

## **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. This additional protection is intended to compensate for delays arising from the need to obtain a Marketing Authorisation for that product. An SPC is a national right and separate applications must be made in each European territory.

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

Articles 2 and 3 of EC Regulation No. 1768/92 are the main provisions governing the availability of SPCs. These Articles stipulate the following.

The product must have been subject to a prescribed regulatory review procedure and, on the date of application for an SPC in the territory concerned:

- (a) the product must be protected by a basic patent in force;
- (b) a valid authorization to place the product on the market as a medicinal product must have been granted;
- (c) the product must not have already been the subject of an SPC; and
- (d) the authorization referred to in (b) must be the first authorization to place the product on the market as a medicinal product.

### ***“Product”***

The availability of an SPC is critically dependent upon what the “product” is, as only one SPC will be granted in respect of a single “product”. (There are some minor exceptions to this rule, but these are outside of the scope of this newsletter.)

The term “product” is defined as being:

*“the active ingredient or combination of active ingredients of a medicinal product”.*

This wording means that an SPC will be available not only for a product containing a new active ingredient, but also for combination products containing mixtures of “old” (i.e. previously authorised) active ingredients, provided that the other conditions for availability of an SPC are fulfilled (including a new authorisation for the combination product and a patent protecting that product). Indeed, a number of SPCs have been granted throughout Europe for combination products comprising two previously authorised active ingredients.

## ***Background to the Case***

Massachusetts Institute of Technology (“MIT”) were the applicant for an SPC in Germany. MIT had developed a new biodegradable matrix, prolifeprosan, and were the owner of a patent to that matrix. The patent claimed combinations of prolifeprosan with a biologically active substance.

The medicinal product Gliadel<sup>®</sup> comprises the anti-cancer agent carmustine embedded in a prolifeprosan matrix. Carmustine is an anti-cancer agent that, since 1979, has been authorised within the European Union for use as a medicinal product. However, the slow release of carmustine from the product Gliadel<sup>®</sup> enables a more effective treatment of the target indication (malignant brain tumors) than that which is possible with the previously authorised forms of carmustine.

MIT’s application for an SPC was refused by the German Patent and Trademark Office (Deutsches Patent- und Markenamt). A subsequent appeal to the German Federal Patent Court (Bundespatentgericht) was also refused. Both decisions were reached on the grounds that prolifeprosan could not be considered to be an “active ingredient” within the meaning of Article 1(b) of Regulation No. 1768/92.

MIT then appealed to the German Federal Court of Justice (Bundesgerichtshof). In support of the appeal, MIT argued that prolifeprosan and carmustine together represent a “combination of active ingredients”, on the ground that, in the product Gliadel<sup>®</sup>, prolifeprosan contributes to the efficacy of carmustine (and is hence not a mere excipient). MIT also pointed to the grant of corresponding SPCs in the UK (on an application prosecuted by Eric Potter Clarkson) and France. On hearing the arguments, the Bundesgerichtshof made a referral to the ECJ.

## ***Questions Referred to the ECJ***

Two questions were referred to the ECJ by the Bundesgerichtshof, which Advocate General Léger summarised in the following, single question.

*“Is there a ‘combination of active ingredients of a medicinal product’ within the meaning of Article 1(b) of Council Regulation (EEC) No. 1768/92 ... in the case of a medicinal combination 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 Decision of the ECJ***

The ECJ’s decision was preceded by an opinion from Advocate General Léger. His opinion was that, considering the overall purpose of the SPC legislation, the answer to the above question should be “yes”, irrespective of the problems of interpretation that this may cause national patent offices.

The decision now issued by the ECJ (which decision cannot be appealed) reaches entirely the opposite conclusion to that of the Advocate General, holding that the expression “active

ingredient” does not include substances *‘forming part of a medicinal product which do not have an effect of their own on the human or animal body’*.”

In other words, the ECJ’s decision means that the term “active ingredient” must now be interpreted in the strict sense. This rules out any possibility for obtaining an SPC for a product that represents a “reformulation” (for the same clinical indication) of a sole, previously authorised active ingredient.

Although reaching a conclusion entirely contrary to that of the Advocate General the ECJ decision at no point criticises the Advocate General’s reasoning. Instead, the ECJ based their decision upon only a few selected passages from the legislation and explanatory memoranda thereto. Interestingly, these passages include some from EC Regulation No. 1610/96 (relating to SPCs for plant protection products), which passages have now, by way of the decision, effectively been confirmed as modifying the law relating to SPCs for medicinal products.

There are many passages in the legislation and explanatory memoranda that the ECJ could have relied upon to reach a different conclusion. The decision of the court to ignore these passages appears to be arbitrary. However, point 28 of the decision may offer an insight into the reasons for this, where it is stated that:

*“it is apparently not unusual for substances which render possible a certain pharmaceutical form of the medicinal product to influence the therapeutic efficacy of the active ingredient contained in it”.*

This might imply that the ECJ were wary of opening the floodgates to SPCs for “trivial” reformulations of known active ingredients. In our view, the ECJ’s decision leaves open few options other than legislative reform if the fruits of extensive research into (and clinical trials upon) reformulations of known active ingredients are to be rewarded with supplementary protection.

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.

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)).

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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