GERMANY

SPCs for medical devices

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While SPCs can be granted for medicinal products in accordance with Regulation (EC) No 469/2009, it has been questioned whether medical *devices* that are also subject to a lengthy product approval process similar to medicinal products could be eligible for SPC protection in the absence of an explicit Regulation in this respect. In the past, the German Federal Patent Court (*Bundespatentgericht* or BPatG) adopted a relatively liberal approach in deciding that SPCs for an implantable medical device comprising a pharmaceutically active substance are allowable (14 W (pat) 12/07). A recent case may signal that the German Federal Patent Court may apply a stricter approach in the future.

The 14th Senate of the BPatG held in decision 14 W (pat) 45/12 that SPCs cannot be granted for medical devices under the Regulation and the corresponding case law of the CJEU. The Leibniz-Institut für Neue Materialien gGmbH filed an SPC application for aminosilane-coated iron oxide nanoparticles, which are directly introduced into a tumour and then heated by the application of an external magnetic field. This treatment results in the destruction or in the sensitisation of the tumour cells for further treatment. The application was based on an EC design-examination certificate in accordance with Directive 93/42/EEC on Medical Devices.

According to Article 1(b) of the Regulation, "product" means the active ingredient or combination of active ingredients of a medicinal product. Since the term "active ingredient" is not defined in the Regulation, the BPatG referred to the CJEU decision *Forsgren* (C-631/13), which held that active ingredients must have pharmacological, immunological or metabolic action of their own. The BPatG concluded that the therapeutic effect of the aminosilane-coated iron oxide particles, which are inactive on their own, is purely physical, and therefore the particles do not fall under the definition of the term "product" as defined by Article 1(b) of the Regulation, thus ruling out the application of the Regulation.

While the BPatG indicated that it favours the grant of SPCs for medical products, it made clear that it will be up to the legislator to implement corresponding legal frameworks. It remains to be seen whether the recent decision marks a new era of stricter rulings on SPCs to medical devices in Germany, or whether it only precludes the grant of SPCs for medical devices that do not have a therapeutic effect on their own.