

EXECUTIVE SUMMARY

General remarks

1. This Study examines the functioning of the system of supplementary protection certificates (SPCs) established in the EU by Regulation 1768/92/EEC on SPCs for medicinal products (now: Reg. 469/2009/EC) and Regulation 1610/96/EC on SPCs for plant protection products (henceforth: the Regulations) from a legal perspective. The functioning of the Regulations is considered in the context of adjacent legislation concerning the marketing authorisations for medicinal and plant protection products. Furthermore, the Study examines the impact of the UPCA on the *Bolar* exemption and the option for creating a manufacturing waiver. Finally, the Study investigates legislative and institutional options for creating a unitary SPC complementing the system of European patents with unitary effect in the internal market (“unitary patents”).

Background of the SPC legislation

2. The purpose of the SPC legislation was to create patent-like *sui generis* rights compensating patent holders for the time loss experienced in two sensitive technological fields where new products are subject to extensive regulatory procedures prior to commercialisation. By establishing common standards in this regard, the EU legislature sought to prevent the emergence of diverging national legislation, so as to safeguard the integrity of the internal market. Furthermore, the SPC Regulations were aimed at preserving the competitiveness of Europe as an attractive location for pharmaceutical and plant-protection-related research. At the relevant time other jurisdictions, such as the US and Japan, had already enacted legislation providing for an extension of the patent term, *inter alia*, in the pharmaceutical field.
3. Although SPCs conform in many ways to patents and are therefore generally recognised as a form of intellectual property (IP), they are clearly distinct from other IP rights. First, SPCs are of a hybrid nature: their grant is contingent on the existence of a basic patent and of a marketing authorisation (MA) covering the product. Second, SPCs are based on the Regulations, i.e. on Union law with direct effect throughout the EU; however, unlike, for instance, Union trademarks and Community designs, they are not unitary titles of protection. Under the current system SPCs are national, territorially restricted rights granted by national offices. Both features – the hybrid nature of SPCs and their construction as national rights based on an act of Union law – contribute to the fact that SPCs are quite unique, both within the EU and internationally. They also account for a number of peculiarities addressed in this Study.

Methodology

4. The Study primarily employs a legal-analytical approach. It identifies and examines the relevant legal sources, undertakes an analysis of CJEU case law and national jurisprudence, and provides an account of the scholarly literature. In addition, the appraisal of relevant issues is also based on a fact-finding

process. For this purpose, the Study includes, on the one hand, an evaluation of data provided by readily available sources, such as registration statistics. On the other hand, data and information were specifically collected for the Study. A questionnaire was distributed to the National Patent Offices (NPOs) in order to identify and document divergences of law and practice as well as issues considered problematic. Furthermore, the experience and opinions of stakeholders were investigated by way of an online survey (conducted by IfD Allensbach) and through qualitative interviews. The representatives of both NPOs and stakeholders were invited to participate in the presentations and discussions at workshops organised in Munich in March and September 2017. The data collected and contributions received are documented in the Annexes to the Study.

System efficiency and demand for reform

5. Measuring the efficiency of an incumbent legal system is difficult. In this regard the Study primarily relies on the evaluations expressed in the communications by the NPOs and by stakeholders. There is general agreement that the system, by and large, fulfils its purposes. However, regarding the details of protection, some legal uncertainties have arisen that could jeopardise the smooth functioning of the SPC regime. In particular, inconsistencies and unclear notions resulting from the CJEU's interpretation of central provisions in the SPC Regulations make it difficult for the NPOs to adapt their own practice to the criteria elaborated by case law without causing divergences in relation to their own previous practice or that of other offices. While originator companies tend to be basically confident that the system will correct itself in the long run, generic manufacturers contend that an overhaul is needed in order to strike the right balance. That a need for adjusting the balance exists is also specifically emphasised by the latter group in view of the limitations of the rights conferred, which are considered to be too narrowly tailored to respond efficiently to the challenges of enhanced global competition. Apart from that, all parties agree that a demand for reform exists as far as the creation of a unitary SPC system is concerned.
6. The Study aims at a systematic review of the SPC legislation. In the limited context of this executive summary, we will focus on three topics: the prerequisites and the scope of SPC protection as interpreted by the CJEU, the breadth of limitations and exceptions, and the creation of a unitary SPC system.

