

## **NO SUPPLEMENTARY PROTECTION IS AVAILABLE FOR NEW INDICATIONS OF PREVIOUSLY AUTHORISED ACTIVE INGREDIENTS**

On 17 April 2007, the European Court of Justice (ECJ) delivered a decision relating to Supplementary Protection Certificates (SPCs).

### ***What is an SPC?***

A Supplementary Protection Certificate (SPC) provides additional protection, for up to five years beyond patent expiry, for a medicinal, veterinary or plant protection products for which a marketing authorisation has been granted.

### ***Availability of an SPC***

EC Regulation No. 1768/92 stipulates that supplementary protection may be awarded for a “product” which is defined as “an active ingredient or combination of active ingredients”. An SPC is available only when the marketing authorisation relied upon is the first authorisation for the product within the European Economic Area (EEA).

### ***The Decision of the ECJ***

Following the referral of questions from the UK Patents Court, arising from appeals handled by our firm, the ECJ considered what is meant by “product” in a case in which the relevant patent protects a second medical application (use) of a therapeutic agent that is the subject of a marketing authorization for a different indication (use). In particular, does the application (use) of the therapeutic agent play any part in the definition of the “product”? This was in the context of a medicinal product, Silkis<sup>®</sup> ointment, which comprises the vitamin D analogue calcitriol, in an ointment form for topical application. Silkis<sup>®</sup> ointment is intended for the treatment of psoriasis, whereas previously authorised formulations of calcitriol were in the form of solutions for injection or capsules for ingestion, for treatment of post-menopausal osteoporosis or management of hypocalcaemia in patients with chronic renal failure.

The ECJ decided that the concept of “product” does not include the therapeutic use. In a case where the relevant patent protects a second medical use of an active ingredient, that use does not form an integral part of the definition of the product.

The ECJ’s decision (which cannot be appealed) means that it will now not be possible to obtain an SPC for a product that represents a “second medical use” of a sole, previously authorised active ingredient. This reinforces the ECJ’s narrow interpretation of the term “product” in an earlier case (C-431/04; see the Newsletters section of our website ([www.eric-potter.com](http://www.eric-potter.com))) that an SPC cannot be obtained for a “reformulation” (for the same clinical indication) of a sole, previously authorised active ingredient.

The decision can be viewed at the ECJ web site (<http://curia.eu.int/jurisp/cgi-bin/form.pl?lang=en> ) or we should be pleased to e-mail it to you in Microsoft Word format on request to our information officer, Karen Pegg ([kpegg@eric-potter.com](mailto:kpegg@eric-potter.com)).

If you require any further information, please contact Dr Stephanie Pilkington, Dr John Miles or Dr Mike Snodin 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.

Please note that all our Newsletters can be found on our website at [www.eric-potter.com](http://www.eric-potter.com).

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