# Is it possible for a substance evaluated under the medical devices' rules to benefit from a SPC?

***Judgement of the Court of Justice of the European Union (CJEU), of 25 October 2018, in the Case C-527/17 Boston Scientific v Deutsches Patent***

When it comes to medicinal products, the 20-year period of market exclusivity granted to the patent holder is not entirety enjoyed by such holder. This is because of the time existing between the patent application for a particular molecule (moment from which the patent period starts to run) and the grant of the marketing authorization (MA) of the medicinal product incorporating such molecule. To solve this issue, the Supplementary Protection Certificate (SPC) was created. Such SPC extends the exclusivity period granted by the patent for an additional term starting from the patent expiration.

For a SPC to be obtained, certain requirements must be fulfilled. One of them is that the substance for which a SPC is requested must have previously obtained a MA as medicinal product intended for the use claimed in the basic patent that the SPC aims to extend.

## Substances in medical devices

There are substances which are an integral part of a medical device and act upon the body in a manner ancillary to such device. Thus, they have been evaluated and authorized for a particular use in accordance with the medical devices' regulations. This is what happens in this case. The substance is *paclitaxel* and its use for "inhibiting or reducing the proliferation and migration of cells in the blood vessel wall" is protected by the basic patent. Boston Scientific integrated such substance in a medical device named TAXUS® (a *paclitaxel*-coated stent) with the objective to prevent blood vessels mechanically expanded by the stent from plugging again. The substance *Paclitaxel* for such specific use, forms an integral part of the medical device TAXUS® and acts upon the body in a manner ancillary to such device. Thus, in this specific case, *Paclitaxel* was evaluated and authorized in accordance with the regulations on medical devices (and not the regulations on medicinal products). However, it is well-known that *Paclitaxel* is commonly used in the treatment of certain types of cancer and, to such effect, it has been authorized as medicinal product.

Under these circumstances, it possible for a substance evaluated and authorized for a specific use only under the regulations on medical devices, to benefit from a SCP?

## Position of the CJEU

The CJEU, in the context of a preliminary ruling from the German Federal Patents Court, has had the opportunity to position itself on this matter. Its view is clear: if a substance is evaluated and authorized for a specific use only according to the regulations on medical devices, then such substance (in respect of this specific use) cannot benefit from a SPC. The reason of the foregoing is that such substance has not been subject -as a medicinal product intended for the use claimed in the basic patent- to a formal authorization procedure under the regulations on medicinal products. This is regardless of whether the quality, safety and efficacy of the particular use of the substance has been verified by methods analog to those that would have been used if such substance was evaluated independently as a medicinal product.