Conditions for granting SPCs: the impact of CJEU case law

7. For a deeper understanding of the impact of CJEU case law, it is necessary to revisit the legislative objectives reflected in the *travaux préparatoires* and in the preamble to the SPC Regulation on medicinal products as enacted in 1992. From those sources it emerges quite clearly that the original intention was to incentivise research in new active ingredients. Indeed, the SPC was to be granted only on the basis of the first MA in the Member State concerned (Art. 3(d) Reg. 469/2009). Only one SPC was intended to be possible for any active ingredient (Art. 3(c) Reg. 469/2009). The combined effect of these provisions was that a certificate should be granted only for substances that were

authorised for the first time as active constituents of a medicinal product. If the product had already been authorised in the past, and the applicant identified new uses or a new formulation of the product and obtained a more recent MA, an SPC was meant to be excluded due to either Art. 3(d) Reg. 469/2009 or Art. 7 Reg. 469/2009, depending on whether the applicant relied on the first or the second MA obtained.

8. This limitation of the subject matter eligible for a certificate corresponded to a conscious decision of the EU legislature. The *raison d'être* of SPCs was not the mere fact that medicinal products (or plant protection products) are subject to a product approval. Such requirements also exist in other technical fields. The main reason for creating SPCs was the assumption that because of the significant amount of pre-clinical and clinical work needed to develop the data necessary for obtaining a marketing authorisation for a new active ingredient, pharmaceutical research could become unprofitable. Expressed in the terminology of IP theory, the reason for the extended exclusivity was that the standard 20-year term of patent protection was deemed insufficient to prevent a market failure (see Recitals 3-6 Reg. 469/2009). At that time, this risk was perceived only for new active ingredients, but not for excipients, adjuvants, new formulations or new indications of old active ingredients. As a consequence, where a substance was already authorised as an active ingredient of a drug, it could still be possible to obtain patents for inventive uses, formulations, manufacturing processes or variants of the substance. But since the prerequisites for obtaining an MA are considerably less demanding in such cases as compared to MAs for new active ingredients, the need for additional incentives beyond ordinary patent protection was considered minor. The interest of the public in obtaining access to the medicament after the lapse of the regular patent term was therefore given precedence.
9. In practice, the system envisaged by the historical lawmakers underwent changes. By resorting to a teleological approach, the CJEU has developed the legislation. This also occurred where the text itself was not ambiguous or contradictory, and even where the intention of the lawmakers could not have been clearer. The results of this process are ambivalent. The Study attempts to evaluate the implications from both an atomistic and a holistic perspective.
10. The first requirement laid down in Art. 3(a) Reg. 469/2009 – that the product be protected by a basic patent in force – was the subject of several preliminary rulings. Nevertheless, the CJEU has so far failed to deliver a clear test for applying Art. 3(a) Reg. 469/2009. We identify three reasons why this is the case. First, the Court ruled in *Medeva* that, in order for the product to be protected within the meaning of Art. 3(a) Reg. 469/2009, it must be “specified” in the wording of the claims of the basic patent. Whether that requirement is fulfilled must be assessed on the basis of the law applicable to the basic patent (*Eli Lilly*). However, the law applicable to the basic patent does not provide for a distinction between products that are “specified” in the wording of the claims and products that are not “specified” in the wording of the claims. Second, the CJEU has not explained the purpose and the policy behind the *Medeva*-requirement. Finally, in *Actavis I* the CJEU introduced the requirement that the product must embody the core inventive advance of the patent. While in *Actavis I* that requirement was based on Art. 3(c) Reg.

