Kluwer Patent Blog

Initiatives to include SPCs in the Unitary Patent system

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The lack of provisions on Supplementary Protection Certificates (SPCs) is seen as a major flaw in the new Unitary Patent (UP) system. Initiatives have been taken to address this issue and recently the European Commission put it on its action list.

Why doesn't the UP Regulation include a provision for SPCs? Anja Lunze, attorney at Taylor Wessing doesn't know. 'It is certainly a little surprising. Perhaps it is due to the rush in which the UP Regulation has been drafted', she thinks. 'To my knowledge, apart from the definition in Art. 2 (h) of the Unified Patent Court (UPC) Agreement, SPCs are only mentioned in Art. 3b, 30, 32 with regard to jurisdiction and its effects and in Art. 83 regarding opt-out; the Rules of Procedure contain some clarifications as to ownership and languages in R 2 and on opt-out in R 5.

Basically, these provisions just say that the UPC has jurisdiction also with regard to SPC litigation and that an opt-out of the classical European patents automatically also opts out the corresponding SPC (R 5.2 RoP). With regard to the latter provision, it is unclear who can declare the opt-out in the event that patent owner and SPC holder differ. Besides it is unclear with regard to classical European patents, even if not opted out, whether the corresponding SPCs can benefit from Art. 34 UPCA (territorial scope of decisions), as they are national rights and only have effect in the country in which they are granted.

Anja Lunze

Even more uncertainties exist when it comes to Unitary Patents and the question whether and how SPCs based on Unitary Patents can be obtained.'

'SPCs are of fundamental importance to the pharmaceutical industries', says Elise Melon of the European Federation of Pharmaceutical Industries and Associations (EFPIA). 'They compensate innovative companies for the loss of effective patent term up to the grant of a marketing authorisation, in recognition of the need for a sufficient period of effective exclusivity to guarantee funding for future biomedical research. Absent explicit certainty as to whether SPCs can be granted on the basis of Unitary Patents, our member companies are unlikely to enter the UP system.'

Earlier this year, the EFPIA, in a joint initiative with the European Crop Protection Association (ECPA) and the International Federation for Animal Health Europe (IFAH-Europe), published a joint position paper, supporting the concept of Unitary SPCs being granted on the basis of Unitary Patents. According to Elise Melon, this is 'the logical continuation of the Member States' decision and agreement to create a Unitary Patent in the first place and would really enhance the attractiveness of the UP system to our sectors, for which SPCs are critical'.


Elise Melon

'Of course, there are still a number of technical and legal questions to be addressed, but it is important that we start looking at how this could work in the near-future. First, we think it is important to rely on the currently existing expertise and second, that the system we set up is as "light" as possible in terms of administrative burden. Finally, it is key that it is framed within the EU court system.

We have therefore proposed that Unitary SPCs are granted by a virtual office, composed of existing SPC experts from national patent offices. This office would need to be legally set up by the EU – as an EU body, but should be able to operate flexibly and through virtual cooperation between national offices. We have suggested a few working principles, but the details of how such a body would process applications would need to be developed with national offices.'

Anja Lunze supports the idea of a Unitary SPC, but points out the EFPIA's initiative, which was presented at the October C5 Life Science Summit in Berlin, 'caused quite some discussions, in particular with regard to the possibilities of review and appeal.'

She thinks the legislative gap should be repaired either by amending the UP Regulation or the SPC Regulation. 'However, it feels more natural to be dealt within the UP Regulation as the competent authority for the grant of UP-SPCs must be determined as well.'

Elise Melon agrees the joint industry proposal needs to be refined, in particular how the system should be set up legally. 'We have been presenting it to a number of stakeholders, who so far received it pretty well, even if some good points have been raised and on which we are working now. In any case, the discussion is definitely ongoing and we are happy to discuss our proposal with all interested parties.'

In the meantime, the concerns from the industry have been picked up by the European Commission. In its strategy report 'Upgrading the Single Market', published on 28 October 2015, the EC wrote: The Unitary Patent system will play an essential role in enabling innovation (…). However, the key challenge now is to get the endgame right, including addressing uncertainties over how the Unitary Patent will work together with national patents and national supplementary protection certificates (SPC) granted under the SPC regime and the possible creation of a Unitary SPC title.'

And under the header 'actions': 'The Commission (…) will consult, consider and propose further measures, as appropriate, to improve the patent system in Europe, notably for pharmaceutical and other industries whose products are subject to regulated market authorisations.'

Both Elise Melon and Anja Lunze think this is a first step in the good direction. Lunze points out, however, that for the foreseeable future the pharmaceutical industry 'will remain rather reluctant to use the UP system because of the major uncertainties of the new court and new case law and also because of the risks of a central revocation action.

Contrary to other industries like e.g. IT and telecommunication, where a product is usually covered by several patents, so that despite of an unsuccessful litigation on one patent injunctive relief against the competitor's product could still be achieved based on other patent, the major particularity in the pharmaceutical industry is that one product sometimes is only protected by one or a few patents. For this reason, even if the patent is considered to be strong with regard to validity, the business risks associated with a litigation in an unknown new system might be considered too high by the patent owners.'

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