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SPCs for medical devices?

A new reference to the CJEU may make it easier to get SPCs for certain medical devices

A new question (C-527/17) has been referred to the CJEU by the German Federal Patent Court on the availability of SPCs for medical devices, in this case a combined medical device and medicinal product that has been authorised under the Medical Devices Directive (93/42/EEC).

Traditionally, it has been difficult (though not impossible) to obtain an SPC for a medical device authorised under the Medical Devices Directive, as we reported previously. One challenge for such SPC applications is Article 2 of the SPC Regulation, which requires the product to be "subject…to an administrative authorisation procedure as laid down in Directive 2001/83/EC…" (a requirement reiterated by Article 3(b)), whereas many medical devices are authorised under different legislation.

A combined medical device and medicinal product may be authorised under either the Medicinal Products Directive (2001/83/EC, mentioned in the SPC Regulation) or the Medical Devices Directive. However, if authorised under the Medical Devices Directive, the quality, safety and usefulness of the medicinal product in the device must still be verified by analogy with the methods specified in Annex I to the Medicinal Products Directive. Therefore, some medical devices authorised under the Medical Devices Directive have been through a process that is in some ways analogous to the Medicinal Products Directive.

Some national offices have interpreted Articles 2 and 3(b) of the SPC Regulation as strictly precluding an SPC for products that have not been authorised under the Medicinal Products Directive, even where the quality, safety and usefulness of a medicinal product component has been verified by analogy with the Medicinal Products Directive (e.g. the UK IPO decision in Cerus Corporation BL O/141/14). However, other national offices or courts have, on occasion, allowed an SPC in similar situations, for example Therasphere®, which was granted an SPC by the German Federal Patent Court in 14 W (pat) 12/07.

The new referral asks whether an authorisation under the Medical Devices Directive for a device containing a medicinal product can be used for an SPC where the quality, safety and usefulness of the medicinal product component has been verified in accordance with the Medicinal Products Directive. The full question appears below, but in essence the CJEU is being asked whether a wide range of medical devices might qualify for SPC protection, where the active ingredient has been suitably authorised. A positive answer could significantly change the period of exclusivity available for a range of medical devices in Europe.

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“Must Article 2 of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products be interpreted as meaning that, for the purposes of that regulation, an authorisation under Directive 93/42/EEC for a combined medical device and medicinal product within the meaning of Article 1(4) of Directive 93/42/EEC is to be treated as a valid marketing authorisation under Directive 2001/83/EC, where, as part of the authorisation procedure laid down in Annex I, Section 7.4, first paragraph, to Directive 93/42/EEC, the quality, safety and usefulness of the medicinal product component has been verified by the medicinal products authority of a Member State in accordance with Directive 2001/83/EC?”

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Need advice?

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