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CJEU shows red card to SPCs for medical devices in Boston Scientific (C-527/17)

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The SPC system was introduced in the European Union in 1992 to compensate for the heavy penalties imposed on pharmaceutical research due to the curtailment in effective patent term resulting from time-consuming and costly regulatory review. As expressly noted in the Explanatory Memorandum to the original SPC Regulation (COM(90) 101 final-SYN 255), the legislative intent was that the SPC system should be applicable to all pharmaceutical research without discrimination, provided that it leads to a new invention that can be patented.

Nevertheless, as set out in Article 2 of the SPC Regulation (EC) 469/2009, a product is only eligible for SPC protection if it has been approved in accordance with the Medicinal Products Directives, i.e. Directive 2001/83/EC or 2001/82/EC.

Medical devices, however, are authorized following a formal assessment by way of CE-marking procedure according to the Medical Devices Regulation (EU) 2017/745 (which recently replaced the Medical Devices Directive 93/42/EEC and the Active Implantable Medical Devices Directive 90/385/EEC), rather than the more restrictive regulatory hurdle as set out in the Medicinal Products Directives 2001/83/EC and 2001/82/EC. As such, based on a verbatim reading of the SPC Regulation, medical devices should not benefit from the SPC system.

Medical devices comprising an active ingredient as an integral part (so-called medical device/drug combinations) are nevertheless also subjected to a more stringent approval procedure by means of a consultation process, in which the national medicines authority of an EU member state or the European Medicines Agency is asked to establish the quality, safety and usefulness of the drug component of the medical device/drug combination. As a result, some patent offices have taken the position that a CE certification for a medical device/drug combination should be treated as being equivalent to a marketing authorization issued in accordance with the Medicinal Products Directives 2001/83/EC and 2001/82/EC, whereas others have ruled that SPC protection is not justified for CE-certified devices.

To resolve this legal uncertainty, the issue was referred to the CJEU by the German Federal Patent Court. In the case at hand, Boston Scientific applied for an SPC for paclitaxel on the basis of the CE certification for a paclitaxel-eluting stent, relying on a

second medical use patent directed towards the anti-proliferative drug paclitaxel for the prevention of restenosis.

The CJEU in its decision *Boston Scientific* (C-527/17) of 25 October 2018 ruled that Article 2 of the SPC Regulation must be interpreted to the effect that a CE-mark approval for a medical device comprising an active ingredient as an integral part cannot be equated to an approval in accordance with the Medicinal Products Directives, even if the active ingredient has been analogously assessed by way of the consultation process.

In reaching this conclusion, the Court emphasized that if an active ingredient contained in a medical device only mediates its effect ancillary to that of the device, the predominant effect of which does not correspond to that of a medicinal product within the meaning of the Medicinal Products Directives, then the effect of this active ingredient cannot be categorized independently from the device. Although the quality, safety and usefulness of the active ingredient must be assessed in analogy to the requirements as set out in the Medicinal Products Directives, this assessment is only carried out in conjunction with the functional specification of the medical device.

While the CJEU was concerned with a specific type of medical device/drug combination in the case at hand, its reasoning and conclusions should likewise apply to all other types of medical devices. Under the current SPC regime, it is therefore not possible to obtain SPC protection for active ingredients on the basis of a CE approval of a medical device/drug combination.

Although the outcome of this CJEU ruling may be disappointing in that it effectively endorses discrimination to pharmaceutical research resulting in a final product where the therapeutic effect of the active ingredient is only ancillary to the overall effect of the product, the ruling does not come as a surprise and, at the very least, it does provide the much-needed legal certainty in this regard.

***Dr. Alexa von Uexküll** and **Oswin Ridderbusch**, both partners at the IP-specialized law firm Vossius & Partner, are the editors of the new handbook "European SPCs Unravelled: A Practitioner's Guide to Supplementary Protection Certificates in Europe" published by Wolters Kluwer.*

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