BRIEFING

Implementation Appraisal

European Parliament

Revision of the Supplementary Protection Certificate Regulations for medicinal and plant protection products

SUMMARY

This appraisal assesses two regulations for intellectual property rights applicable to the specific case of medicinal products and plant protection products – the Supplementary Protection Certificate Regulations (SPC Regulations for short). The analysis highlights the outcome of the European Commission's assessment, discrepancies in implementation between Member States, and the complexity of striking a balance between various interests, since both regulations aim to reconcile public health imperatives, the need to foster research and development, and the interests of the pharmaceutical industry. The initiative may either put in place a unitary supplementary protection certificate and/or a single ('unified') procedure for granting national supplementary protection certificates. The objective is to make supplementary protection certificates more accessible and efficient for the health sector.

Background

Supplementary protection certificates (SPCs) are a ***sui generis*** **intellectual property rights (IPRs)** for **medicinal products and plant protection products** (PPPs) subject to regulatory authorisation. The SPC Regulation for medicinal products was adopted in 1992 and revised in 2009, while the SPC Regulation for PPPs dates from 1996. SPCs, within the IPR framework, are at a **crossroads of economic and societal issues**. They affect availability of medicines (or PPPs in the agricultural sector); the competitiveness of pharmaceutical companies, be they are innovators[1] or manufacturers of generics and biosimilars; and – to some extent – incentives for research and development (R&D). SPCs are interlinked with other IPRs and must be addressed taking into account the broader reforms addressing intellectual property (IP), the pharmaceutical industry, competitiveness, and R&D, including new medicinal technologies.

SPCs are inseparable from the patents to which they relate. A patent is a legal title that 'can be granted for any invention having a technical character provided that it is new, involves an 'inventive step', and is susceptible to industrial application. A patent can cover how things work, what they do, what they are made of and how they are made'. The patent holder has the exclusive right to prevent others from making, using or selling the invention without his/her permission. SPCs are IPRs conferred on patented medicinal products and PPPs. Given the long period of clinical trials necessary for validating and marketing these products,[2] the granting of a patent risks being too short and ineffective; the short-term running exclusivity may deter decisions to invest in R&D. SPCs extend the term of a patent by up to five years, thereby aiming to offset the loss of effective patent protection. This system provides incentives for companies to invest in R&D of medicines and PPPs. The exclusivity attached to IP protection is, indeed, a compensation for this investment. Objectives

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of the SPC system also include preventing the delocalisation of R&D centres out of the EU and fostering common regulatory standards.

If a paediatric investigation plan is conducted, an extra six months can be added for medicinal products. The adoption of this provision was triggered by the challenges encountered in developing medicines for children (paediatric medicines) and rare diseases (orphan medicines[3]). Those diseases affect a small number of patients. Without incentives and rewards, investment in R&D for new medicines are not economically viable. The SPC was complementary to the regulations[4] adopted to foster the development of medicines children and for rare diseases.[5]

In the debate on access to medicines, innovation and global competitiveness, the role of IPRs emerged as a significant one. The question arose of whether IP protection mechanisms are helpful or harmful for increasing access to medicines; arguably, any form of exclusivity from IP protection influences the prices and/or delays access to generics. Generics and biosimilars, whose entry on the market is said to trigger price reductions (generics are 50 % cheaper on average) improve access to medicines correlatively. There are also doubts on the relationship between SPCs and the development of new medicines tackling unmet medical needs.[6] SPCs are similar to patents, of which they prolong the exclusivity period, and correspond to medicinal products developed to be economically viable. They cannot be a stand-alone tool to redirect investment on medicinal products for rare use.

Another challenge consists in striking a balance between the need for an **innovative and competitive industry** and **healthcare** needs. EU manufacturers lose markets reportedly because of the SPC system's fragmented implementation. In the context of its new pharmaceutical strategy for Europe,[7] the Commission echoed these concerns, noting that differences in the application of IP and SPCs in Member States lead to 'duplications and inefficiencies thus hampering the competitiveness of industry'. Therefore, one of the strategy's flagship initiatives on competitiveness aims 'to optimise the SPCs system, to make it more transparent and efficient as foreseen in the Intellectual Property Action Plan – 2022' where the Commission noted that the SPC system was relevant, but suffered from fragmented implementation across Member States. The Commission indicated that it would assess 'the possibility to introduce a **unified SPC grant mechanism and/or create a unitary SPC title**'. It announced that it would 'also look closely at how to further optimise incentives and rewards to boost innovation and ensure 'continuous supply of medicines, including generics and biosimilars'.

The revision of existing rules on SPCs is part of a set of initiatives on IPRs that also comprise a further two new initiatives, on compulsory licensing and standard-essential patents.

