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SPC reform progresses to plenary vote in European Parliament

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The SPC reform which is currently undergoing the legislative procedure in the European Union has taken a further decisive step forward, as the European Parliament's Committee on Legal Affairs (JURI Committee) has approved an amended version of the draft text of the four new EU regulations on SPCs for medicinal and plant protection products as well as corresponding unitary SPCs.

Following the publication of the initial legislative proposals for these four new regulations by the European Commission on April 27, 2023 (as previously reported on this blog), the JURI Committee issued draft reports proposing a number of amendments on October 13, 2023 (as previously reported) and subsequently collected further amendments suggested by Committee members until November 2023.

Based on the numerous amendments proposed for each of the four draft regulations (more than 200 amendments in the case of the regulation on unitary SPCs for medicinal products), a set of compromise amendments was tabled on January 19, 2024 and subjected to a vote in the JURI Committee on January 24, 2024. All compromise amendments to all four draft SPC regulations were unanimously accepted (see here for video footage of the voting on the four new SPC regulations in the JURI Committee session, the supporting documents, the results of the voting, and the European Parliament's corresponding press release).

The amendments to the four draft SPC regulations as now approved by the European Parliament's JURI Committee can be found here:

- **Draft regulation on SPCs for medicinal products (recast)**: Approved amendments to the Commission's initial proposal
- **Draft regulation on unitary SPCs for medicinal products**: Approved amendments to the Commission's initial proposal
- **Draft regulation on SPCs for plant protection products (recast)**: Approved amendments to the Commission's initial proposal
- **Draft regulation on unitary SPCs for plant protection products**: Approved amendments to the Commission's initial proposal

Among the various amendments made by the JURI Committee, the following points are particularly noteworthy:

- A definition of the term “economically linked” has been introduced, providing that “‘*economically linked’ means, in respect of different holders of two or more basic patents protecting the same product, that one holder, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with another holder*.” This definition is relevant to the provision in Article 3 which allows the grant of multiple SPCs for the same product only on condition that they are filed by different patent holders who are “not economically linked”. As a consequence of this new definition, independent companies having concluded a license agreement should normally not be regarded as “economically linked” and should thus be able to each obtain one SPC for the same product on the basis of their respective patents, which is a sensible clarification.
- In cases where the SPC applicant relies on a marketing authorization (MA) held by a third party, the draft legislation requires that an SPC shall not be granted without the consent of the third-party MA holder. The amendments endorsed by the JURI Committee clarify that “the consent of the third party” shall be submitted together with any new SPC application. In which form this will have to be done, however, still remains unclear.
- The provisions on the examination procedure for centralized SPC applications and unitary SPCs have been amended to specify that the European Union Intellectual Property Office (EUIPO) must assess compliance of SPC applications with the new condition in Article 3 requiring that different patent holders must be “not economically linked” in order to be able to each obtain one SPC for the same product, as well as the requirement in new Article 6(2) calling for the consent of a third-party MA holder. In line with this, the grounds for the invalidation/revocation of an SPC have been expanded to cover all the conditions set out in Article 3 and Article 6(2), including the “not economically linked” condition as well as the consent of a third-party MA holder.
- In SPC examination proceedings, the EUIPO will be supposed to issue an examination opinion within 6 months after the publication of the corresponding SPC application in normal cases. Where reasons for urgency can be asserted, such as the imminent expiry of the basic patent, an expedited examination can be requested by the SPC applicant, in which case the EUIPO shall issue an examination opinion within 4 months.
- In examination and opposition proceedings before the EUIPO as well as in appeal proceedings before the Boards of Appeal of the EUIPO, the corresponding oral proceedings shall, as a norm, be held in public (whereas oral proceedings before the examination and opposition panels were originally intended to be not public). The amended draft regulations further set out that “full transparency shall be ensured” throughout opposition proceedings “which shall be open, whenever possible, to public participation”.
- It has been clarified that EUIPO decisions on oppositions shall include a “detailed reasoning”, and that oppositions can also be filed against positive examination opinions relating to applications for paediatric extensions. Where several oppositions have been filed, they shall be dealt with jointly, and the EUIPO shall issue a single decision on all oppositions.
- The selection criteria for the appointment of examiners from national patent offices to be involved in SPC examination or opposition proceedings before the EUIPO have been focused on “relevant expertise” and “experience”. Moreover, no SPC examiners shall be appointed from national patent offices that do not examine the Article 3(c) and 3(d) conditions (in contrast to the initial legislative proposals which allowed one examiner from such national patent offices per panel). In addition, when setting up an examination or opposition panel, the EUIPO shall ensure “relevant expertise and sufficient experience in the examination of patents and supplementary protection certificates” and shall, in particular, ensure that at least one of the tree members of each panel “has a minimum of 5 years of experience in patent and supplementary protection

certificate examination". Conversely, the criterion of "geographical balance between the participating [national patent] offices", which previously occupied the first place in the list of applicable criteria, has been downgraded to be considered only "where possible". This new focus on expertise and experience in the examination of patents and SPCs together with the definition of corresponding tangible minimum requirements should be helpful to ensure a high quality of the future SPC examination proceedings before the EUIPO.

