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The Court of Justice decides on SPCs for combination products

The Court of Justice of the European Union (CJEU), the highest court in Europe, has explained how to obtain Supplementary Protection Certificates (SPCs) for combination products. It does so in decisions in two similar cases, *Medeva* and *Georgetown et al*.

These decisions have far-reaching consequences for the pharmaceutical and plant protection industries.

The Decisions

In the two cases the marketing authorisation related to a product which did not have the same active ingredients as those protected by the patent. The CJEU decided that, in cases of such a mismatch, an SPC can still be directed to the patented active ingredients.

If the patent protects only A, an SPC can be directed to A, even if the marketing authorisation is for A + B. Where a marketing authorisation is for A + B + C, but the patent only protects A + B, the SPC can be for A + B, and so on.

This is good news for the vaccine industry. Many vaccines combine a number of active ingredients in an authorised product, but not all of those active ingredients are protected by a single patent. Following the CJEU decision, the manufacturer may be entitled to an SPC the patented active ingredients (if the marketing authorisation is the first for those ingredients).

However, a number of issues remain unresolved.

How to determine what is "protected by" the patent?

The CJEU decided that the product, "protected by" the patent, is specified in the claim wording, but did not explain how much detail was needed for the product to be "specified".

Previously, the UK Intellectual Property Office (UK-IPO) has granted an SPC for the product A + B where the patent claimed A, together with a carrier and, optionally, other therapeutic ingredients. The UK-IPO deemed that the claims covered A + B even though B was not explicitly recited.

It is questionable whether the UK-IPO would now grant such an SPC, in particular whether it would deem B to be "specified" in that claim. Whether a claim to A in combination with an antibody (where B is a known antibody) would be considered to protect A + B is similarly uncertain.

The CJEU did give some guidance, however. It stated that, if a patent claims a product having two active ingredients, but does not claim an active ingredient individually, an SPC cannot cover that ingredient alone.

How to determine what is the "product" of the marketing authorisation?

The CJEU decided that an SPC can be directed to the patented product when the product of the marketing authorisation contains not only the claimed active ingredients, but also other active ingredients.

If the marketing authorisation relates to a combination of more active ingredients (A + B + C) than claimed in the patent (A + B), an SPC can cover the claimed product, i.e. A + B.

The CJEU qualified this with the crucial point that such a marketing authorisation must represent the first authorisation of any product containing the claimed combination of active ingredients. So the marketing authorisation must be the first to cover A + B alone or with other active ingredients.

Other issues

How do you determine infringement of an SPC?

The CJEU also reviewed infringement of SPCs.

The Court decided that an SPC for a single active ingredient can be infringed by a combination drug containing the ingredient. This will have an impact on another pending referral in *Novartis vs Actavis/Teva*, which we previously reported here (Kirsty to add link).

How many SPCs per patent?

Before the CJEU delivers its decision, the Advocate General (AG) is asked to deliver a non-binding opinion.

The AG argued that only one SPC could be granted for any one patent. This opinion was based on a previous CJEU decision. This was a shock to those in the field, who had interpreted the decision to restrict SPCs to only one SPC ***per product***, per patent. For many years national authorities have allowed multiple SPCs for single patents, based on this interpretation.

The CJEU did not refer to the AG's opinion, preferring merely to restate its earlier decision on the point. It is highly likely that national authorities will not change their practice in the light of the CJEU not explicitly supporting the AG's position.

Conclusions

This decision is good news for applicants who want SPCs for combination products, where there is a mismatch between the marketing authorisation and the patent claims.

A number of issues remain unresolved. There are a number of other pending referrals on combination products and the CJEU may clarify those issues in some of these referrals. We will, of course, report on any significant decisions.