

How many SPC's per patent?

The Court of Justice of the European Union (CJEU), the highest court in Europe, has been asked to definitively decide how many supplementary protection certificates (SPCs) can be obtained per patent.

It had previously been thought that multiple SPCs for single patents are allowable provided each SPC is directed to a different product. However, some doubt had been cast on this interpretation by the CJEU during its previous decision on combination product SPCs in *Georgetown et al.* proceedings (reported here).

The questions referred

When the District Court of The Hague came to interpret the CJEU decision in *Georgetown et al.*, the Court decided that it was not clear whether the CJEU intended that only one SPC per patent is possible or whether only one SPC *per product* per patent is possible.

Therefore, the Court is seeking clarification on whether it is possible to obtain multiple SPCs on a single patent where the patent protects multiple products.

The Court also asked that, if only one SPC per patent could be granted, how they should deal with the situation that several SPC applications are pending simultaneously, and one application is decided on before the other applications. In particular, they asked whether surrender of one SPC in favour of another SPC would be allowed.

Background to the referral

Georgetown has a patent protecting four active substances and holds a marketing authorisation for the combination of these substances.

Georgetown applied for an SPC for each individual active substance. The Dutch Patent Office refused the first SPC application they examined for the single active because two SPCs to two different combination products had already been granted based on the same patent. The SPC other applications are still pending, awaiting the outcome of the first application.

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Georgetown had offered to surrender its two SPCs for the combination products if it meant they would be able to obtain an SPC for the single product.

Georgetown argued that surrendering an SPC has retrospective effect and therefore, after the surrender, the two combination product SPCs should be deemed to never have been granted, so that the single product SPC becomes the only SPC granted on that patent.

The Court found that the SPC regulation provides the right to surrender but does not mention retrospective effect. Nonetheless, the Regulation is not clear on whether a surrendered certificate would or would not preclude a new SPC for the product being granted. Therefore, the Court decided to refer questions to the CJEU.

Conclusion

The CJEU decision on these matters will have a large impact on the pharmaceutical industry.

Many national Patent Offices have previously granted multiple SPCs per patent as they understood the SPC Regulation to provide for one SPC *per product* per patent. Some of those SPCs could be found invalid if the CJEU decides this interpretation is incorrect.

If the CJEU decides that only one SPC per patent is possible, patentees could circumvent this by applying simultaneously for several patents each protecting one single product, instead of protecting several products in one patent.

We await the CJEU decision with interest.