Dehns

Patent and Trade Mark Attorneys

# Guidance on the interpretation of the Supplementary Protection Certificates Regulation

Supplementary Protection Certificates (SPCs) are a form of patent term extension, as explained in our basic briefing note.

The wording of the Supplementary Protection Certificate (SPC) Regulations, which governs SPCs in all EU and EEA member states, is deceptively simple. Essentially, it sets out that: *A medicinal or plant protection product must be protected by a basic patent in force and be subject to a valid marketing authorization (MA) in the country of interest; the product may not already have been the subject of a certificate, and the MA for the product must be the first to place the product onto the market.*

However, in practice, the SPC Regulation has proven to be highly unclear, which has prompted a steady flux of referrals to the Court of Justice of the EU. Some of the key guidance that can be derived from these judgments is summarized below.

## A product 'protected' by a patent

The CJEU has indicated that a determination as to whether a product is protected by a patent must be made under national law. Nevertheless, several CJEU decisions are relevant to this assessment.

Perhaps the simplest and most intuitive requirement is that the product must fall within the scope of the claims. For example, if a patent claims active ingredients A and B in combination, but not individually, a product which only comprises A as the active ingredient would not fall within the scope of this patent. Such a patent could therefore not support an SPC for active ingredient A alone.(1)

However, whilst is necessary that the product falls within at least one claim of the basic patent, this alone is not sufficient. Thus, it is not appropriate to use a simple 'infringement' test. Instead, several decisions have indicated that the product must be 'identified' or 'specified' in the claims.

In particular, the grant of an SPC for a combination of active ingredients is precluded unless both active ingredients are identified/specified in the claims. For example, where a patent claim is directed to compound A, a product comprising the combination of A and B would fall within the scope of the patent, but only by virtue of the presence of compound A. The patent could therefore not serve as the basic patent for an SPC for the combination product.(2, 3)

A currently unresolved question is whether an SPC for a combination product may be based on a patent that

at grant did not include any claims that specified the relevant combination of active ingredients, but that was amended post-grant to include such a claim. This question went unanswered in one referral[10], but may well resurface again.

A generic or functional definition that embraces the product is permissible, provided that the claims relate 'implicitly but necessarily and specifically' to the active ingredient in question.[4] It remains unclear precisely what is required to meet this proviso, so a recent referral once more asked the CJEU to answer the question

"What are the criteria for deciding whether 'the product is protected by a basic patent in force' in Article 3(a) of the SPC Regulation?"

The referring judge suggested that the product must embody the 'inventive advance' of the basic patent.[9] If the CJEU were to follow this suggestion, then this may well have significant implications for SPCs for combination products. In a scenario where the inventive advance of the patent is a single active ingredient, even a claim that explicitly specifies a combination of that active ingredient with a further specific active ingredient may not be sufficient to support an SPC application for a combination product.

## A Marketing Authorisation (MA) to place the product on the market as a medicinal product

The MA must be for a product that includes the relevant active ingredient. Thus, provided that the MA is for a product that includes active ingredient A, it can serve as the basis for an SPC for active ingredient A, even if the MA is for a combination of A with active ingredient B and/or C.[2, 3] This may be contrasted with the fact that a patent that only claims a combination of active ingredients cannot serve as the basis for an SPC for a single active ingredient.

The MA must be the earliest relevant MA to place the drug on the market within the EEA. Typically, this will be the first MA to place the drug on the market. However, certain exceptions apply. For example, where a drug is authorised under a first MA for certain uses, and a new therapeutic indication is developed for that drug, a subsequent MA may be obtained in relation to the new indication and this subsequent MA may serve as the basis for an SPC, although certain provisos apply.[5]

Delays in the granting of MAs mean that it is not always possible to obtain an MA before the relevant patent expires. In such a situation, it does not seem possible to obtain a SPC. However, this issue has been referred to the CJEU, so a final answer is expected in due course.[6]

It is currently possible to base an SPC application on the MA of a third party. However, this does not seem to tally with the objectives of the SPC regulation, so it would not be surprising if this position were to change in the future.

## Scope of SPCs

Article 4 of the SPC Regulation provides that an SPC "shall only extend to the product covered by the authorisation" and Recital 9 of the SPC Regulation confirms that the protection granted should be "strictly confined" to the authorised product.

Thus, an SPC does not extend the life of the patent on which it is based. It confers the same rights as the patent only insofar as the patent relates to the specific product which is the subject of the relevant marketing authorisation.

For example, a patent may claim a broad class of molecules, whereas the scope of the SPC may be limited to the member of that class which is the subject of the relevant marketing authorisation.

However, some uncertainty exists as to the scope of an SPC regarding derivatives/variants of the product defined in the marketing authorisation. For chemical compounds, it has been established that salts and esters of the active ingredient specified in the marketing authorisation can be covered by an SPC (provided that they fall within the scope of the patent claims).[7]

It remains unclear to what extent variants of a biological active ingredient are covered by an SPC, as little guidance has been issued by the CJEU. There are, however, a few decisions by national courts and the EFTA court suggest that the scope of SPCs pertaining to biological active ingredients is fairly limited.

In this regard, in a case concerning antibodies, a Dutch court reasoned that the regulatory requirements regarding biological medicinal products suggest that two similar biological products cannot be assumed to have the same therapeutic value and that, therefore, they are not the same product under the SPC Regulation. Consequently, the court held that the scope of an SPC should be limited to the specific product identified in the MA.[11] This decision was essentially confirmed by a Norwegian appeal court dealing with a case concerning virus-based vaccines.

The scope of an SPC is, of course, important in determining the issue of infringement. However, a recent opinion by the EFTA court suggests that the scope

of an SPC is also critical with regard to its validity. The EFTA court opined that an SPC "is invalid to the extent it is granted a wider scope than that set out in the relevant marketing authorisation".[8] It remains to be seen whether such an SPC would only be invalid insofar as its scope extends beyond the scope of the MA, i.e. be partially invalid; or whether such an SPC would be wholly invalid. It is also as yet unclear whether such an invalidity would be fatal, or whether it could be remedied.

Our website is regularly updated with further developments.

References


1 C-518/10 (Yeda)
2 C-322/10 (Medeva)
3 C422/10 (Georgetown University)
4 C-493/12 (Eli Lilly)
5 C-130-11 (Neurim)
6 C-567/16 (Merck)
7 C-392-97 (Farmitalia)
8 E-16/14 (Pharmaq v Intervet).
9 [2017] EWHC 13 (Teva v Gilead)
10 Case C-577/13 (Actavis)
11 2000809060/1/H3 (Yeda)


## Further advice

The Dehns Pharmaceutical and Life Sciences teams have significant expertise in obtaining and advising on SPCs. Please contact using the details below.


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