Legal framework

In the EU, there are two – and soon three – levels of possible IP protection:

1. At national level, national property offices (NPOs) implement a Member State's national legislation; national courts enforce the national legislative and regulatory framework.
2. At EU level, the European Patent Convention establishes a one-stop shop for the filing, examination and granting of **European patents** by the European Patent Office (EPO). Once granted, a European patent is validated in each EU Member State in which protection is sought. It confers the same rights as a national patent, and national courts are competent for its enforcement. The system was launched in 2012 with the EU patent package, a legislative initiative consisting of two regulations and an international agreement that laid the ground for the unitary patent (UP) protection in the EU.
3. The UP system depends on the establishment of the Unified Patent Court (UPC), a specialised jurisdiction competent for both the UP and 'classic' European patents. Currently, 17 Member States out of the 24 signatories of the agreement on setting

up the UPC have ratified it. Its provisional application period started on 19 January 2022; the operation of the new system will start on 1 June 2023 among Member States having ratified the agreement.[8] Following the entry into force of this part of the unitary EU patent package, in addition to the current possibility of obtaining a European patent granted by the EPO, applicants would have the possibility of applying for a **single patent with unitary effect**.[9] 'Unitary effect' means that the patent will provide uniform protection with equal legal consequences in all countries participating in the UPC.

Considering the imminent launch of the system, and the difficulties in the pharmaceutical sector highlighted by the COVID-19 crisis, the revision of the SPC rules as announced in the 2023 Commission work programme is timely. The SPC regime does not provide for a unitary system, even though the regulation applies directly in Member States. This will be at the core of the discussions on the revision.

The EU legislation on SPCs consists of two regulations: Regulation (EC) No 469/2009 and Regulation (EC) No 1610/96, covering medicinal products and PPPs, respectively. Provisions of both regulations are largely similar, with the exception of SPCs granted to paediatric medicinal products, which may be subject to an extension under certain conditions. This briefing will refer to the two regulations as the **SPC Regulations**, stressing their specificity where they differ.

The SPC framework contains some exceptions. Firstly, the **Bolar exemption**,[10] which allows the testing for generics/biosimilars while they are still under the patent/SPC protection period of the reference medicine. The rationale for this exemption is to enable the swift introduction of generic medicines shortly after the patent/SPC term of the original product has expired. Otherwise, tests for regulatory approval of generics would only start once the SPC has expired. This could delay their market entry by months or even years. Secondly, the 2019 amending Regulation (EU) 2019/933 introduced the **SPC manufacturing waiver**.[11] This exception permits: i) the manufacturing of generics and biosimilars that are still under SPC protection in the EU, provided that these products are exported to third countries without SPCs or where SPCs have expired earlier;[12] or (ii) the storing of a product subject to an SPC before placing it on the EU market after SPC expiry. The waiver aims to support access to medicines in developing countries in particular, and to promote competitiveness of EU-based pharmaceutical companies worldwide.

The SPC Regulations cover specific categories of products, qualified as PPPs or medicinal products, and defined in the first article of each regulation, taking into consideration the purpose for which these products are used. **PPPs** are **active substances and preparations** containing one or more active substances intended to protect plants (or plant products) against harmful organisms or prevent the action of such organisms, influence the life processes of plants, preserve them, destroy undesirable plants or parts of plants, and check or prevent undesirable growth of plants. **Medicinal products** are presented as **substances** (or combination thereof) for treating or preventing disease in human beings or animals, and any substance or combination thereof, which may be administered with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or animals. According to the 2009 Regulation, 'product' means the active ingredient (AI) or combination of active ingredients of a medicinal product.

Considering the complexity of the substances concerned, and the legal, economic and health implications, the detailed terms of the definitions are sometimes subject to controversial interpretations, for instance on what encompasses an 'active ingredient' in the 2009 Regulation compared with an 'active substance' in the PPPs Regulation.[13] The Court of Justice of the EU (CJEU) has developed a case law in an attempt to clarify these terms, in particular in relation to what constitute medicinal products, the definition of which appears less detailed.[14]

The **scope** of the SPC Regulations is limited to products that are protected by a **basic patent** in a Member State and that were subject to an administrative market authorisation procedure (in the Member State) prior their marketing (Article 2). A 'basic patent' protects the product's claims, which

can range from a product as such, to a process of obtaining a specific product/outcome, to an application of that product.[15] Even if the patent relates only to the method of manufacturing a product or its use, without the AI as such being the subject of the patent, the method or use might be subject of an SPC. This basic patent can be a national or a European patent.

