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Scope of SPCs may be extended

Supplementary protection certificates (SPCs) are provided under Regulation 1768/92/EEC and extend the lifetime of patents covering medicines by a maximum of five years. In particular they provide compensation for the effectively reduced lifetime of such patents caused by the lengthy marketing approval procedures which have to be followed before new medicines can be launched on the market.

If the filing requirements of SPCs as they are laid down in Article 3 of the Regulation were to be taken literally, SPCs could only be granted for novel and first-to-the market drugs, but not for novel applications of known drugs, be it in the form of a novel formulation or indication. This literal interpretation, however, seems to contradict the objectives of Regulation 1768/92/EEC whose ultimate purpose is to improve public health in general by encouraging pharmaceutical innovations that are the result of long and costly research (recitals 1 and 2 of the Regulation), irrespective of whether this research is directed to novel compounds, methods or applications. Drawing a distinction between formulations/indications and compounds seems particularly unjustified, given that full clinical testing is usually required in all cases in order to obtain marketing approval.

These specific legal issues were addressed by two recent referrals to the European Court of Justice (ECJ), one by the German Supreme Court (C-431/04) and the other by the UK High Court (C-202/05) which we recently reported on (June and October 2005 editions). On November 24, Advocate General Léger delivered his Opinion with respect to the German referral that relates to the allowability of SPCs for formulations that are a novel combination of a known drug and a specific excipient.

In his Opinion, the Advocate

General emphasizes that the objective of the Regulation is to encourage research, not only into novel drugs as such, but also into novel applications for known drugs by developing auxiliary substances which improve the pharmacological effect of the drug.

While the Advocate General clearly states that an SPC should not be granted if the characteristics of a known medicine are only slightly changed, he concludes that, when a major innovation is at stake, for example if a known drug attains entirely new properties in terms of efficacy and safety when combined with specific excipients, an SPC should be allowable. In such cases, the term “combination of active ingredients” according to Article 1 (b) of the Regulation should be construed beyond its literal meaning to encompass combinations of a pharmacologically active ingredient and an excipient as well.

SPCs for formulation patents may thus soon become a reality if applicants can demonstrate significant therapeutic advantages for the novel combination of drug and excipients. In view of the cost to potential benefit ratio, innovative companies must seriously consider filing SPCs for formulation patents.

If the ECJ follows the Advocate General’s line of argument, it may also be that SPCs for novel indications will soon form an additional asset in the IP portfolio of proprietary drug manufacturers.