SPC policy issues over the last year

The inclusion of proposals for a Unitary Patent Office and Unitary SPCs as part of the EU Patent Package was big news in 2023. If the proposals go ahead the new office will be part of the EUIPO and will be staffed by examiners from national patent offices.

By the time you read this article the proposals will have advanced through the complex political system that is the EU and the eventual shape of the legislation may resolve some of the issues below or generate others!

There are four proposed regulations: two adapt the current medicinal and plant protection schemes to create centralised procedures; two set up unitary rights where a Unitary Patent has been obtained. Details of the proposed changes are set out in this Review by Caitlin Heard and Claire Dorese in their article on European Commission reforms: SPCs, SEPs and compulsory licences.

Users of the SPC system welcome the opportunity to reduce the duplicative legal effort, and expense, of filing in 27 member states by filing in only one instead. The application fee will likely be significant, and well into five figures. However, this will still be less than pan-European filing and prosecution costs in each country and the prosecution costs, if there are office actions, will be minimal.

A proposal to require agreement of the marketing authorisation holder as a condition for obtaining an SPC will prevent hostile SPCs granting. This is a sensible restriction and brings EU 'patent extension' law into line with other jurisdictions where it is available.

There are some issues which are of concern. A pre-grant opposition period is proposed. Will this lead to significant delays before an enforceable SPC will be granted? An appeal instance in the EUIPO and then a further appeal to the General Court of the European Union (GCEU) suggest this may be the case. Where a Unitary SPC is obtained there may also be opportunity for a post-grant invalidation action at any time before the EUIPO. Users understandably would prefer only post-grant actions before the UPC which is designed to deal with high value SPC litigation and which is supposed to have exclusive jurisdiction over non-opted out SPCs under Art. 32 UPCA.

A ban on second SPCs where the owners are 'economically linked' seems too wide. Limiting this to applicants being part of the 'same undertaking' would be more acceptable. Unless otherwise defined the initial proposal will affect the economic balance and expectations in ongoing licence agreements and distort negotiations between licence partners going forward.

Lastly attempts to codify some CJEU cases in the Recitals appear unnecessary. Where the law is established, codification is unnecessary and runs the risk of failing to faithfully replicate how the case law in understood. Some of the attempted codifications may, instead, lead to a lack of clarity in what the law means and give rise to new litigation. Given repurposing is frequently held up as a societal good, that a Recital potentially removes the incentive of an SPC where two old active ingredients are used to make a new combination product is distinctly unhelpful.

The last amendments to the SPC Regulations introduced a manufacturing waiver for generics. The first case on these provisions issued in November in Munich between Janssen Biotech and Formycon who wished to manufacture a biosimilar for Stelara. Formycon made a notification under the waiver but refused to indicate the export market to Janssen. The court agreed that unless Janssen could evaluate whether equivalent protection existed in the export market they could not know if the waiver applied or not and were entitled to an injunction.

It has been a quiet year at the CJEU with two SPC cases pending, C-119/22 and C-149/22, both relating to SPCs owned by Merck Sharp & Dohme, relating to challenges to the validity of combination products A and B where A received an SPC from the same patent and was a new molecule, and the combination with B, an old molecule, received a subsequent marketing authorisation. A hearing for both cases took place in February 2023 and a twice-postponed Advocate General's opinion is due in April 2024. Decisions are expected by the middle of next year. It will be interesting to see how the court resolves conundrums that resulted on the interface between the newer case law on Article 3(a) in C-121/17 *Teva* v *Gilead* and C-650/17 *Royalty Pharma* cases and the older *Actavis* cases, C-443/12 and C-577/13 that focused mainly on Article 3(c).

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