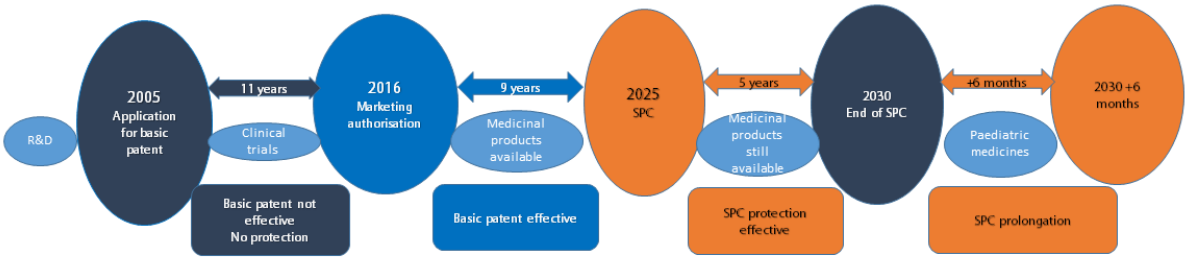
Conditions for obtaining an SPC include a **valid marketing authorisation (MA)**. An MA is the entitlement for placing the product on the market, if the MA was granted in accordance with Directive 2001/83/EC on the Community code relating to medicinal products for human use and Regulation (EU) 2019/6 on the Community code relating to veterinary medicinal products (see Article 3(b).[16] Whereas the identification of one single product/substance that received an MA is straightforward, there are numerous cases implying a combination of substances/active ingredients The CJEU clarified the link between the product(s) concerned and the subject matter of the MA.[17]

The product **must not have been the subject of a certificate**; again, it is key to identify clearly the product concerned, the subject matter of the patent, and the patent holder. For instance, the holder of more than one patents for the same product cannot benefit from more than one SPC for that product. In reality, there are many situations where the link between a patented product and a certificate is not straightforward. There could be several basic patents for one product, for example in a situation where: i) patent holder A has a patent that protects the product per se; ii) patent holder B has a patent for a process for making the product; and patent holder C has a patent for a therapeutic use of that product. The courts often will clarify the question and/or refer it for interpretation to the CJEU.

The MA must be the **first one ever granted** to the product (Article 3(d)).[18] Articles 7, 8, 9 specify requirements for lodging an application, including the timeframe, the content of the application, and the relevant authority. The application has to be filed in each Member State where the SPC is sought and the national relevant authority and courts will deal with it.[19] The 2009 Regulation comprises additional details on extending the SPCs. When the authority grants or rejects the SPC, Member States' legislation may dispense the authority to verify some of the conditions, for instance if the product has already been the subject of a certificate or if the MA is the first one (Article 10). Notification of the granting of a certificate are published (Article 11). Member States may require the payment of annual fees for the SPC (Article 12).

The **duration of the certificate** is calculated to take into account the time taken to obtain the first MA. The duration is equal to the period that elapsed between the date on which the application for a basic patent was lodged and the date of the first MA, minus a period of five years (Article 13(1). Moreover, an SPC cannot last longer than five years (Article 13(2). In the example below, five years are withdrawn from the 11 years that have elapsed since the filing of an application for a patent. The six remaining years are reduced to five in accordance with the legal maximum.[20] Despite this limit, the example shows how SPCs allow for an effective protection of 14 years that otherwise would be reduced to nine years because of the long testing periods for obtaining an MA. The example below includes the additional six months allowed for paediatric medicines.

Example



Source: Compiled by the author, EPRS.

The certificate may be **invalid** or subject to **revocation** if conditions to grant it were not fulfilled, including on request from a third party filed with the competent authority (Article 15). These changes are, in any case, published. Any decision taken by the relevant authority or requested by a third party is subject to an appeal under the applicable national law (Articles 18-19).

European Commission reports and consultation activities

European Commission ex-post evaluation

On 8 March 2022, the Commission published a call for evidence in support of its initiative. The online public consultation from 8 March to 5 April 2022 gathered 61 contributions, more than half of them provided by companies and business associations, the third main contributor being citizens, with 17 % of contributions. The Commission's evaluation, which covers the period from 1992 to October 2020, considers all EU Member States during that period. Its scope is limited to SPCs. It does not analyse IPs in their entirety, nor how they interact, and does therefore not include a comprehensive analysis of questions on the impact of IP or their use to distort competition rules, as this would go beyond the scope of evaluation.[21]

Effectiveness was assessed for each of the three objectives.

- The first objective was to encourage R&D of new products for EU patients and PPP consumers. The analysis of available data and perceptions of major stakeholders indicate that the implementation of SPCs has had some positive impact on innovation since the 1990s. However, it also shows that other factors may influence the allocation of investment in pharmaceutical and PPP research.
- The second objective was to attract R&D centres and prevent R&D centre delocalisation. The impact was positive, and, in some cases, decisive.[22] However, in a context of global competition, the Asian market is increasingly becoming attractive for investment. Even if the EU pharmaceutical industry remains highly attractive for investment in R&D, including for PPPs, several other factors are key in determining the geographical location of R&D. SPCs are among the positive factors, but the industry also considers other determining drivers.[23]
- The third objective was to introduce a uniform SPC system at EU level. Member States were expected to grant SPCs under the same conditions in order to facilitate the free movement of medicines and PPPs within the single market. As analysis shows, where Member States are left with leeway to implement provisions, there is fragmentation across the EU. This has been observed at various stages:
  - in granting procedures;[24]
  - in the length of examination, which may be detrimental to generics companies that for business planning reasons, need to know rapidly about a product's eligibility;
  - in outcomes of the examination procedure of applications, the same product being granted an SPC in one Member State but rejected in another;
  - in conflicting outcomes of court proceedings in different Member States.