469/2009, *Actavis II* refers to Art. 3(a) Reg. 469/2009 as well. As a result, it is unclear whether the inventive-advance test supplements or replaces the *Medeva*-requirement, or if it should apply only when Art. 3(c) Reg. 469/2009 is also relevant. Against this background, the Study identifies possible options for clarifying Art. 3(a) Reg. 469/2009, all based on the law applicable to the basic patent. The choice among the different options is a matter of policy. In consideration of the possible purposes underlying the case law of the CJEU, the Study recommends adopting the inventive-advance test elaborated by the English courts.

11. The teleological approach has significantly impacted the other requirements laid down in Art. 3 Reg. 469/2009. For instance, the prohibition in Art. 3(c) Reg. 469/2009 was interpreted as precluding the grant of a second certificate only when the same applicant filed the second application. This is exactly the opposite of what the rule provides for; it even goes beyond Art. 3(2) Reg. 1610/1996, which limits the grant of a second certificate to the case in which two applications are co-pending. In *Neurim*, the Court held that the scope of the patent must be considered in assessing whether an MA is the first one issued for an active ingredient, thereby relativising the principle that the issue of an SPC and its duration must be based on the first MA in the Member State and in the EU/EEA. However, nothing in the wording of Art. 3(d) and Art. 13 Reg. 469/2009 suggests that the scope of the patent is of any relevance for determining the first MA for a specific active in a Member State and in the EU/EEA. The consequences of the decision are unclear. Some NPOs understand *Neurim* as being applicable only to the factual scenario referred to in the headnotes of the judgment (a product for which an MA for veterinary use had been obtained subsequently being the subject of an MA for human use). Other NPOs – the clear majority – also apply *Neurim* when the earlier MA was for the same species as the MA submitted in support of the application for a certificate.
12. The impact of CJEU jurisprudence on the scheme originally provided for by the legislation is substantial. By abandoning the principle of one SPC per new active ingredient and admitting SPCs for products already authorised in the past, it risks undermining the balance of interests on which the SPC legislation was based. The Study recommends that the gap between written law and case law be closed. The choice between the different options is policy-oriented. If the arguments inducing the Court of Justice to liberalise the SPC system are considered convincing and better suited to the needs of pharmaceutical innovation, they deserve to be codified. If the arguments in favour of granting only one SPC per active ingredient on the basis of the first MA granted in the Member State are still considered valid, the pertinent case law should be corrected.

Third-party issue

13. Neither the *travaux* nor the preamble to the SPC Regulations convey a clear notion of who is meant to be the beneficiary of the protection granted. On the one hand, this could be the holder of any patent that covers the product for which the certificate is requested. On the other hand, it could be only the patentee that has invested in the development of a marketable product and

has obtained the MA submitted in support of the application for a certificate. The lack of precision in this regard is irrelevant as long as the patent proprietor and MA holder are the same person or act in accordance with each other. However, if they are separate entities and cooperation is denied, the question arises whether the patentee can obtain a certificate even if it has not contributed to the development of the product and the unrelated MA holder (and potential infringer) disagrees. The Study suggests that this is an issue which must be resolved by the legislature and not by the courts. Indeed, it turns upon the fundamental policy question of what the purposes of the legislation are and who its intended beneficiary is. If the aim of the SPC regime is to encourage investments in the development of marketable products after an invention is made, then only the patentee that has contributed directly (MA ownership) or indirectly (licence agreement; joint development agreement) to developing the product covered by the MA should benefit from the supplementary protection.

