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First changes to ongoing SPC reform outlined by European Parliament

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A sweeping reform of the European Union's legislation on supplementary protection certificates for medicinal products and plant protection products is currently underway, which features the introduction of a new centralized SPC examination procedure at the EUIPO as well as the creation of a new unitary SPC on the basis of the unitary patent, as previously reported on this blog.

While the initial legislative proposals tabled by the European Commission on April 27, 2023 have received largely positive feedback, a number of details have been harshly criticized by stakeholders and professional associations (see, e.g., the comments from the Chartered Institute of Patent Attorneys (CIPA), the European Patent Institute (epi), the Compagnie Nationale des Conseils en Propriété Industrielle (CNCPI), the Deutsche Vereinigung für gewerblichen Rechtsschutz und Urheberrecht (GRUR), and the German group of AIPPI).

The four draft regulations proposed by the European Commission are now scrutinized by the European Parliament's Committee on Legal Affairs (JURI) and, in parallel, by the Council of the EU before a revised version of these regulations will eventually be adopted. This could happen as early as on February 26, 2024, which has been indicated as a tentative date for a possible decision in a plenary session of the European Parliament. With the current legislative period coming to an end, there will be considerable pressure to finalize and adopt the SPC reform before the next European elections which take place in June 2024.

Meanwhile, the JURI Committee has recently published a draft report on each of the four planned new SPC regulations:

- Draft report on the proposal for a regulation on the unitary SPC for medicinal products of October 13, 2023,
- Draft report on the proposal for a regulation on the SPC for medicinal products (recast) of October 13, 2023,
- Draft report on the proposal for a regulation on the unitary SPC for plant protection products of October 13, 2023, and
- Draft report on the proposal for a regulation on the SPC for plant protection products (recast) of October 13, 2023.

These draft reports set out a number of amendments to the initial proposals of the European Commission. Among others, the following modifications are envisaged:

- While the initially proposed regulations allow 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", there is no definition of this new qualifier. The JURI Committee intends to introduce a definition of "economically linked" that hinges on direct or indirect control, namely: "'*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 would appear to exclude license agreements between independent entities, which is a welcome clarification.
- When filing an SPC application that relies on a marketing authorization held by a third party, the draft regulations require that an SPC "shall not be granted … without the consent of that third party". In line with this, the JURI Committee intends to specify that the EUIPO shall not only examine the compliance of an SPC application with all the "Article 3 conditions" but also with the condition requiring the consent of a third-party marketing authorization holder. In addition, "the consent of the third party" is to be explicitly included in the list of documents to be submitted together with an SPC application. It still remains unclear, however, in what form a proof of such consent should be submitted and, e.g., whether a confirmation from the SPC applicant alone would be sufficient or whether a declaration from the third party is obligatory.
- The required consent of a third-party marketing authorization holder is to be listed among the grounds of invalidity but, rather bizarrely, only in the new regulation on unitary SPCs for plant protection products and not in any of the other three SPC regulations. It might be that this point has been overlooked in the draft reports on these other regulations.
- Insofar as examiners from national patent offices are involved in the examination and opposition panels at the EUIPO, their expertise and experience in SPC and patent matters as a relevant selection criterion will be much more strongly emphasized. Remarkably, the initially foreseen provision obliging the EUIPO to ensure "*geographical balance amongst the participating [national patent] offices*" is to be replaced by the imperative to ensure "*relevant expertise and sufficient experience in the examination of patents and supplementary protection certificates*".
- In a similar vein, while the initial proposals from the European Commission provide that no more than one examiner (in a three-member panel) should come from a national patent office that has made use of the exemption to not examine the conditions of Article 3(c) and 3(d), the JURI Committee intends to tighten this requirement to completely exclude any examiners from national patent offices that do not examine the Article 3(c) and 3(d) conditions. This measure would certainly help improving the quality of the EUIPO's decisions.
- It has been clarified that 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. Moreover, where several oppositions have been filed, they shall be dealt with jointly, and the EUIPO shall issue a single decision on all these oppositions.
- New grounds for the invalidity of an SPC are to be introduced, including the withdrawal of the marketing authorization underlying an SPC. In the case of unitary SPCs for medicinal products, additional new grounds for invalidity include 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 (unless the SPC holder waives its rights for markets where the medicinal product has not been launched). These new invalidity grounds seem highly problematic for several reasons. In addition, there is reason for concern that these new grounds for invalidity could make unitary SPCs less attractive than bundles of national SPCs.
- Various provisions are to be amended to specify that all submissions to the EUIPO must be made electronically. Thus, SPC applications as well as third-party observations, oppositions,

invalidation actions (where applicable), and appeals shall be filed at the EUIPO in electronic form only.