The main stakeholders reported discrepancies regarding the publication of SPC-related information and/or their accessibility, and most concluded that there was a detrimental lack of transparency, predictability and legal certainty. These discrepancies affect both SPCs holders and third parties such as generic manufacturers. There were also reports of differences in the implementation of the Bolar exemption.

The assessment of **efficiency** considered the **ratio between the benefits of the SPC regime and the costs associated with these benefits**. The SPC system is designed to foster R&D; innovation comes with costs that should ideally be compensated by benefits afforded by the extended protection under an SPC. Analysis suggests that innovation is compensated in various ways, in

particular by additional sales of medicinal products over the years, and by making new medicines available as a result of R&D. Prices impacted by other factors are not considered as decisive in the costs-benefit ratios. Furthermore, with the introduction of the **Bolar exemption**, it seems that the delayed introduction of generics on the market (and the related price reductions) due to SPCs was not counterproductive. These delays are expected to be both limited and proportionate compared with the gains from increased innovation.

The SPC system concerns only a limited number of medicinal products, leaving a wide range of other **medicines available and affordable**. The average duration of an SPC is limited to three and a half years. This is a benefit compared with the decreasing term of protection under a basic patent. There are arguments for the real benefit of SPCs in comparison with investment in R&D. However, most SPC holders, as well as a study on the economic impact of SPCs, stressed that cutting the duration of the SPC would be detrimental to innovation.

On the other hand, **costs owing to the fragmentation of the legal framework** are deemed more detrimental to the cost-benefit ratio. For SPC users, in particular SMEs and start-ups, discrepancies between grant and litigation procedures across Member States generate legal uncertainty, as well as additional costs and red tape. Likewise, fees vary from one Member State to another. For generic and PPP manufacturers, who have to monitor SPC grant procedures in order to complete their business plans, legal discrepancies across the EU cause additional costs and legal uncertainty. For consumers, patients and health authorities, the fragmentation raises concerns as to whether the pharmaceutical industry may have to neglect less attractive markets. This could impair the availability and affordability of new medicinal products in some Member States. Similarly, NPOs are affected to different degrees, depending on the size of the market where they operate, with potential negative consequences. For all stakeholders, consultations showed considerable support for transforming the SPC system into a unitary one.

Finally, as indicated earlier, the lack of full transparency has a detrimental impact on legal certainty.

In respect to **relevance**, the three initial objectives remain highly relevant. In a global context of high competitiveness and societal changes, innovation in the pharmaceutical and PPP sectors is key. For the same reasons, attracting R&D centres and preventing delocalisation are still on the EU agenda, as the COVID-19 pandemic has – unexpectedly – shown. The setting up of a unitary system is in line with other EU priorities such as the need for strengthening the single market, and called for by most stakeholders. In view of the problems caused by legal discrepancies between Member States, the SPC waiver was adopted to facilitate the manufacturing and storing of generics and biosimilars in 2019. Questions also exist on the relevance in relation to **technological developments**. SPCs were designed to support a certain type of innovation, namely the development of new active ingredients. With the emergence of new medical technologies, questions arose on the applicability of SPCs. In some cases, the CJEU clarified the scope; in cases of *incremental research*, based on existing products, SPCs are not applicable but could be granted under certain conditions pertaining to the existence of a *secondary medical use patent*.[25] There do not seem to be major obstacles to granting SPCs for *biotechnology techniques*, and for *personalised medicines*[26] depending of specific conditions relating to a secondary medical-use patent and an MA. SPCs are not granted for medical devices per se, nor for *companion diagnostics*, except possibly when administered *in vivo*.[27] SPCs are reportedly not available for many *nano-medicines*.[28] Challenges still exist with regard to *unmet medical needs*.

The evaluation concluded that there was **internal coherence**; both SPC Regulations are largely similar, and the CJEU has clarified certain dissimilarities. The SPC framework's specificities make it more complex to ensure **external coherence** with other EU rules. First, the nature and implementation of SPCs are fully dependent on the basic patent framework and MAs, except for the recent SPC waiver. SPCs interlink with the EU patent package and the Unified Patent Court, which will deal with SPCs for Member States, provided they ratified the UPC agreement. Second, the regulatory law applicable to MAs provides for several type of MAs, and is therefore challenging for

the proper application of SPCs. Third, some Member States apply the Bolar exemption beyond EU pharmaceutical legislation. Fourth, the most relevant international agreements do not address SPCs directly However, the SPC Regulations facilitated the inclusion of SPC-related provisions in EU bilateral trade agreements, enabling better protection of medicines and PPPs in non EU-countries.

Despite shortcomings owing to fragmented application, most of the relevant stakeholders concur on the **EU added value** of the EU SPC framework. The alternative of implementing only national legislation would have been detrimental to the functioning of the single market, and thus to equal access to medicines.