Rights conferred and limitations

14. Article 5 of the Regulations stipulates that SPCs confer the same rights as the basic patent and that the same limitations and obligations apply, but subject to Art. 4. Under Art. 4 of the Regulations, the certificate confers a purpose-bound protection. Indeed, the latter is limited to uses of the product as a medicinal product or plant protection product that has been authorised before the expiry of the certificate. As a consequence, it is not clear whether the mere manufacturing of the active ingredient protected as such by the basic patent for export or stockpiling purposes would infringe the certificate or not.
15. The introduction of new limitations beyond those stipulated for patents is of interest in particular in the context of so-called manufacturing waivers. Such provisions can take the form of a limitation allowing companies to manufacture SPC-protected products either to export them (export waiver) or to keep them in stock until the SPC has lapsed (stockpiling exception). From a legal perspective, manufacturing waivers in both forms are consistent with the purpose of the SPC Regulations to provide an extended period of time to compensate for the delay in the commercial exploitation of the invention that arises in consequence of the requirement for a marketing authorisation under Directives 2001/82 and 2001/83. That rationale is satisfied if the exclusive rights granted by the SPC only extend to activities that are delayed by such requirement. The production of an active ingredient or of a medicinal product including the active ingredient for export or stockpiling purposes does not require a marketing authorisation. Therefore, allowing these activities after the expiration of the basic patent does not run counter to the legal objectives of the SPC system. However, the question of whether the introduction of such limitations is warranted in order to provide a level playing field for generic companies located in the EU and those having their basis in jurisdictions where no corresponding restrictions apply raises a number of economic and political issues that require further investigation.
16. Both patents and SPCs are subject to the so-called *Bolar* exemption, which allows using protected subject matter in order to conduct studies and trials for regulatory approval. The majority of the EU Member States provide for a *Bolar*

exemption that is broader at least to some extent than the minimum standard laid down in Art. 10(6) Dir. 2001/83 or Art. 13(6) Dir. 2001/82. However, with the UPCA coming into force, the national provisions implementing Art. 13(6) Dir. 2001/82/EC and Art. 10(6) Dir. 2001/83/EC will no longer apply to European patents with unitary effect or to those European patents without unitary effect that are enforced before the UPC. Instead, the exemption laid down in Art. 27(d) UPCA will apply: this includes a dynamic reference to Art. 13(6) Dir. 2001/82/EC and Art. 10(6) Dir. 2001/83/EC, thus requiring a narrow interpretation. By contrast, national patents or European patents not litigated before the UPC may remain subject – in most EU Member States – to more liberal rules. The Study contends that the resulting fragmentation should be avoided in favour of a uniform approach. Taking account of the fact that in the course of the Study a broad approach to the *Bolar* exemption was welcomed, or at least not rejected, by a majority of stakeholders, and considering that the majority of the EU Member States have implemented a *Bolar* exemption that goes beyond the minimum standard, the Study recommends first amending Dir. 2001/82 and Dir. 2001/03 so that activities aimed at generating data for filing an MA for innovative products in the EU/EEA are also allowed. Further, the Study recommends extending the exemption to activities geared towards the acquisition of an MA in a non-EU/EEA country. This must be set forth in a separate act of Union law, since the latter activities are outside the scope of Dir. 2001/82 and Dir. 2001/03. In view of the referral to Union law included in Art. 20 UPCA and of the reference to Dir. 2001/83 and Dir. 2001/82 included in Art. 27(d) UPCA, such amendments will operate directly in proceedings before the UPC. An amendment of the UPCA to bring the wording of Art. 27(d) into line with the reform could further be smoothly adopted under Art. 87(2) UPCA.

17. Another issue of interest for both patents and SPCs in this context concerns the fact that the *Bolar* exemption or the experimental use-exemption do not apply to third parties that supply substances required for conducting a clinical trial or a research study. Several authors in the scholarly literature endorse the view that the legal objectives underpinning the two exemptions are ill-served by a restrictive approach that penalise mostly entities (like SMEs or universities) that rely on third-party suppliers. The Study proposes a bundle of legislative measures to ensure that delivery of substances by third parties is allowed if the activity of the supplied person is covered by the experimental use- or *Bolar* exemption.

Extension of the SPC regime?

