

SUPPLEMENTARY PROTECTION CERTIFICATES IN ROMANIA AND BULGARIA

Romania and Bulgaria are set to join the European Union (EU) on 1 January 2007. Their accession will mean that Supplementary Protection Certificates for human and veterinary medicinal products, as well as for plant protection products, will become available in those countries under EU legislation.

Supplementary Protection Certificates

Supplementary Protection Certificates (SPCs) provide additional protection, for up to 5 years beyond patent expiry, for a product (medicinal or plant protection) that requires a marketing authorisation.

Transitional Provisions for Bulgaria and Romania

From 1 January 2007, it will be possible to apply for an SPC in Romania and Bulgaria for a product if, at the date of application:

- (a) the product is protected by a basic patent in force;
- (b) a valid authorization to place the product on the market as a medicinal/plant protection product has been granted (in accordance with relevant legislation);
- (c) the product has not already been the subject of an SPC; and
- (d) the authorization referred to in (b) is the first authorization to place the product on the market (within the country in question).

The normal deadline for making such an application is 6 months from the date of the authorisation in (or valid in) the country in question.

However, if:

- (1) the normal deadline expires before 1 January 2007; *and*
- (2) the first authorisation to place the product on the market in a member state of the European Economic Area (EEA) was granted after 1 January 2000,

then the deadline for making the SPC application in Bulgaria or Romania will be extended to 30 June 2007.

Action Point

If, in either of Bulgaria or Romania, you have both patent cover and a marketing authorisation for a medicinal product (human or veterinary) or a plant protection product, you should consider applying for Supplementary Protection for the product. Urgent action may be required, as the deadline for making such an application could be as early as mid-2007.

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

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Park View House · 58 The Ropewalk · Nottingham · NG1 5DD · UK
Tel: +44 (0)115 955 2211 Fax: +44 (0)115 955 2201
E-mail: epc@eric-potter.com Website: www.eric-potter.com