Stakeholders' consultation

In support of the 2020 evaluation, **public online consultations** with six stakeholder groups took place. Group I comprised the general public. Group II included originators such as universities, start-ups, SMEs and large companies conducting research to develop new products. Group III comprised companies dealing with generics. Group IV concerned large EU consumers/purchasers of PPPs or medicines; health professionals and associations; health and price-setting authorities; and patient associations. Group V focused on national authorities such as the NPOs and EU Member States courts, and IP agents and attorneys. Group VI included industry/trade authorities. The consultations gathered 231 replies.

In addition, the Commission used consultations contracted by third parties. In the context of its legal study, the Max Planck Institute conducted two detailed surveys (the Allensbach surveys). One survey addressed detailed and technical questions for patent offices and IP practitioners (including judges), while the other concerned the pharmaceutical industry.

European Parliament position / MEPs' questions

In its resolution of 2 March 2017 on **EU options for improving access to medicines**, Parliament stressed the link between **IP, access to medicines and innovation**. It insisted on the need for a stable and predictable IP regulatory framework, as well as its proper and timely implementation, as essential to creating an innovation-friendly environment, supporting patient access to innovative and effective treatment. It recalled that the aim of IP is to benefit society and promote innovation, and expressed concern about the abuse/misuse thereof. Parliament recommended that the Commission analyse the overall impact of IP on innovation and on patient access to medicines, and in particular, to analyse in a study the **impact of SPCs**, data exclusivity and market exclusivity on the quality of innovation and competition.

Following the COVID-19 crisis, IP and SPCs became increasingly part of the debate around R&D, access to medicines and competitiveness. On 10 July 2020, in its resolution on the **EU's public health strategy post-COVID-19**, Parliament insisted that a robust IP system must be maintained in the EU, to encourage R&D and manufacturing in Europe. It called on the Commission 'to assess the impact of IP incentives on biomedical innovation in general and to explore credible and effective alternatives to exclusive protections for the financing of medical R&D, such as the numerous tools based on de-linkage mechanisms'.

In its resolution of 11 November 2021 on the **IP action plan to support the EU's recovery and resilience**, Parliament further examined IP. The resolution stressed the need to establish a unitary SPC regime, and called on the Member States to support the establishment of a unitary SPC title 'as a logical extension of unitary patent protection'. Parliament underlined that SPC granting procedures are inefficient, and impede innovators and producers to the detriment of patients' equal access to treatments. It is necessary, insisted the EP, to have a level playing field for makers of generics and biosimilars in the EU, and insisted on innovation being a key driver for the timely supply of medicines, their affordability and swift availability.[29] It stressed that a revision of the Bolar exemption can only be done after a comprehensive impact assessment.

In its resolution of 24 November 2021 **on the pharmaceutical strategy**, Parliament reiterated the link between the role of SPCs and the development and marketing of generics and biosimilars. It called on the Commission to re-evaluate the added value of the SPC regime, and to revise where appropriate the use of SPCs in order to prevent delays in access to generics and biosimilars. Parliament stressed that establishing a SPC unitary system can foster the competitiveness of generics and biosimilars while facilitating patients' equitable access to treatment. It stressed that 'the use of SPCs should be allowed only in exceptional and justified cases'.

MEPs questions

During the previous legislature (2014-2019), questions concerned mainly the adoption process of an SPC manufacturing waiver and its impact on access to medicines, as illustrated by two questions.

Written question by **Joëlle Mélin (ENF)**, 30 January 2018

The Member recalled the outcome of a 2017 judicial case, where the French judicial authorities ruled that the SPC issued by a laboratory was not valid, allowing instead the marketing of generics. The Member recalled that three other Member States had rejected the manufacturer's SPC request, and that generics were already available in these states. However, in other Member States, the SPC was a barrier to access to generics, thus hindering access to preventative HIV treatment. The Member requested clarifications on the Commission's timetable for its draft revision of the SPC Regulation.

Written answer given by **Ms Bieńkowska** on behalf of the Commission, 28 June 2018

The Commission clarified that further to the announcement in the 2015 single market strategy, it adopted a legislative proposal on 28 May 2018 that proposes a targeted adjustment to the existing SPC Regulation through the introduction of a manufacturing waiver for export purposes.

Written question by **Brian Hayes (PPE)**, 19 July 2018

The Member noted concerns by the industry that the proposal to introduce a manufacturing waiver for export purposes does not go far enough to alleviate existing barriers. The Member asked why the new proposal would prevent earlier access to medicines for European patients by allowing generic companies to produce only for export outside of the EU, and as a result of day-one launch of generics after an SPC expiry. He also asked the Commission to explain why the proposal applies only to future medicines and not to existing ones, which are to come off-patent over the coming years, thereby denying more immediate access to affordable medicines to European patients.

