

THE UKIPO GRANTS THE FIRST “NEGATIVE TERM” SUPPLEMENTARY PROTECTION CERTIFICATE

On 14 April 2008, the UK Intellectual Property Office reached a decision that has important consequences for the duration of protection available to certain medicinal products.

Supplementary Protection Certificates

SPCs provide additional protection, beyond patent expiry, for products (medicinal or for plant protection) that require a marketing authorisation.

Extension of SPC Duration

Until a law change in early 2007, the duration of an SPC could be represented by the following, simple formula.

{(Date of 1st relevant Marketing Authorisation) - (Patent Filing Date)} - 5,
to a maximum of 5 years.

Thus, under the old law:

- (i) the maximum duration of an SPC was 5 years; and
- (ii) there was no benefit in applying for an SPC if less than 5 years had elapsed between the date of patent filing and the date of the relevant Marketing Authorisation (as the resulting SPC would have a nominally negative term).

Since the change of law, the term of an SPC can be extended by 6 months. For products not previously authorised, the 6-month extension of SPC term is available if the results of a Paediatric Investigation Plan (PIP) are included in an application for Marketing Authorisation for that product.

More details relating to the 6-month extension to SPC term can be found in our Newsletter no. 119, entitled “*Extensions to supplementary protection certificates from conducting paediatric trials*” and dated 16 February 2007.

In an article entitled “*Making the Most of Paediatric SPC Extensions*”, published on 7 July 2007 in *RAJ Pharma*, Mike Snodin and John Miles of this firm argued that the 6-month extension of SPC term should enable applications for SPCs to be granted even if less than 5 years has elapsed between the date of patent filing and the date of the relevant Marketing Authorisation. Two possible ways of calculating the resulting SPC term (with 6-month extension) were put forward in that article, with one (“Model C”) providing a more generous term than the other (“Model A”).

Both Newsletter 119 and the above-mentioned journal article may be viewed from the “IP updates” section of our website.

UKIPO Decision

Following an application filed by Merck & Co. Inc., the UKIPO was asked to grant an application for an SPC that, without the 6-month extension, would have a “negative” term (i.e. it would nominally expire *before* it took effect at the end of the term of the patent upon which it was based).

On the basis that a 6-month extension would, if granted, provide the SPC with a positive term of about 2.5 months, the UKIPO granted Merck’s application for an SPC. At present, the SPC is set to expire *before* the patent upon which it is based.

The manner in which the UKIPO has calculated the SPC term is in accordance with the less generous model ("Model A") put forward in the above-mentioned journal article. It is not yet clear whether Merck & Co. will appeal the decision upon the basis of arguments that the more generous model ("Model C") should be applied, thereby providing additional SPC term of about 3.5 months (to give the maximum 6-month "paediatric extension").

Action Point

Please contact us for advice if you have a medicinal product for which:

- (a) a Marketing Authorisation could be (or has been) issued in Europe before 5 years has expired from the date of filing of a patent protecting the product; and
- (b) the results from clinical trials in the paediatric population have been (or will be) submitted to one or more regulatory bodies in Europe.

If conditions (a) and (b) above are both met, then you could be entitled to more Supplementary Protection than you think.

If you require any further information about SPCs, please contact Mike Snodin or John Miles at our Nottingham office.

The information in this Newsletter was correct at the date of release. More up to date information is available by contacting Potter Clarkson LLP. All comments contained here are of a general nature and full professional advice should be sought on any specific problem. Please note that all our Newsletters can be found on our website at www.potterclarkson.com.

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