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VCI-POSITION

Key legal questions regarding the unitary SPC system must be answered quickly

The pharmaceutical industry and the plant protection products industry are among the most innovative and research-intensive industrial sectors in Europe. In 2022, companies in the German pharmaceutical industry alone invested around 9.37 billion euros in research and development. Manufacturers of crop protection products in the EU expect to invest €4 billion in the innovation of biopesticides alone and €10 billion in innovations in precision and digital technologies by 2030.

Both sectors are particularly dependent on the protection of their innovations through intellectual property rights. Alongside the corresponding patents, SPCs are the cornerstone for protecting innovations in the pharmaceutical and crop protection industries.

A uniform European SPC system can strengthen Europe as a research location in the long term: it means less bureaucracy, lower costs and fewer resources for companies when they apply for supplementary protection certificates – and the restoration of lost time in patent protection due to necessary authorization procedures. The introduction of a “unitary SPC” is also an essential prerequisite for the industries concerned to use the new European patent system and to apply for European unitary patents. Only if there is legal clarity that SPCs with unitary effect are available based on European unitary patents will the industrial sectors concerned be able to benefit from the advantages of the unitary patent system.

The VCI has therefore long emphasized the urgent need for the rapid introduction of unitary SPCs in Europe and has therefore welcomed the European Commission's proposals for the creation of the unitary SPC.

However, we are very concerned that there is still a lack of legal clarity regarding two key issues: doubts have arisen in the Council regarding the legal basis of Art. 118 TFEU used by the EU Commission for its proposals for regulations. In addition, there is a lack of reliable expertise on the question of whether the options discussed in the Council, which provide for the delegation of the granting procedure for unitary SPCs to the European Patent Office (EPO), are compatible with EU organizational law.

We therefore demand that the unresolved legal questions be clarified now!

The negotiations must not lose momentum because of these issues. Companies in the chemical-pharmaceutical industry are dependent on the legally secure implementation of the Unitary SPC.

Therefore, there must be a swift agreement between the EU Commission and the Council on the **question of whether or not enhanced cooperation between the EU Member States is required on the basis of Art. 118 TFEU.**

With regard to the question of the office responsible for granting unitary SPCs, the EU Commission and the then Hungarian Council Presidency have presented various options that envisage the EUIPO as the competent authority. The member companies of the VCI are of the opinion that the realization of the unitary SPC based on this allocation of competence, in particular on the basis of “option 3”, would be a legally feasible and in substance acceptable way. However, some changes would need to be made to the details of the structure, in particular regarding the establishment of a “consultation body” and the replacement of the rotation procedure with the principle of the registered office when determining the local responsibility of the NPOs.

Before the legislative bodies of the EU therefore deal in detail with the advantages or disadvantages of transferring the SPC granting procedure to the EPO, the **question of whether it is permissible to delegate the SPC examination procedure to a non-EU authority** must first be clarified as part of an in-depth legal examination. The necessary examination of this question must also be carried out swiftly to have a reliable basis for further discussion.

Parallel to the clarification of the legal issues, work on the details of the future SPC system should also be continued intensively. The VCI priorities for the unitary SPC remain unchanged as follows:

1. central issuance with a high level of competence

We are in favor of a central examination body/issuing authority so that the necessary harmonization in the issuing procedures can be guaranteed. The composition of the examination body of such a body should be based on the “virtual office” concept, i.e. a small examination body with assigned examiners from the national offices that already grant SPCs today.

2. legal recourse to the Unified Patent Court (UPC)

Invalidation actions, invalidity counterclaims and appeal proceedings against decisions of the granting authority should fall under the jurisdiction of the UPC. The UPC has the greatest expertise with regard to the patent law and technical issues that arise.

3. rapid implementation of the Unitary SPC

We want the Unitary SPC to be introduced quickly without long delays. As long as the Unitary SPC is not implemented, the new Unitary Patent System will not be able to be used effectively by companies in the chemical and pharmaceutical industry.

4. willingness to engage in dialog

We are striving for a dialog with the new granting authority within the framework of the development of competencies to be carried out there in matters of SPC granting and are relying on the granting authority's willingness to engage in dialog.

In addition, the vast majority of VCI member companies reject the possibility of a “pre-grant opposition” as part of the SPC granting procedure.

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- The VCI is registered in the lobby register under the registration number R000476 for the representation of interests vis-à-vis the German Bundestag and the Federal Government.

The VCI and its trade associations represent the interests of around 2,300 companies from the chemical-pharmaceutical industry and chemical-related industries vis-à-vis politicians, authorities, other sectors of the economy, science and the media. In 2023, the member companies of the VCI had a turnover of around 245 billion euros and employed over 560,000 people.