Position Paper

Unitary SPC & single procedure for the granting of SPCs

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Introduction

This paper describes the Medicines for Europe position in relation to the possible Unitary Supplementary Protection Certificate (SPC) and the discussions around the introduction of a unified procedure for granting (bundles of) national SPCs. The stated objective is to reduce fragmentation in the SPC system by reviewing certain elements of the legislation.

Due to the very delicate nature of intellectual property (IP) for its impact on patient access to generic and biosimilar medicines, national healthcare budgets, and competition more generally, any change to the current IP system needs to be fully justified and thoroughly reflected upon to be carefully calibrated against all the interests at stake.

The points and arguments described below represent key considerations to avoid that any measure introduced in Europe will actually unjustifiably change the delicate IP balance and create any unintended effects, from which the SPC, over the years, has demonstrated not to be exempted (*e.g.*, forced delocalisation, extension of its scope, lengthy litigation, *etc.*).

In this respect, Medicines for Europe strongly believes that substantive changes to the SPC regulation (in particular in relation to the requirements in Article 3) and/or non-legislative guidelines on best practices of national patent offices and case law of the CJEU would not increase legal certainty. These are rather more likely to create further uncertainties, which would again take years to clarify and harmonise. This may annihilate efforts recently made by the CJEU, which is converging towards a certain level of stability and progressively returning to an interpretation which is both more consistent with the objectives of the regulation and easier to apply by national courts and patent offices, hence allowing better harmonisation.

Policy Developments & the Actual Fragmentation

The European Commission published on 8 March 2022 a Call for Evidence for an Impact Assessment on "Medicinal & plant protection products – single procedure for the granting of SPCs".

The Call for Evidence makes reference to several acts, studies and documents published in the past years, including the EC Intellectual Property action plan, the European Parliament resolution of 11 November 2021 on an IP action plan, the 2020 Commission evaluation of SPC legislation and EC public consultation of 2018.

Rue d'Arlon 50 - 1000 Brussels - Belgium
T: +32 (0)2 736 84 11- F: +32 (0)2 736 74 38
www.medicinesforeurope.com

The Call for Evidence focuses almost exclusively on the stated need for a simplified SPC granting procedures, which is one, but not the only, aspect of the existing fragmentation of the SPC system in Europe.

The Call for Evidence makes minimal or no reference to the **prominent need to tackle fragmentation in the enforcement and litigation phase of SPC lifecycles, which is arguably the highest priority for ensuring timely patient access to generic and biosimilar medicines, increasing legal certainty and addressing sustainability concerns with national healthcare budgets**. The Call for Evidence disregards **the core of the problem with the SPC system: *multiple litigation* and *conflicting court decisions at a national level***.

The Call for Evidence refers to four of the **five identified challenges** in the SPC Evaluation, which are (i) divergent outcomes of the grant procedures across EU countries, (ii) lack of unitary SPC protection for the future unitary patent, (iii) suboptimal transparency of SPC-related information, and (iv) high cost and administrative burden for SPC users. The Call for Evidence omits the fifth challenge identified in such evaluation, namely ***"[c]onflicting outcomes of court proceedings"***.[1]

Indeed, the European Commission's IP action plan recognises the issue in Europe of "*parallel litigation in multiple EU countries*"[2] and identifies the need to introduce a centralised litigation system to *"improve legal certainty and avoid parallel [court] proceedings in multiple Member States, considerably reducing litigation costs*".[3]

The objective of removing multiple litigation in EU Member States - and the subsequent conflicting court decisions - is essential for increasing savings for national healthcare budgets, support their sustainability and ensure timely competition on the market.

The societal impact of timely entry of generic and biosimilar medicines on the market is not a factor included in this Call for Evidence, which therefore needs to be urgently recalibrated and carefully considered it. Indeed, the EP Resolution on the IP action plan stresses that, in the context of the reform of the SPC system aimed at tackling fragmentation, "*a level playing field for makers of generics and biosimilars in the Union is essential"*.[4]

The **importance of removing multiple litigation in EU Member States for the whole industry** is demonstrated by the findings of the EC public consultation of 2018 that "*a great majority of originators consider that [the unitary SPC] could boost the value of investments*" as "*it would reduce red tape relating to registration and to litigation*" and "*would offer a specialised court*".[5]

The "***urgent need for a unified specialized patent litigation system in Europe***" is also stressed in the 2009 EC Final Report on the Pharmaceutical Sector Inquiry that highlights the "*broad consensus*" for such a litigation system.[6]

[1] 2020 European Commission Evaluation of the SPC, p. 35
[2] 2020 European Commission IP Action Plan, p. 2
[3] Ibid., p. 4
[4] 2021 European Parliament Resolution on the IP action plan, para. 16
[5] 2018 European Commission Public Consultation on SPCs and patent research exemptions, p. 6
[6] 2009 European Commission Final Report on the Pharmaceutical Sector Inquiry, p. 18 and p. 519.

