

SPCs - Decisions rain down from the Court of Justice of the European Union

Between late November and mid-December, there was a flurry of activity at the CJEU (Europe's highest court), with a number of decisions being handed down that are relevant to SPCs - **a unique form of intellectual property right** that provides an additional monopoly that comes into force after expiry of a patent.

These cases have been widely followed by the Supplementary Protection Certificate (SPC) community in Europe and elsewhere, because they deal with the substantive requirements for obtaining SPCs under European law and have far-reaching implications for the pharmaceutical and plant protection industries.

The main clutch of these decisions related to combination medicines, and the requirements for a basic patent validly to protect such a product when authorised. The other decision (Merck Sharp & Dohme Corp; C-125/10) related to so-called "zero-term" SPCs and ruled that these are indeed available to SPC applicants. All these decisions have been broadly positive for the innovative pharmaceutical industry, although clearly, the decisions will not suit everyone.

The **first decision** to issue was Medeva/Georgetown (C-322/10 & C-422/10), in which the Court of Justice of the European Union (CJEU) explained how

to get an SPC for a combination drug, and confirmed that an SPC for a single active ingredient can be used to stop sales of a combination drug containing the same active ingredient.

The CJEU was faced with two difficult issues that have vexed the SPC system for years. The first issue (under Article 3(a) of the SPC regulations) is whether a patent with claims that describe only one active ingredient from a combination of active ingredients in an authorised drug can be used to obtain an SPC for that drug. This is a common scenario, particularly in the vaccine field where patents are generally filed for single classes of active ingredients (antigens) many years before combination uses are identified. The Court decided that an SPC could be granted for a combination of active ingredients only if those active ingredients were "specified in the wording of the claims". In rejecting a direct infringement test, this approach would seem consistent with the approach previously applied by several national

courts, although we envisage future difficulties in deciding whether the active ingredients in a combination drug are adequately "specified in the wording of the claims" to satisfy the test.

The **second issue** (under Article 3(b)) is whether the authorisation of a drug that contains a combination of active ingredients can be used to obtain an SPC for only one active ingredient from that combination. This issue was also decided generously for SPC applicants, allowing SPCs to be granted for single active ingredients that are authorised for use with other active ingredients. Crucially, however, an SPC for a single active ingredient (or combination of active ingredients) that is authorised for use with other active ingredients will only be allowable if the authorisation represents the first time that it has been authorised.

Lurking behind both issues was a **third issue** of wide importance to industry. This is whether an SPC for a single active

ingredient can be infringed by sales of a drug that contains this active ingredient in combination with other active ingredients. This issue was again decided generously for SPC holders, suggesting that an SPC for a single active ingredient will be infringed by sales of a combination drug that contains the same active ingredient and other active ingredients.

Despite these positive aspects to the decisions, SPC applicants will be more concerned by the possible endorsement by the Court of the “one SPC per patent” rule proposed in the Advocate General’s earlier opinion in these referrals. Many commentators felt that the Advocate General had misunderstood the CJEU’s earlier Biogen decision in reaching this opinion, in particular by failing to consider whether more than one SPC could be granted for different active ingredients covered by a single patent.

Worryingly, the CJEU does not seem to explicitly rule out the Advocate General’s interpretation, so SPC applicants will have to rely on its reference to the Biogen decision to argue that the previous practice based on this decision remains correct.

Shortly following the Medeva/Georgetown decisions, the Court issued Reasoned Orders in the remaining pending cases in which similar questions had been asked of the Court. These were [Yeda Research and Development Company \(C-518/10\)](#); [Daiichi Sankyo Company \(C-6/11\)](#); and [University Of Queensland \(C-630/10\)](#). Although there are some interesting insights in the detail of these decisions, it can broadly be stated in summary that the logic applied does not diverge from the Medeva/Georgetown cases described above.

Conclusion

There now remain three pending referrals at the CJEU on SPC matters – two relate to the *Novartis v Actavis* proceedings in the UK and Germany, and ask whether the protection conferred by a certificate

granted for a single active ingredient (in this case valsartan) extends to an embodiment that contains this single active ingredient in combination with another active ingredient (in this case valsartan + hydrochlorothiazide). Given what the Court has already said on this issue in Medeva/Georgetown, it may well be that we can expect Reasoned Orders in these cases too.

The third pending SPC case is Neurim (C-130/11) which predated the Novartis referrals and is unrelated. If Neurim is successful in persuading the Court of its position, this would significantly increase the number of patents to approved follow-on medical uses that might qualify for SPC protection.

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Need advice?

Carpmaels & Ransford has been at the forefront of SPC law and practice for many years and last year filed more national SPC applications than any other UK firm. We handled the Queensland SPC referral at the CJEU, and also represent Neurim in its pending referral. For more information, please contact; email@carpmaels.com.

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