- A more stringent timeframe is now foreseen for appeal proceedings before the Boards of Appeal of the EUIPO. In particular, any written reply to the statement of grounds of appeal shall be submitted within 3 months from the filing of the statement of grounds. The competent Board of Appeal shall then fix a date for oral proceedings within 3 months from the filing of the reply to the statement of grounds of appeal or within 6 months from the filing of the statement of grounds, whichever is earlier, and shall issue a written decision within 3 months from the oral hearing.
- A number of further amendments aiming at improving the speed and transparency of SPC proceedings before the EUIPO have been introduced, as well as amendments making submissions by electronic means obligatory.

Notably, these amendments as now endorsed by the JURI Committee no longer include some of the previously proposed amendments that had been heavily criticized, such as the introduction of new grounds for the invalidation specifically of unitary SPCs, including the withdrawal from the market of a medicinal product, a suspension of marketing, and the failure to place the medicinal product on the market in all EU member states covered by the unitary SPC.

Conversely, no significant amendments have been made to the pre-grant opposition system and to the handling of invalidation/revocation actions filed against unitary SPCs by the EUIPO.

In order to be passed into law, the new SPC regulations need to be adopted by the European Parliament and the Council of the EU, which serve as the EU's co-legislators. As a next step, the draft regulations as amended by the JURI Committee will now be put to a first reading in the plenum of the European Parliament, which has been scheduled for February 26, 2024. Meanwhile, the Council of the EU is deliberating in parallel but has not yet made its position public.

In view of the reservations voiced by several member states, including Germany, on the planned introduction of a pre-grant opposition procedure and other specific aspects of the SPC reform, it remains to be seen what further amendments might still be made before the new SPC regulations are finally adopted. At the same time, with the current legislative period coming to an end (and the next European elections taking place in June 2024), there will be considerable pressure to quickly finalize and adopt the SPC reform. Therefore, and in view of the qualified majority voting in the Council of the EU, it would appear rather unlikely that any fundamental changes to the current versions of the draft SPC regulations will still follow.

Oswin Ridderbusch *and* ***Alexa von Uexküll*** *are the editors of the handbook* ***European SPCs Unravelled: A Practitioner's Guide to Supplementary Protection Certificates in Europe (Second Edition)****, which was published by Wolters Kluwer in 2021.*

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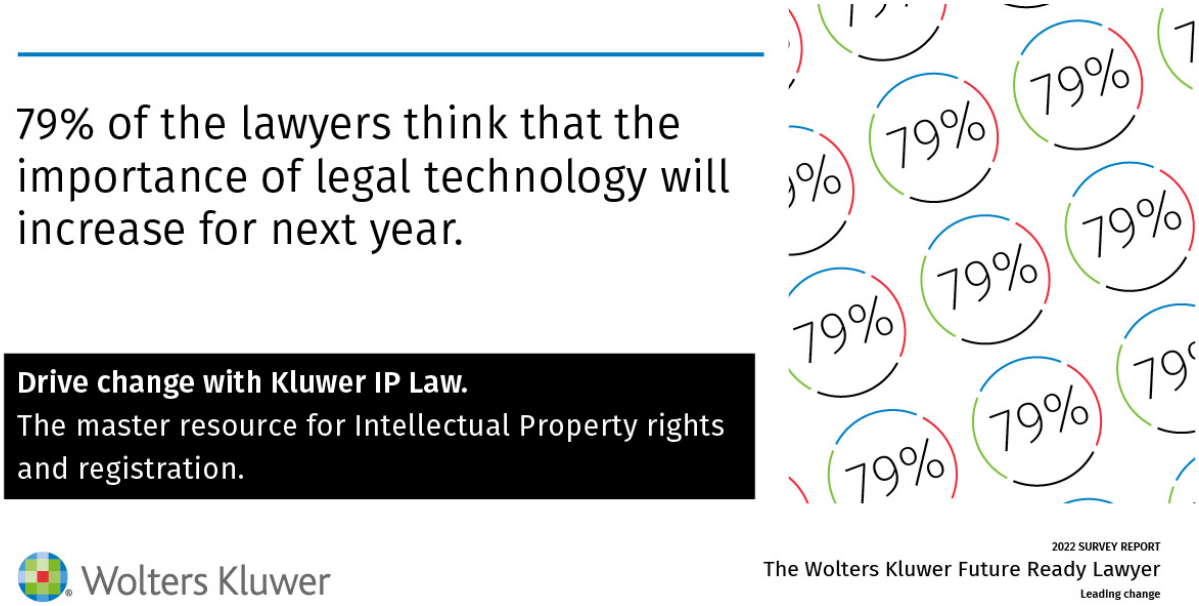

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