JENKINS

• Patent issues

*Jenkins Information Sheet/02/13*

# SUPPLEMENTARY PROTECTION CERTIFICATES


**To compensate for the short effective patent life of pharmaceuticals, the EU Council put into place regulations providing for Supplementary Protection Certificates (SPC) for Medicinal Products. According to these regulations, where a medicinal product is first authorized to be put on the market more than 5 years after the date of the patent application for the product, an SPC can be granted that extends the protection conferred by the basic patent for up to 5 years beyond the normal term of the patent. The patent protection is extended only in respect of the product covered by the marketing authorization.**

## LEGISTATIVE FRAMEWORK

Regulation (EEC) No. 1768/92 creating Supplementary Protection Certificates for medicinal products entered into force on 2 January 1993 and was amended by Regulation (EC) No. 1901/2006 to extend the SPC duration for medicinal drugs for paediatric use. Subsequent amendments were consolidated in Regulation (EC) No. 469/2009.

Regulation (EC) No. 1610/96 creating similar certificates for Plant Protection Products entered into force on 8th February 1997.

## CONDITIONS FOR OBTAINING A CERTIFICATE

According to Article 3 of Council Regulation (EEC) No. 1768/92, a certificate shall be granted if, in the Member State in which the application is submitted and at the date of that application:

1. the product is protected by a basic patent in force;
2. a valid authorization to place the product on the market [as a medicinal product] has been granted in accordance with Directive 65/65/EEC or Directive 81/851/ EEC, as appropriate;
3. the product has not already been the subject of a certificate;
4. the authorization referred to in b) is the first authorization to place the product on the market as a medicinal product."

## THE "PRODUCT"

The "product", for which the SPC is sought, is defined as the "active ingredient or combination of active ingredients of a medicinal product". The term "active ingredients" is generally interpreted to include any closely related derivatives (e.g. salt or ester), unless the derivative can be regarded as a new active ingredient.

A certificate concerns products and cannot cover manufacturing processes or uses. The current position is that, if a product is used to treat different conditions, separate marketing authorisations may be required, but the certificate will only cover the product for any authorised use within the limits of the patent.

However, increasingly pharmaceutical research involves new formulations of old active substances and the European Patent Convention expressly recognises the patentability of "second and further medical uses" of known substances and the health and economic importance of such uses. Thus, in 2012, the Court of Justice of the European Union (CJEU) issued a preliminary opinion to the effect that, if a marketing authorisation was previously granted for a first use (e.g. veterinary use), then a SPC based on a later authorisation for a new use (e.g. for human use) should not be refused, provided that the first use was not covered by the patent.

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## THE PATENT

It is important to clarify that the certificate does not extend the term of a patent. Instead, it extends the protection conferred by the patent beyond the term of the patent only with respect to the product covered by the marketing authorisation, i.e. a certificate only covers a single product. However, different products may be the subjects of different certificates, even if they are protected by the same patent.

A certificate cannot be granted which covers active ingredients which are not specified in the claims. This also means, if a patent claims a product composed of two active ingredients, then a SPC cannot be granted for one active ingredient in isolation.

Also, the CJEU recently indicated that, if the patent protects one active ingredient but the marketing authorisation is directed to a combination of active ingredients (e.g. a combinations of vaccines), then a certificate can be granted for the active ingredient covered by the patent, even if it co-exists with other active ingredients in the marketing authorisation.

## THE MARKETING AUTHORISATION

In the UK, the marketing authorisation must be the first authorisation to place the product on the market in the UK, although there may have been an earlier authorisation elsewhere in the EU.

The authorisation must have been granted at the time of filing the application for a certificate but there appears to be no requirement that the authorisation should be in force (i.e. it may be withdrawn or have lapsed) before the date of application for the certificate.

## DURATION OF THE CERTIFICATE

The certificate takes affect at the end of the lawful term of the patent. The term of the certificate is equal to the period that elapsed between the filing date of the patent and the date of the first authorisation in the Community reduced by five years.

The term of the certificate cannot exceed five years, although when paediatric studies were carried out, an additional six months can be granted. It is interesting to note that, the term of a certificate may be equal to zero or negative. This is relevant where the six month paediatric extension is sought, as one of the conditions is that there must be a granted SPC, regardless of its term.

## APPLYING FOR A CERTIFICATE

In the UK, the application for the certificate must be filed at the UK IPO within six months of the date on which the first marketing authorisation was granted or, if the authorisation was granted before the patent, the period of six months runs from the date of grant of the patent. The six month paediatric extension must be filed no later than six month before the expiry of the certificate.

## SUPPLEMENTARY PROTECTION CERTIFICATES PATENT ATTORNEYS

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