The need to tackle multiple SPC litigation & conflicting national court decisions

The case study of Truvada

Truvada (Emtricitabine/Tenofovir): a critical medicine for HIV prevention and treatment that can reduce HIV transmission by over 90%

Patent expiry: July 2017 **SPC expiry**: February 2020

The SPC was challenged and invalidated in several EU national courts at different points in time (in certain countries, court procedures were just longer) and ultimately considered illegitimate by the CJEU

Because of delayed national court decisions, generics could not enter those markets despite invalidating decision all around Europe

In the Netherlands, the generic entry reduced price for a 30-day supply from €344,28 to €47,95

In Portugal, the delayed court decision led to a loss of over €109 Million saving, equivalent to 1.1% of total 2018 health budget, impacting treatment for over 95.000 patients

Considerations on a Unitary SPC

The Unitary SPC is intended to complement the legal framework of the unified patent system. According to the European Commission, it would have the objective to increase predictability, transparency and legal certainty.

In light of the above, **Medicines for Europe believes that a Unitary SPC, which would entail SPC litigation before a Unified Patent Court, has the potential to increase legal certainty in the interest of the whole industry as long as certain safeguards and considerations be contemplated in order to ensure a well-functioning SPC system**. In particular:

- **Geographical scope**: Unitary SPCs would increase the geographical scope of SPC protections. Today, SPCs are, on average, not registered in 8 out of 27 Member States. Where SPCs are not registered, generic and biosimilar medicines can provide patient treatment at patent expiry, therefore earlier than in other SPC protected markets. With a Unitary SPC, the protection would automatically extend to all UPC countries, potentially delaying access to treatment in those countries that today are generally not covered by SPC protection and where the reference product may not be available. The impact is very significant for treatments for which access increases significantly once a generic or biosimilar enters the market. Such a geographical extension has the potential to prevent equitable access to generic and biosimilar treatment where no alternative treatment is on the market or can be placed on the market. It is therefore essential that unitary SPCs are granted and maintained in force only if and as long as the requirements of Article 3 of the SPC regulation are met in each MS covered by such SPCs.
- **Basic substance patents**: In order for the system to be balanced and allow further harmonisation unitary SPCs should only be available on the basis of unitary patents.
- **Underlying MAs**: for coherence and clarity, unitary SPCs should only be available and maintained on the basis of a valid marketing authorisation.

- **Granting body**: a permanent virtual body may be established taking advantage of the high expertise and best practices of SPC specialised patent offices (like the Netherlands or Germany).
- **Quality and Transparency**: the system must *(i)* ensure the highest levels of quality and transparency in examination processes, and *(ii)* include a formal mechanism for quality assessment of examiners that takes into consideration, among other things, outcomes of case-law. Quality is essential for a credible SPC system. SPC applications should be published in an online public register as soon as practically possible after filing and all documents from the file should be made publicly available online. Should the register include SPC expiry dates, a clear ban of patent linkage should be made in EU legislation in order to avoid that such publication be used to stop P&R or procurement decisions, which would be contrary to EU law, as clarified by the European Commission.[7]
- **Pre-grant oppositions**: in order to ensure quality of granted SPCs, the system should foresee a pre-grant opposition mechanism, which the World Intellectual Property Organisation defines as a "*simple, quick and inexpensive mechanism that ensures the quality and validity*".[8] Its absence is the cause of the existing confusion on SPC grant and enforcement.
- **Accountability of the granting body**: considering the huge impact of granted SPCs on national healthcare budgets, on patient access and on litigation, the granting body should be fully and clearly accountable. Appropriate mechanisms for regular review and reporting by EU institutions should be in place to swiftly correct any unforeseen deficiencies.
- **No double SPC protection** (national and unitary) should exists in a single Member State. Situations where companies would need to litigate twice the same SPC should be avoided.

Considerations on a Unified Procedure for Granting National SPCs

Differently from the Unitary SPC system, which entails the UPC as unified litigation forum, **the unified procedure for granting (bundles of) national SPCs would NOT immediately address the pressing issue of fragmentation resulting in multiple national litigation and conflicting national court decisions**, since during a transitional period of 7 years (potentially extended to 14 years) national SPCs, whether locally or centrally granted, could still be litigated before national courts (and will have to be if the basic patent has been opted out of the UPC jurisdiction). Indeed, it aims to only simplify the procedure for obtaining an SPC but would not completely address the need identified by the Commission in the Call for Evidence and in the IP action plan "*to tackle the remaining fragmentation of EU's IP system*".

