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THE SPC SYSTEM: A FLAWED SYSTEM IN NEED OF REFORM? THAT IS THE QUESTION... ASKED BY THE EUROPEAN COMMISSION

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The European Commission has just launched a call for evidence to reform the SPC system and proposes a unitary SPC.

In view of the imminent launch of the Unified Patent Court ("UPC")[1] and following the publication, in 2020, of its "Intellectual Property Action Plan",[2] its "Pharmaceutical Strategy for Europe"[3] and its report on the evaluation of the current Supplementary Protection Certificate ("SPC") regime,[4] the European Commission launched on 8 March a call for evidence to gather opinions on a possible reform of the SPC system.[5] This call for evidence is open until 5 April.

SPCs are intellectual property rights that extend the protection conferred by a patent on a medicinal or plant protection product for up to 5 years, to compensate for the period - between the grant of the patent and the grant of the marketing authorisation ("MA") of the product covered by the patent - during which the patent cannot be exploited.

At present, SPCs, whether based on a national or European patent and on a national or Community MA, are granted by the patent offices of each EU Member State, under the conditions set out in European Regulations No. 469/2009 for medicinal products[6] and No. 1610/96 for plant protection products[7] ("SPC Regulations"). Each SPC is therefore a national title issued by a national office, and actions - such as invalidity and infringement - relating to SPCs are within the competence of the national authorities.[8]

For the time being, *the grant regime and scope of* SPCs are not expected to change with the introduction of the unitary patent: EU Regulations 1257/2012 and 1260/2012 do not provide for a "unitary SPC". On the other hand, *the jurisdiction to hear SPC-related actions* will change: while actions relating to SPCs granted on the basis of national patents will continue to be within the exclusive jurisdiction of national courts, those relating to SPCs granted on the basis of a European patent or a European patent with unitary effect will be within the exclusive jurisdiction of the UPC,[9] unless the SPC at stake has been opted-out.[10]

Following several consultations initiated since 2018,[11] the Commission considers that the current system would present the following four pitfalls:

1. Discrepancies in the outcome of grant procedures: the SPC Regulations and the relevant case law of the CJEU are applied inconsistently by national offices, with the result that the same SPC application may be granted by some offices but rejected by others, with some offices even granting an SPC with a different scope than the one requested by the applicant in its initial SPC application.
2. No unitary protection by a unitary SPC for the future European patent with unitary effect ("unitary patent").
3. Insufficient transparency of information on SPCs, especially in terms of publication and public availability of such information.
4. High costs and administrative burdens for SPC users.

According to the Commission, the current system would create a great deal of legal uncertainty for both originator companies and generic companies and would be particularly detrimental to SMEs that would not apply for SPC since they cannot afford the costs of obtaining SPCs in the EU.

Regarding originator companies, one may wonder whether they do not somehow find some advantages in the current system, which makes it very costly and complex to challenge SPCs as soon as they are active in more than one European country. On the question of the under-representation of SMEs among SPC applicants, the list of SPCs filed after 1 January 2019[12] confirms that the vast majority of SPC applicants are companies belonging to international pharmaceutical groups. It remains to be seen whether this under-representation is not also linked to other factors (cost of clinical trials, etc.) which, if they do not change, will continue to hinder the filing of SPCs by SMEs even after a reform of the system.

This being said, the Commission identifies three main areas for improvement for the SPC system:

a. The status quo: no change to the current system. Future unitary patents would then only be extended by national SPCs and none of the problems identified above would be solved according to the Commission, which therefore does not seem to be in favour.

b. Creation of non-legislative instruments such as common guidelines formalising the "good practices" of the offices as well as the content of the case law of the CJEU on SPC Regulations. This raises the question of which practices should be considered "good". Furthermore, to achieve harmonisation, it will not be sufficient to *compile* the case law of the CJEU in a single document. Indeed, the current lack of harmonisation is mainly due to a lack of uniform interpretation of said case law.

c. Legislative changes, whether or not in combination with non-legislative instruments. In this respect, the

Commission proposes various approaches. The first one would be the creation of a centralised system for the grant of SPCs by a single office which would be responsible for (i) the grant of a unitary SPC[13] and/or (ii) the grant of national SPCs but following a single procedure, in the manner of the EPO granting the European patent which is then validated on a country-by-country basis. Another option, which could be cumulative with the first one, would be to incorporate the best practices of the offices and the content of the case law of the CJEU into a legislative instrument.

