as multiple SPCs can be obtained for a single product when those SPCs are based upon separate patents held by different legal entities

(see Case C-482/07, *AHP Manufacturing BV v Bureau voor de Industriële Eigendom*).

11) Recital (14) of Regulation (EC) No. 1610/96 (the Regulation creating SPCs for plant protection products).

extra-cellular domain of the human EGF receptors of said tumor cells in an antigen-antibody complex, said tumor cells being characterized by their expression of human EGF receptors and mitogenic stimulation by human EGF" (which appears in Claim 1 of the patent) sufficiently "identifies" (or "specifies") the active ingredient Erbitux™ (the antibody in the authorised medicine).

Taking these observations together, it may be that two separate points can be inferred. The first point is that the active ingredient(s) may be sufficiently "specified" (or "identified") in the claims of the basic patent without being named explicitly as individual compounds. The second point is that it seems that the Court of Justice may have intended to allow a product to be defined as multiple active ingredients only in the circumstances where that combination of ingredients represents an innovation that is distinct from each of the active ingredients on its own. In the instances where the true innovation lies in only one of the active ingredients, SPC protection can be applied for (and obtained) on the basis of that single ingredient. This approach is summarised in the table below.

Innovation	Permissible product definition	Scope of SPC
A	A	Authorised uses of medicaments (or plant protection products) containing A ¹²
A + B	A + B	Authorised uses of medicaments (or plant protection products) containing A + B ¹²

Thus, if there are different patents relating to A and A + B (that is, patents having different filing dates), this could be seen as

an indication that A + B represents a different innovation to A, deserving of its own (separate) SPC protection.

However, it is of course also possible for the same patent to contain claims to both A and A + B. Thus, it will be interesting in future to see how the patent offices and courts handle cases in which both of A and A + B could be argued to be 'specified in the wording of the claims' of a single patent.

Summary

The *Medeva* and *Georgetown et al.* decisions represent the dawn of a new era in the law relating to SPCs. The impact of the decisions will be felt immediately in relation to the definitions of 'product' that will be permissible (in connection with Article 3(a) and Article 3(b)). Although this means that some granted SPCs may now be of questionable validity, a much wider range of options has been opened up for innovators whose active ingredients are authorised for the first time in combination with other actives.

Further, it is expected that it will soon be formally confirmed that the scope of an SPC encompasses (within the scope of the basic patent) any authorised medical or veterinary uses of medicaments whose active ingredient(s) include those defined in respect of the product of the SPC.

Finally, further judicial interpretation is likely to be required to clarify precisely what is meant by 'specified in the wording of the claims', as well as whether it really is the case that multiple SPCs can continue to be granted in respect of patents that protect more than one product.

Putting aside the issues where there is a need for further clarification, the *Medeva* and *Georgetown et al.* decisions should be welcomed by the pharmaceutical and agrochemical industries as representing a carefully balanced approach that rewards genuine innovation with an appropriate degree of protection.

12) Within the scope of the basic patent.