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SPCs for novel indications

We recently reported on a referral to the European Court of Justice, which may bring about the possibility for getting supplementary protection certificates (SPCs) for formulation patents (*MIP*, June 2005). This month we report on another referral to the ECJ, the outcome of which could also have a significant economic impact.

According to Regulation 1768/92/EEC, SPCs are granted for novel pharmaceutical products and effectively prolong the lifetime of patents covering corresponding medicines.

Article 3 of the Regulation stipulates that an SPC shall be granted if (1) the product is protected by a basic patent, (2) has obtained marketing authorization, (3) has not already been the subject of an SPC or (4) of an earlier authorization. According to Article 1(b) the product is defined as “the active ingredient” or “combination of active ingredients”.

The Regulation appears to preclude SPCs for a second medical indication, which is defined as a “novel” use of a “known” drug. The reason is that a typical second medical indication patent covers not the corresponding drug as such, but rather its novel medical use. In many cases, the drug has also already been marketed for another medical use. Thus, a request for an SPC on the basis of a second medical indication patent, at first glance, seems to violate Articles 3(a) and (d) of the Regulation.

However, according to recitals 2, 3, 8 and 9, the Regulation should provide leverage for the reduced effective lifetime of patents for medicinal products because of the long mandatory marketing authorization procedures. In the Commission’s Explanatory Memorandum on its proposal for the Regulation, paragraphs 12 and 29 explicitly state that the proposal should not be confined to new products only,

but also to new applications of known products.

This legally unsatisfactory situation may soon be clarified as the UK High Court has recently referred to the ECJ the question whether the product according to Article 1(b) may be defined with respect to its use.

In this particular case, the corresponding basic patent EP 0 129 003 B2 protects the use of a known drug for treating certain skin disorders. However, an earlier marketing authorization had been granted for treating renal failure and osteoporosis with the same drug.

The ECJ’s decision may thus open the door to SPCs on novel medical indications by removing the obstacles set by Article 3(a) and (d). The economic importance of this decision will not escape the reader’s notice.