Written answer given by **Ms Bieńkowska** on behalf of the European Commission, 8 October 2018

The Commission explained the rationale behind its proposal, stating that it aims to balance the interests of the whole spectrum of stakeholders, i.e. patients and generic and originator companies. As the Commission noted, the first objective of the proposal is to foster competitiveness of EU-based manufacturers of generics and biosimilars, and that it will thus also benefit EU patients. According to the Commission, supplying the EU market as soon as the SPC expires will be facilitated by the existence of manufacturing facilities in the EU, set up to produce and export medicinal products during the term of the SPC. The applicability in time of the proposal represents a suitable compromise between the need for legal certainty for SPC holders and respect of the EU Charter of Fundamental Rights and for swift applicability of the waiver so as to avoid delaying its benefits.

In the current legislature, there has been one specific question on the future unified SPC regime.

Written question by **Pernille Weiss (PPE)**, 24 April 2022

The Member underlined how the strong legal foundations of IPRs including the SPC regime are a key tool for attracting innovative companies to settle and expand in the EU. The Member asked whether the forthcoming proposal for a single procedure for the granting of SPCs would complement rather than alter the existing regime, and how the Commission would address the

system's fragmentation. The Member also asked how the Commission would mitigate risks to the predictability and stability of the SPC regime once the new proposal is introduced.

Written answer given by **Mr Breton** on behalf of the European Commission, 21 June 2022

In its reply, the Commission stated its objective to improve the current SPC procedures, and complement the unitary patent, thereby making the system more predictable, transparent and efficient for its users. For the Commission, the high costs and heavy administrative burden caused by the fragmented implementation of the SPC system justify the need to increase legal certainty and to provide unitary SPC protection in relation to forthcoming unitary patents.

Council of the European Union

In 2016, the Council adopted conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States, underlining the role of IP. The Council stressed that 'the functioning of the pharmaceutical systems depends on a delicate balance and a complex set of interactions between MAs and measures to promote innovation, the pharmaceutical market, and national approaches on pricing, reimbursement and assessment of medicinal products'. It recalled that 'a division of competences between Member States and the EU level' make it challenging to reconcile the safeguard of common interests, the access of patients to safe, effective and affordable medicinal products and the sustainability of national health systems. In this context, the Council invited the Commission to analyse the overall impact of SPCs on innovation and on the availability and accessibility of medicinal products, including generic medicinal products and the use of the 'Bolar' patent exemption.

On 18 June 2021 in its conclusions on intellectual property policy, the Council recalled the objectives of granting SPCs 'to compensate innovators for the loss of effective patent protection resulting from the time needed for mandatory clinical trials and MAs procedures'. However, the Council stressed that due to the national implementation of SPCs, different decisions might be adopted within the EU, resulting in parallel legal proceedings, 'potentially causing inefficiency, legal uncertainty and lack of clarity and predictability'. The Council therefore highlighted the importance of working towards a more coherent system, and the efforts in the IP action plan to improve the SPC system.

European Court of Justice

Extensive CJEU jurisprudence exists. A study on the legal aspects of SPCs in the EU analysed this case law, and its impact on implementation of the legislation, in detail. It noted that the 'CJEU has developed the legislation. (…) The results of this process are ambivalent'. It stressed the substantial impact of the jurisprudence on the original scheme, speaking of 'a gap between written law and case law'. The study argued that the balance between interests at stake is a matter of policy options, suggesting that more consistency is needed.

A number of significant cases illustrate the stakes and the complexity of conditions for granting patents and SPCs. They reveal the subtle balance between the search for an interpretation in line with the objectives of the SPC Regulations and a literal interpretation of the texts. The evolving interpretation of **conditions for obtaining** an SPC (Article 3) illustrate difficulties.

a) If a **basic patent** designates *only one active ingredient from a combination of active ingredients* in an authorised medicinal product, the Court analysed whether an SPC for that medicine can be obtained on the basis of such a patent.[30] In 2011, the Court ruled in *Medeva* that an SPC can only be granted for AIs '*specified* in the wording of the claims of the basic patent'. In 2013, in *Eli Lilly*, the Court added that specified could encompass a functional definition of the AI, 'on condition that … the claims relate, implicitly but necessarily and specifically, to the AI in question'. The ruling still left space for interpretation.