It remains to be seen to what extent these modifications will be finally endorsed by the European Parliament's JURI Committee and also what amendments are envisaged by the Council of the EU. In particular, it may be expected that the highly controversial pre-grant opposition system and possibly also the handling of invalidation actions against unitary SPCs by the EUIPO could still be put into question. Within the Council, the Working Group on Intellectual Property (Patents) is already working on the four draft SPC regulations, but its deliberations are not publicly accessible at this stage. Yet, it seems safe to assume that further changes to the draft SPC legislation will be coming down the road.

UPDATE:

The German Federal Council (*Bundesrat*) has meanwhile filed observations on the planned SPC reform (received by the European Parliament on November 9, 2023), in which several points are criticized, including the introduction of a pre-grant opposition procedure. The Federal Council's comments on this latter point read as follows (in English translation):

> *The proposed regulation provides for the possibility for third parties to submit objections to the EU Intellectual Property Office prior to the granting of certificates and thereby lodge an opposition against intended decisions. The Federal Council fears that this possibility could be abused to a considerable extent.*
>
> *In the opinion of the Federal Council, this possibility could result in a certificate possibly not being granted before the underlying basic patent expires. The rights holder would lose their intellectual property, at least temporarily, without being able to sue for infringement or obtain a preliminary injunction against potential infringers. As the duration of the opposition proceedings is also not limited in time and as several appeal instances may follow, there is a real risk that the rights holder will suffer considerable damage.*
>
> *The Federal Council therefore considers it much more sensible to follow the examples of the USA and Japan. It is perfectly sufficient if the validity of a certificate can be contested after it has been granted.*

The submissions from the German Federal Council can be found here:

- https://connectfolx.europarl.europa.eu/connefof/app/exp/COM(2023)0222 (PDF version)
- https://connectfolx.europarl.europa.eu/connefof/app/exp/COM(2023)0231 (PDF version)

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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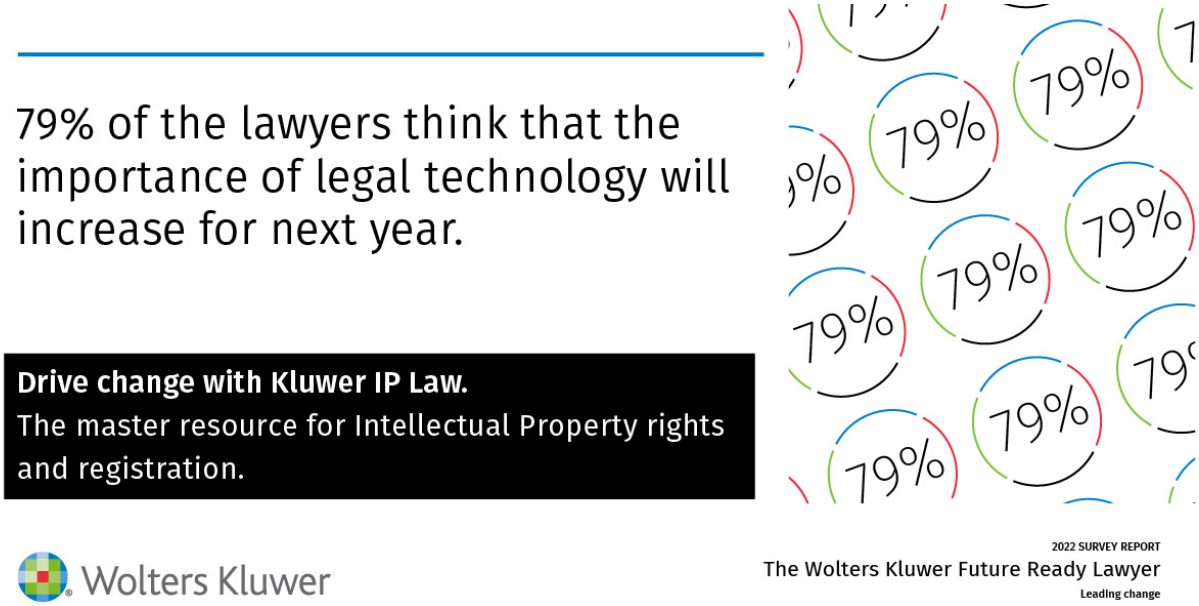

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