

## **THE DATE OF A SWISS MARKETING AUTHORISATION CAN DETERMINE THE DURATION OF A SUPPLEMENTARY PROTECTION CERTIFICATE (SPC)**

On 21 April 2005, the European Court of Justice (ECJ) delivered a decision which means that, although Switzerland is not part of the European Union (EU) or European Economic Area (EEA), Swiss marketing authorisations can determine the duration of SPCs in those territories.

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

An SPC extends the period of protection for a patented medicinal product as a way of compensating for delays in commercialising the product arising from the need to obtain a marketing authorisation. An SPC is a national right and separate applications must be made in each European territory. However, the duration of each SPC is calculated on a European Community basis.

### ***Article 13 - Duration of an SPC***

The duration of an SPC (calculated in accordance with Article 13 of the SPC (Medicinal Products) Regulation 1768/92) is equal to the period between:

- (a) the date of filing of the application for the patent upon which the SPC is based; and
- (b) the date of the first authorisation to place the product on the market in the Community, *minus 5 years*,

but the term is capped at a *maximum of 5 years*.

### ***“The Community” and “Duality” of Liechtenstein***

According to the EEA agreement, “the Community” in Article 13 is to be read as including all contracting parties to the agreement. Liechtenstein is a contracting party, but Switzerland is not. However, through its regional agreement with Switzerland, Liechtenstein automatically recognises Swiss marketing authorisations.

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

The question then arose as to whether the fact that Swiss authorisations are valid in Liechtenstein means that they represent a marketing authorisation in “the Community” (thereby making them relevant to the determination of the term of all SPCs in the EU and EEA). Since some patent offices have thought that the answer was “yes” and others “no”, the ECJ was also asked whether a competent authority within the EEA is obliged to correct the term of any SPC whose duration has been erroneously calculated.

***The ECJ Decision (combined case numbers C-207/03 and C-252/03).***

The ECJ ruled that the answer to the first question was “yes”. This decision was reached on a plain reading of the SPC Regulation and the EEA agreement. The ECJ indicated that this decision is in conformity with one of the purposes of the SPC Regulation, which is to provide the holder of the certificate a maximum of 15 years of exclusivity from the time the medicinal product concerned first obtains authorisation to be placed on the market in the EEA.

The ECJ did not see the need to answer the second question, since the court asking it (the UK High Court) was dealing with cases where the SPC duration had been correctly calculated. Also, where the SPC term had been incorrectly calculated (in Luxembourg), the court concerned did not pose the question. Therefore, it is still uncertain whether an SPC that has incorrectly been awarded a term that is too long will automatically have its duration curtailed.

***Practical Consequences***

This decision will have the effect of substantially reducing the market exclusivity in Europe for many medicinal products. For example, the Novartis and Millennium products to which the ECJ decision relates would have had between 6 and 28 months of additional SPC term if the ECJ had decided differently.

Of course, products that have not yet received any marketing authorisations are not affected by this decision. However, for such products, there is now a careful balance that needs to be struck regarding when an application for marketing authorisation is made in Switzerland.

In response to the ECJ’s decision, Switzerland and Liechtenstein have already made moves to reduce the need to delay applications for marketing authorisation in Switzerland. That is, it has been agreed that, as of 1 June 2005, Swiss marketing authorisations will only become valid in Liechtenstein 12 months after issuance.

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)).

Our firm has considerable experience of SPC applications. If you need further information, please contact Dr Mike Snodin.

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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