

SUPPLEMENTARY PROTECTION CERTIFICATES AND EUROPEAN UNION ENLARGEMENT

Action may be necessary well before the end of October 2004 in order to maximise protection for medicinal or plant protection products.

The EU has a Supplementary Protection Certificate (SPC) system for patentees of medicinal or plant protection products where a long period has been required to obtain authorisation for placing the product on the market. The certificate applies to a specific authorised product which is protected by a relevant patent. The maximum protection afforded in combination with the patent is 15 years from the authorisation date. The certificate itself can have a maximum life of five years.

A similar system already operates in some of the countries (accession countries) that join the European Union on 1 May 2004. Others are introducing such a system following accession. Action within six months of the accession date (ie by the end of October 2004) may be necessary in order to secure maximum protection in the accession countries and hence in the European Union as a whole.

Possible Action

If you have (i) patent cover and (ii) authorisation to market the product in any of the accession countries (Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia or Slovenia) for a medicinal or plant protection product, you should consider the possibility of extending the period of protection under the new regulations. Several accession countries have transitional provisions under which it may be possible to file SPC applications for products which already have a marketing authorisation, but this only applies until the end of October 2004. Accordingly, urgent action may be required.

If you require further information, please contact Stephanie Pilkington 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 Eric Potter Clarkson. All comments contained here are of a general nature and full professional advice should be sought on any specific problem.

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