The creation of a unitary SPC, while supported by part of the pharmaceutical and phytosanitary sector,[14] is not without raising many questions, notably:

Which MA? Logically, one might think that a unitary SPC could be granted to the holder of a unitary patent and a Community MA. However, such a MA is only available for medicinal products: to date, there is no Community MA for plant protection products. Such a system would introduce a dichotomy between the treatment of SPCs on medicinal products and SPCs on plant protection products. Could a unitary SPC then be granted on the basis of a national MA, following a decentralised procedure or by mutual recognition? In this case, the objective of introducing a completely unitary and uniform system could be missed, as the scope of marketing authorisations could vary from one country to another.

For which territory? The Community MA is valid in the territory of the EU Member States as well as Iceland, Norway, and Liechtenstein, which represents a total of 30 States. On the other hand, the unitary patent will only have effect in the territory of 24 Member States of the UPC Agreement, as countries such as Spain and Croatia do not wish to participate in the UPC.[15] In this case, it would seem that the coexistence of a “truly” unitary SPC and national SPCs cannot be avoided.

Which Office? The Commission does not specify whether it is to create an *ad hoc* Office for the issuance of SPCs or to entrust the grant of unitary or national SPCs to an existing national Office. The major issue in issuing and litigating based on SPCs is the non-uniform interpretation of EU law, fuelled by decisions of the CJEU which are not characterised by great clarity.[16]

In March 2021, Medicines for Europe[17] warned of further impacts that the adoption of a unitary SPC could have, including on access to treatment in some countries.[18]

In short, whatever solution is chosen, none of them will fully solve all the problems identified by the Commission at once. Above all, whatever system is chosen, the same problems of the CJEU decisions will continue to arise.

One can only invite the legislator to be vigilant: the solution that would solve all the existing problems will not necessarily be the best one, and by focusing too much on solving the undesirable effects of the current system, the risk is to create new, unexpected but no less undesirable ones.

In any case, the suspense should not last long as the Commission indicates that it intends to adopt the selected proposal(s) by the 4th quarter of 2022.

[1] See our recent articles on the subject: "UPC: Top start... yes, but how?" and "UPC: a forceps birth at the risk of a premature deat h?"

[2] COM (2020) 760, available at this link

[3] COM (2020)761, available at this link

[4] Evaluation of EU Regulations No. 469/2009 and No. 1610/96 on supplementary protection certificates for medicinal and plant protection products, available at this link

[5] Call for papers

[6] Regulation (EC) No. 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary prot ection certificate for medicinal products

[7] Regulation (EC) No. 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supple mentary protection certificate for plant protection products

[8] See in particular Article 15.2 of the SPC Regulations

[9] For the actions listed in Article 32 of the UPC Agreement (including invalidity and infringement actions)

[10] However, the rules governing the opt-out of SPCs are not without their difficulties, as highlighted by our colleagues at Bristows in 2015 https://www.bristowsupc.com/commentary/spcs-and-the-upc/

[11] In particular the Commission's 2018 enquiry and the Allensbach enquiry

[12] Survey made by us from the SPC database of the INPI

[13] The Commission recalls that Article 118 TFEU could be used as a legal basis for the creation of a unitary SPC.

[14] Thus, as early as 2015, the ECPA (European Crop Protection Association, renamed "CropLife Europe"), the EFPIA (European Federation of Pharmaceutical Industries and Associations) and the IFAH-Europe (International Federation for Animal Health, renamed "AnimalhealthEurope" in 2017) published a joint communiqué calling for this reform.

[15] Poland should join the UP system soon

[16] See referral by High Court of Justice (England and Wales) in proceedings [2019] EWHC 388 (Pat) between Eli Lilly and Genentech - C-239/19

[17] Formerly the European Generic Medicines Association, representing some of the major players in the biosimilar, generic and value-added medicines sector in Europe. File of this entity on the European Transparency Register: https://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=48325781850-28

[18] https://www.medicinesforeurope.com/wp-content/uploads/2021/02/Medicines-for-Europe-Position-Paper-on-Unitary-SPC-Unified-Mechanism-for-SPC-granting-March-2021.pdf