In 2018, in Teva v Gilead, the Grand Chamber clarified the scope of the patents that can be used to obtain SPCs in light of the interests at stake. Gilead, an innovator, claimed validity of an SPC granted

for an anti-HIV medicinal product resulting from the combination of two AIs; the basic patent was granted for only one of the AIs. Producers of generics disputed the validity of the SPC. The Court ruled that a combination of AIs is protected when the basic patent refers specifically to that combination of AIs, even without expressly mentioning each of them. An expert or 'person skilled in the art' must be able to identify the combination of AIs, as well as the individual ingredients. The Court ruled considering all the interests at stake, including those of public health. It concluded that 'to accept that an SPC could grant to the holder of the basic patent protection, which goes beyond the protection guaranteed by that patent (…) would be contrary to the requirement to balance the interests of the pharmaceutical industry and those of public health as regards the encouragement of research within the European Union by the use of SPCs'. It ruled that 'the claims cannot allow the holder of the basic patent to enjoy, by obtaining an SPC, protection which goes beyond that granted for the invention covered by that patent'.[31] In this case, several national courts subsequently annulled the SPC.

b) On the question of whether the **marketing authorisation** of a medicinal product that contains a combination of AIs can be used to obtain an SPC for only one AI from that combination, the Court replied positively in *Georgetown University*. Such an MA can be used only if this is the first authorisation.

c) On the questions surrounding the scope of a **first authorisation**, there have been changes over time. In *Neurim*,[32] the Court concluded that if an AI had been authorised in any earlier MA within the EU, even if the earlier authorisation related to a different use in a different species, this does not preclude the grant of an SPC on a new MA. The application must be within the limits of protection conferred by the basic patent.[33]

Some argued that this ruling provided an incentive for companies to engage in the research of new uses of previously authorised AIs. Others claimed that it risked encouraging 'evergreening' practices. Questions remained as to the possibilities of applying this jurisprudence more widely.[34] Subsequent decisions of the Court got more restrictive. In *Abraxis Bioscience*, SPCs were requested for *new formulations* of previously approved AIs, relying on the first MA. The Court ruled that such an MA cannot be considered the first, since the AI had been previously authorised. In 2020, in *Santen SAS*, the Court confirmed this ruling in the event of a *new therapeutic application* of an AI previously authorised for a different therapeutic use.[35] The Court held that the notion of 'product' does not depend on the way in which the product is used, thereby dismissing conclusions from *Neurim*.

The changes in the case law reveal the need for and difficulties in striking a balance between the SPC regulations' main objectives: on the one hand, encouraging pharmaceutical research by favouring a broader interpretation of conditions for granting SPCS, and on the other, ensuring the interests of public health by favouring earlier access to medicines at reasonable prices through generics. Two referrals are currently pending on **whether an SPC for a combination of AIs can be granted if an SPC for one of the single agents of that combination already exists**.[36]

ENDNOTES

1 Innovators (or originators) are companies that develop new medicines or active ingredients. They are typically the SPC holders, but are becoming leaders in the production of biosimilars; see glossary in the Commission evaluation.

2 Testing may take a significant amount of time (around 12 years), which consequently has to be withdrawn from the patent protection lifetime of 20 years from its filing date, see A Whistlestop Guide to SPCs, February 2020.

3 An orphan medicine is a 'medicine for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition that is rare (affecting not more than five in 10 000 people in the EU) or where the medicine is unlikely to generate sufficient profit to justify R&D costs'.

4 The Regulation on medicinal products for paediatric use and the Regulation on orphan products are often dealt with concomitantly, because most rare diseases may appear already in children, and many children's diseases are rare.

5 The evaluation on both regulations concluded that even if this reward is partly fulfilling its role, it has not shown to be effective in stimulating the development of medicines whose development for adults is not attractive. Obtaining this reward may be complex, as companies have to request it individually at the various national patent offices.

6 It is a condition for which there exists no satisfactory method of diagnosis, prevention or treatment, or if such a method exists, it should bring major therapeutic advantage to those affected. There is no common definition among stakeholders.

7 The 2020 pharmaceutical strategy aims to support industry in promoting research and technologies, and to address market failures exposed by the pandemic. Its four pillars are: i) ensuring access to affordable medicines for patients and addressing unmet medical needs; ii) supporting competitiveness, innovation and sustainability of the EU's pharmaceutical industry and the development of high-quality, safe, effective and greener medicines; iii) enhancing crisis preparedness and response mechanisms, diversified and secure supply chains to address medicines shortages; iv) ensuring a strong EU voice in the world by promoting high-level quality, efficacy and safety standards.

8 For details about the start date, see European Patent Office.

9 A European patent application granted by the EPO will either end up as one or more validated patents or turn into a single patent with unitary effect. It will be up to the patent holder to decide which option suits him/her best.

10 The Bolar exemption is laid down in Article 41 of Regulation (EU) 2019/6 on veterinary medicinal products and repealing Directive 2001/82/EC; for medicinal products, see Directive 2001/83/EC, Article 10(6).

11 The 2017 public consultation, prior to the 2019 revision, had two main conclusions: i) a combination of factors influence companies' decisions on investing; ii) the SPC regime is globally effective, despite its fragmented implementation.

12 The amendment came into effect on 1 July 2019. SPCs granted prior to this date are not affected.

13 See corresponding Article 1(a) in both regulations.

14 See analysis in the Max Planck Institute study on the legal aspects, in particular pp. 133-144 on what an active substance vs an active ingredient could be. For PPPs, see example of controversy in 2013 *Bayer CropScience AG* where the CJEU that deemed possible to consider safeners to be covered by the term 'active substances'.