18. Plant protection products and medicinal products are not the only products whose marketing is subject to the prior grant of an authorisation. *De lege lata*, the question is whether an authorisation granted under any piece of legislation other than Dir. 2001/82/EC or Dir. 2001/83/EC should be sufficient to trigger the grant of an SPC. This question is in particular relevant for drug/device combinations. *De lege ferenda* this raises the issue of whether an SPC-like compensation regime must also be created for products in other technical fields. The principle of equal treatment under Union law and the prohibition of discrimination under WTO law are equally relevant here. The study addresses both issues with a focus on medical devices.

19. With respect to medical devices as such, the Study does not offer a recommendation, since the question is of an economic nature. By contrast, it identifies the legal criteria that should govern the potential action of the lawmakers in this field. These criteria should ensure respect of international law and primary Union law, provided that the prohibition of discrimination under Art. 27 TRIPS also applies to SPCs. The reason why specific medicinal products can be protected by SPCs is that the regulatory procedures are preceded by clinical trials that require considerable time and investments in the case of new active ingredients, so that the lawmakers assume that ordinary patent protection will not be sufficient to recover such investments. If a similar risk is documented in the field of medical devices, an extension of the SPC protection would be recommended.
20. With respect to drug/device combinations, the Study considers it appropriate to admit SPC protection when all conditions for granting the certificate – except an MA granted under Art. 8 Dir. 2001/83 – are met. However, a situation in which an active ingredient is authorised for the first time for medicinal use only as an ancillary substance to a medical device is absolutely exceptional. The question is, therefore, only of practical relevance because of *Neurim*.

Creating a unitary SPC

21. In accordance with a large majority of NPOs and stakeholders, the Study endorses the view that the unitary patent should be complemented by an SPC of equal dimensions. It is true that *de lege lata* SPCs – as national rights – can already be obtained on the basis of a unitary patent, and that such rights can be enforced extraterritorially in proceedings before the UPC. However, the lack of a single granting procedure for SPCs would constitute a lacuna in the upcoming unitary patent system. After presenting and examining the institutional and legal options for establishing a unitary SPC system, the Study contends that a choice must be made between mandating an EU institution – already existing, newly established, or “virtual” – or entrusting the EPO with this task. In the case of an EU institution being charged with the grant, appeals must be directed to the General Court, whereas appeals against decisions made by a Unitary SPC Division located at the EPO could be filed at the UPC. From the point of view of expertise and consistency of the system, the second option appears preferable. On the other hand, from a legal point of view the first option is more easily implemented. Involving the EPO requires a more complex approach. However, as pointed out in the Study, the legal hurdles are not insurmountable. The majority of the stakeholders consulted in the Study favoured a system in which (i) a team of experts from the NPOs (virtual office or virtual Unitary SPC Division) examines the application and grants the certificate, and (ii) the UPC hears appeals lodged against decisions rejecting the application.
22. Regarding the kind of MA that can support the application for a unitary SPC, there is no technical cogent reason for not allowing also national MAs as a basis for a unitary SPC. The Study considers it feasible, in accordance with proposals advanced by stakeholders, to grant a unitary SPC on the basis of a bundle of national MAs, with its territorial scope being restricted accordingly.

Within this model two options are explored: the option of an SPC with static territorial scope that could be combined with national SPCs; and the option of a unitary SPC with a dynamic territorial scope that could extend to any other Member State where an MA is granted before the expiration date of the patent. In the field of plant protection products for which no Union authorisation is available, the model of a unitary right with dynamic territorial scope is clearly recommended. With respect to medicinal products, the choice is less obvious. In most cases it will be possible for the applicant to make use of the centralised procedure. For the remaining cases it may be acceptable to resort to a bundle of national SPCs.

23. Irrespective of the institutional design of the Unitary SPC Division, the legal framework accompanying its establishment will have to include guidelines and implementing rules structuring and informing procedural practice. The Study emphasises the importance of such rules as an instrument not only for enhancing the transparency and consistency of administration at the Unitary SPC Division, but also for bolstering coordination and harmonisation of practice in a horizontal and a vertical fashion, i.e. among the national offices and at the national and European level.