EIP

SPCs: When does a patent protect a product?

The law governing supplementary protection certificates (SPCs) is in theory harmonised within the EU. However, different interpretations have arisen with the result that there are presently nine cases pending before the Court of Justice of the European Union ("CJEU"). However, with regard to one of the most vexing issues, namely when, for the purposes of SPCs, does a patent protect a product, it seems there may continue to be some uncertainty.

A supplementary protection certificate (SPC) is a form of patent term extension, which can extend aspects of a patent's monopoly for up to five years. It is awarded to compensate the owners of patents for medicinal or plant protection products for the period of patent protection which is effectively lost due to the owners being unable to market their product whilst that product undergoes regulatory approval.

Consequently, in order to obtain an SPC, the relevant regulatory authority must have granted a market authorisation for the product and there must also be a granted patent which protects that product. The product in this sense means solely the active ingredient(s) of the authorised product. However, the question of when a patent can be deemed to "protect" the active ingredient(s) has given rise to a great deal of uncertainty within the EU. The national courts of some EU Member States have taken the view that if the unauthorised use of the active ingredient(s) would infringe the patent, then the patent protects those ingredients ("the infringement test"). Most Member States, however, have rejected this test in favour of a stricter requirement that requires the patent, or indeed the claims of the patent, to specifically cite the active ingredient(s). This can be problematic where, for example, the product is a combination product with multiple active ingredients, as it may well be the case that a patent covers only one of the active ingredients in the combination. In these circumstances, and if the stricter test is adopted,

the product (e.g. a multi-disease vaccine) will infringe the patent but not the SPC (i.e. not the patent once extended).

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This issue has been referred to the CJEU in the joined cases of C-322/10 Medeva BV v Comptroller-General of Patents, Designs and Trade Marks and C-422/10 Georgetown University, University of Rochester and Loyola University of Chicago v Comptroller-General of Patents, Designs and Trade Marks. Although the court has yet to rule on this, the Advocate General ("AG") has now issued her opinion; the CJEU tends to follow the AG's opinion in about 80% of cases, and so this is a good guide as to what the court may decide.

In the AG's opinion, the infringement test should not be used. For a patent to be eligible for patent term extension, the active ingredient(s) should form the subject matter of the patent, according to the rules governing the basic patents (i.e. the national laws of the Member States). Consequently, if the product comprises multiple active ingredients, those multiple actives should "form the subject matter of the basic patents". What this will mean may, and probably will, vary between Member States, but will mean that the combination of actives must have been envisaged in some way in the patent.

However, the AG also ruled that where a marketing authorisation has been granted for a particular combination of active ingredients, it is legitimate when applying for an SPC for a patent covering only one of those actives to then define the product for the purposes of the SPC as only that active which the patent covers. Consequently, the AG has sought to provide a way for patentees to obtain patent term extensions for multi-active products when the patentees only have a patent relating to one of those actives.

Assuming this decision is followed by the CJEU, it will provide a means for new applicants for SPCs to apply their patents for single or a sub-set of active ingredients to products comprising multiple active ingredients. However, this will not help existing applicants whose SPC applications did not define the product in a way which the AG has approved of but which was previously thought to have been potentially unacceptable. It may be possible for these existing applications to be amended, but this will depend upon the approaches taken by the various national patent offices, again giving the potential for disharmony between the EU Member States. There may well be further uncertainty when trying to decide whether a product forms the subject matter of the patent, although there are four more cases pending before the CJEU which may yet add more clarity to this issue.