15 Article 1(c) Regulation (EC) 469/2009 and Article 1(9) Regulation (EC) N°1610/96.

16 Before entering the EU market, medicines must undergo strict testing and an assessment of their quality, safety and efficacy. Directive 2001/83/EC for medicinal products and Regulation 2019/6 for veterinary products that repealed the Directive 2001/82/EU lay down provisions for their authorisation, manufacture and distribution in the EU.

17 The authorisation must be for a product that includes the relevant AIs. The MA granted for a combination of A+B can be the basis for an SPC only for A. See CJEU judgments *Medeva* and *Georgetown University*.

18 For more details on clarifications by the CJEU, see the relevant case law below.

19 When the Unified Patent Court enters into force, nationally granted SPCs may be centrally enforced.

20 See recitals 9 and 10, which underline the need to consider all the interests at stake, including those of public health.

21 For instance, there is circumvention of IP protection rules for the 'evergreening' of patent rights to avoid competition. 'Evergreening' typically describes strategies for extending the protection on a medicinal product through accumulation of monopoly rights – such as secondary patents on formulations or new combinations of AIs, and forms of exclusivity – beyond what could be considered fair; see Access to medicinal products, EPRS, 2021, p. 31. See also CJEU case law below.

22 During consultations, 33 innovators stated that the eligibility for SPC protection had been decisive in the development of new products. Seventeen out of the 33 developed it in Europe. In another survey, 57 % of the originators agreed that the SPC prevented relocation (Allensbach survey by MPI).

23 Such as the proximity of research universities, access to high-skilled labour, and the ease of recruiting patients or accessing treatment groups. See the list of other factors on p. 29 of the evaluation, and the SWOT analysis in Annex 9 concerning the EU as a location of R&D investment on the pharmaceutical and PPPs sectors.

24 As shown by the implementation of Article 3(c) and (d), for which Member States have no verification obligation.

25 There is second medical use 'where a substance or composition is already known for one medical use, and may still be patentable for a second or subsequent medical use, provided that use is novel and inventive (Article 54(5) EPC). For the arguments in favour of more patent protection for second medical uses, see Importance of second medical use protection is growing, Kluwer Patent Blog, 22 May 2021.

[26] A medical treatment using analysis of individuals' phenotypes and genotypes (e.g. molecular profiling, medical imaging, and lifestyle data) to: i) tailor the right therapeutic strategy to the right person at the right time; ii) determine a person's predisposition to disease; or iii) deliver timely and targeted prevention; see glossary in the Commission evaluation.

[27] A companion diagnostic is a medical device, often an *in vitro* device, which provides information that is essential for the safe and effective use of a corresponding medicine or biological product. The test helps a healthcare professional determine whether a particular therapeutic product's benefits to patients will outweigh any potential serious side effects or risks.

[28] Nano-medicine is a branch of medicine that seeks to apply nanotechnology to the prevention of disease and to imaging, diagnosis, monitoring, treatment, repair, and regeneration of biological systems. Nanotechnology is the use of matter on atomic, molecular, and supramolecular scales including for medical purposes.

[29] On 6 April 2022, Parliament adopted resolution on global approach to research and innovation. It underlined that health, preventive medicine and healthcare have at their core the principles of open access, data sharing, IPR management and the '3 As' – availability, accessibility and affordability; these principles should apply to research projects that develop medicinal products and technologies to serve the local communities while improving access to health services.

[30] This is key in the vaccine field where patents are often filed for single AI classes years before combination uses are identified.

[31] See case paragraph 41 CJEU.

[32] In its study (pp. 230-239), the MPI concluded: 'Whether or not a patent for the new use of an AI already authorised for medicinal purposes deserves SPC protection is a decision that must be made by the lawmakers. Therefore, we recommend closing the gap between the wordings of Art. 3(d) and the case law'.

[33] In this case, the first MA was granted for melatonin as a veterinary product; the second MA was requested for melatonin (named circadin) as a human medical product. The United Kingdom NPO refused to deliver this authorisation, claiming that this was not the first MA; for more details, see Neurim -- 'the most important SPC judgment ever', 22 July 2012.

[34] For instance, to allow SPCs for any new therapeutic applications, different formulations, dosages and methods of administration of previously authorised products.

[35] This refers to SPC based on a 'second medical use' patent. In this case, cyclosporine was an AI that was initially authorised in 1983 for a product named 'Sandimmun' aimed at preventing rejection of transplants. In 2015, a second MA was granted for the product 'Ikervis', with cyclosporine as one AI, which aimed to treat severe keratitis. The Santen company applied for an SPC in France based on a European patent claiming an ophthalmic emulsion in which the AI is cyclosporine. In its application, Santen referred to the MA it had been granted in 2015.

[36] *Merck Sharp & Dohme Corp* and *Teva and Teva Finland*; see Recent ECJ case-law-and-latest referrals preliminary rulings on SPC Regulation, 29 September 2022.

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