

**NO SUPPLEMENTARY PROTECTION IS AVAILABLE FOR
REFORMULATIONS (FOR THE SAME INDICATION) OF KNOWN ACTIVE
AGENTS (ECJ DECISION C-431/04)**

On 4 May 2006, 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 5 years beyond patent expiry, for a medicinal product.

Availability of an SPC

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

Where an active ingredient has previously been authorised on its own, a further SPC in respect of a medicinal product containing that active ingredient is usually available only if the product comprises a “combination of active ingredients”.

The Decision of the ECJ

The ECJ considered the question of whether the term “combination of active ingredients” encompasses a mixture of two substances, one of which is a known substance with pharmacological properties of its own and the other makes it possible to increase significantly the therapeutic effects of the first substance. The precise question related to the medicinal product Gliadel[®], which comprises the anti-cancer agent carmustine embedded in a prolifeprosan matrix.

Overtaking a prior opinion of the Advocate General, the ECJ decided that the expression “active ingredient” must be interpreted in the strict sense, i.e. as a substance having pharmacological activity on its own. Thus, there can be no “combination of active ingredients” in products such as Gliadel[®] (in which only one, prior authorised, ingredient is “active”).

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 “reformulation” (for the same clinical indication) of a sole, previously authorised active ingredient.

A question that was not addressed by the ECJ in this decision was whether a different conclusion could be reached if the “reformulated” product is for a new indication. This is an issue that will be considered by the ECJ in an upcoming case (Yissum Research and Development Company, relating to the active ingredient calcitriol) that Eric Potter Clarkson is handling. We anticipate that a decision in this case will be issued within the next 18 months.

A more detailed discussion of this decision may be found in the Newsletters section of our website (www.eric-potter.com).

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).

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.

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