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SPCs for medical devices?

CJEU rules against an SPC for a medical device authorised under the Medical Devices Directive

An SPC application to extend patent term must be accompanied by a valid marketing authorisation. Uncertainty exists regarding what types of authorisation meet the requirements of the SPC Regulation (469/2009) for medical devices that incorporate medicinal products, so-called 'drug-device combinations'. In recent judgement C-527/17, the CJEU refused an SPC application on the basis of one type of medical device authorisation, in a move that may raise questions about whether medical device manufacturers receive sufficient patent term after authorisation to incentivise further research.

Introduction

Drug-device combinations can be authorised under the Medicinal Products Directive (2001/83/EC, 'MPD'). Such authorisations are explicitly covered by the SPC Regulation as valid marketing authorisations for the purposes of requesting an SPC.

Drug-device combinations can alternatively be authorised under the Medical Devices Directive (93/42/EEC, 'MDD'). The MDD is not explicitly mentioned in the SPC Regulation, so on a literal reading an MDD authorisation might not be the type of authorisation required by the SPC Regulation.

However, under the MDD, some drug-device combinations undergo assessment equivalent to assessment under the MPD. As previously reported, the referral behind decision C-527/17 concerns whether MDD authorisations based on an equivalent assessment to that required under the MPD are eligible for SPC protection.

Decision

The decision makes two important points that precluded grant of an SPC on the basis of an MDD authorisation in this case.

First, the CJEU stated that medicinal products and medical devices are mutually exclusive categories. Medicinal products (covered by the MPD) exhibit a principal mode of action that is immunological, metabolic or pharmacological. Medical devices (covered by the MDD) exhibit a principal mode of action that is not immunological, metabolic or pharmacological.

Drugs may exhibit immunological, metabolic or pharmacological action by themselves, and so would be considered medicinal products. However, the same drugs may be incorporated into medical devices in which the action of the drug is ancillary to the device such that the drug-device combination is not a medicinal product, as can occur when a drug-device combination is authorised under the MDD.

Therefore, the CJEU found that, based on the facts in C-527/17, the particular MDD-authorised drug-device combination did not qualify as a medicinal product within the meaning of the SPC Regulation, even though the combination comprised a drug that could be considered a medicinal product if separate from the device.

Second, the CJEU stated that even where a drug-device combination is authorised under the MDD using an assessment equivalent to that of the MPD, that assessment considers the drug as an integral part of the device, and not as a standalone medicinal product. For this reason, the Court decided that the MDD authorisation in C-527/17 did not meet the requirements of the SPC Regulation because it did not assess the medicinal product *per se*, regardless of any equivalence between the MDD and MPD assessments.

So, this is bad news for medical device manufacturers and may influence their decision making process where they are able to choose between authorisation via the MPD or MDD. In addition, it is likely to fuel questions about whether the ever-increasing regulatory burden on medical device manufacturers is eroding effective patent term due to growing regulatory delays.

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Need advice?

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