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Extended protection for medical devices – a hot topic in the UK

Manufactures of medical devices are requesting an increasing number of patent term extensions in a bid to recover the cost of getting regulatory approval. Recent decisions show that the UK IPO is taking a strict approach when examining patent term extensions for medical devices, but there are still situations where extra protection might be available.

The Leibniz Institute for New Materials (Leibniz) requested a UK patent term extension (known as a supplementary protection certification or SPC) for its NanoTherm product that kills cancer cells by using hot iron nanoparticles, but its application was recently refused by the UK Intellectual Property Office (UK IPO).

What is a SPC?

An SPC is a patent term extension for a patented medical product that has received marketing authorisation in Europe. An SPC can extend patent protection for the product by up to five and a half years. Readers may be familiar with European SPCs for pharmaceuticals, but SPC applications have also been filed for medical devices.

SPCs are based on a patent and a marketing authorisation. There are several routes for requesting marketing authorisation for a medical product in Europe, including the Medicinal Product Directive (MPD) and a number of Medical Device Directives (MDDs). Only the MPD is mentioned in the SPC Regulation. Nonetheless, Leibniz argued that an SPC application could also be based on a MDD authorisation. If allowed, this approach would substantially increase the number of SPCs available for medical devices.

Leibniz's SPC application

Leibniz's NanoTherm device is an iron oxide nanoparticle formulation. These nanoparticles are injected directly into a tumour and then subjected to an alternating magnetic field, causing the particles to heat up and destroy the tumour cells. The iron nanoparticles have a coating to make them stick to the cancer cells and so the damage is localised to the tumour.

Despite including an injectable solution, Leibniz's NanoTherm product was authorised under a Medical Device Directive (MDD), as its principle mode of action is via physical means. It was defined as a "Class III" medical device, meaning that it constituted a high risk, so authorisation was required before sale. Having gone through this process, Leibniz requested the SPC which would compensate for regulatory costs and the patent term lost while the regulatory process was completed.

The SPC Regulation requires that the patented medical product must have received marketing authorisation "in accordance with" the MPD. The MDD is not mentioned in the SPC Regulation, so the UK IPO argued that Leibniz could not base their SPC application on a MDD authorisation.

Leibniz argued the SPC Regulation should not be read literally and instead "in accordance with" should mean any valid authorisation granted by analogy with the MPD. Leibniz noted that the MDD and MPD cross-referenced certain requirements for receiving a marketing authorisation, and suggested this meant that its authorisation granted under the MDD was "in accordance with" the MPD. Leibniz also argued that the requirements for obtaining authorisation for its NanoTherm product under the MDD were "at least as onerous" as obtaining authorisation under the MPD and so they should be granted an SPC to reward them for their hard work.

The UK IPO disagreed and held that the assessment criteria for a medical device and a medicinal product were not the same and so the authorisations

under the MDD were not "in accordance with" the MPD, even for the highly regulated "Class III" of medical devices. The officer noted that the regulatory process distinguished between MDD devices, where the principal mode of action was physical, and MPD medicinal products, which act by pharmacological, immunological or metabolic means. Therefore, he stated that even though it may be time consuming to get authorisation under either the MDD or the MPD, he saw a clear distinction between the different types of authorisations, so Leibniz did not get their SPC.

The finding in Leibniz followed the UK IPO's approach to Cerus' SPC application for their Intercept product which decontaminates blood using light-activated compounds. Cerus relied on a MDD authorisation and so the UK IPO refused its SPC application.

These decisions show that a MPD authorisation is likely to be required to apply for an SPC in the UK. In contrast, other jurisdictions such as the Netherlands and Germany have been more generous and allowed SPCs based on medical device authorisations. The UK Courts or the Court of Justice of the European Union (CJEU) could overturn the UK IPO's approach, and the CJEU's teleological approach might give more weight to the large amount of investment involved in bringing some medical devices to market.

Which devices can get an SPC?

At least at the UK IPO, it is preferable to have an authorisation under the MPD. A device can fall under the MPD where it contains a drug that assists with the function of the device via pharmacological, immunological or metabolic means. These devices may include pre-filled syringes, nebulisers pre-charged with a medicinal product or patches for transdermal drug delivery as well as devices with a coating of active ingredient, provided that the drug is not ancillary to the device's function.

In order to get an SPC, the first authorisation in Europe needs to occur at least four and a half years after the patent's filing date. This can cause problems where an earlier marketing authorisation existed for the active ingredient before a device also containing that ingredient was authorised. However, the definition of "first marketing authorisation" was liberalised in the CJEU's Neurim decision. Following Neurim, there may be further options for filing SPC applications for medical devices.

Comment

The UK IPO has been taking a strict approach to SPCs for devices and at present it seems that SPC protection may be obtained only with a MPD authorisation, but this may be challenged in the UK Courts. For devices with a MPD authorisation, recent changes in the law following the CJEU's Neurim decision open up more possibilities for filing SPCs.

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Need advice?

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