Such fragmentation in the enforcement and litigation phase of SPCs is **the core problem of the SPC system that directly affects national healthcare budgets and timely patient access to generic and biosimilar medicines treatments**.

In this light, a unified procedure for granting (bundles of) national SPCs, in line with the concept of EU uniformity justifying this measure, **can only be considered balanced and coherent with the objective to tackle**

[7] Pharmaceutical Sector Inquiry Final Report, 2009: pages 130, 315, 330, 480, 532.
[8] Available on the WIPO website: https://www.wipo.int/scp/en/revocation_mechanisms/opposition/index.html

fragmentation if it at least provided a form of unified scrutiny of SPCs, eg. a pre-grant opposition system, and other key safeguards:

- **Pre-grant oppositions**: in order to ensure quality of granted SPCs, the system should foresee a pre-grant opposition mechanism, which the World Intellectual Property Organisation defines as a "*simple, quick and inexpensive mechanism that ensures the quality and validity*".[9] Its absence is the cause of the existing confusion on SPC grant and enforcement.
- **Granting body**: a permanent virtual body may be established taking advantage of the high expertise and best practices of SPC specialised patent offices (like the Netherlands or Germany).
- **Basic substance patents**: In order for the system to be balanced and allow further harmonisation, it should not be possible to apply centrally for a bundle of SPCs on the basis of a unitary patent. The central SPC application system resulting in the grant of a bundle of SPCs should only be available if the basic patents relied on are part of a bundle of classic European Patents, in force in each designated Member State.
- **Underlying MAs**: for coherence and clarity, SPCs applied for centrally should only be available and maintained on the basis of a valid marketing authorisation.
- **Quality and Transparency**: the system must *(i)* ensure the highest levels of quality and transparency in examination processes, and *(ii)* include a formal mechanism for quality assessment of examiners that takes into consideration, among other things, outcomes of case-law. Quality is essential for a credible SPC system. SPC applications should be published in an online public register as soon as practically possible after filing and all documents from the file should be made publicly available online. Should the register include SPC expiry dates, a clear ban of patent linkage should be made in EU legislation in order to avoid that such publication be used to stop P&R or procurement decisions, which would be contrary to EU law, as clarified by the European Commission.[10]
- **Accountability of the granting body**: considering the huge impact of granted SPCs on national healthcare budgets, on patient access and on litigation, the granting body should be fully and clearly accountable. Appropriate mechanisms for regular review and reporting by EU institutions should be in place to swiftly correct any unforeseen deficiencies.

Conclusions

Medicines for Europe believes that, as it has always been the case in previous changes to IP legislation, **any change to the IP system in Europe should be thoroughly reflected upon, in consideration of the potential impact on generic and biosimilar medicines market entry, healthcare budgets and access to medicines for patients**.

Making substantive changes to the SPC regulation (in particular in relation to the requirements in Article 3) and/or adopting non-legislative guidelines on best practices of national patent offices and case law of the

[9] Available on the WIPO website: https://www.wipo.int/scp/en/revocation_mechanisms/opposition/index.html
[10] Pharmaceutical Sector Inquiry Final Report, 2009: pages 130, 315, 330, 480, 532.

CJEU would not increase legal certainty. Rather, such substantive changes or guidelines are more likely to create further uncertainties, which would again take years to clarify and harmonise.

A Unitary SPC would be created for coherence with the unitary patent system and with the objective to tackle fragmentation and legal uncertainty. However, the considerations made above about both its concrete impact on the current EU IP system and the way it would practically function should be carefully assessed in order to avoid any unintended effects, which the SPC, over the years, has demonstrated to have produced on different aspects (*e.g.*, forced delocalisation, extension of its scope, lengthy litigation, *etc.*). **The conditions regarding the granting body and its accountability, the highest quality, the pre-grant oppositions, the coverage and no double SPCs are all essential elements for the system to be balanced and well calibrated**.

Since it would not immediately address the fragmentation issues at enforcement and litigation level, **a unified procedure for granting (bundles of) national SPCs could only be considered if a pre-grant opposition system is included, in order to ensure a minimal level of central scrutiny of SPCs. The abovementioned conditions related to: granting body and its accountability, the highest quality, the coverage and no double SPC protection should also be included in such a system.**

Medicines for Europe is ready to further contribute constructively to the debate around these two topics.