Intellectual property: Revising legislation on supplementary protection certificates


This briefing provides an initial analysis of the strengths and weaknesses of the European Commission’s impact assessment (IA) accompanying the above-mentioned proposals, submitted on 27 April 2023 and referred to the European Parliament’s Committee on Legal Affairs (JURI). The proposals were included in the Commission’s 2022 work programme.

Supplementary protection certificates (SPCs) are intellectual property (IP) rights that make it possible to extend the IP protection from a patent for an additional period (up to 5 years after patent expiry, plus a possible 6-month extension for paediatric medicinal products) for patented medicinal and plant protection products (PPPs). They are authorised by a regulatory authority and are intended to compensate for the loss of effective patent protection on account of lengthy authorisation procedures (e.g. compulsory clinical trials, testing). Under the existing legal framework, SPC protection is only available at national level. Building on an evaluation of the current legal SPC framework, the Commission considers that the substance of the EU’s current legislation on SPCs is still fit for purpose. However, the current system suffers from a fragmented landscape with complex and costly procedures, and it is not innovation-friendly. In addition, in June 2023 the EU unitary patent entered into force, enabling a single patent for all Member States.

The present package of four legislative proposals (two are recast regulations for medicinal and for plant protection products) has been designed to reform the SPC legal framework by introducing a ‘unitary SPC’ to complement the unitary patent, and a centralised examination procedure, implemented by the EU Intellectual Property Office (EUIPO), in cooperation with the national patent offices (NPOs) in the EU. The initiative was included in the Commission’s 2020 IP action plan, and optimising the SPC system is addressed in the 2020 pharmaceutical strategy for Europe.

Problem definition

The IA starts by outlining the political and legal context. The initiative is based on the 2020 evaluation of the SPC system for medicinal and plant protection products, in line with the ‘evaluate first’ principle. Although the existing EU legislation seems to remain relevant, the evaluation identified shortcomings. These included: fragmented implementation across Member States; inefficiencies and a lack of transparency, predictability and legal certainty; red tape and extra costs for businesses, especially SMEs; and extra costs and administrative burden for national administrations owing to examination and grant procedures being exclusively Member State based.
In its conclusions of 10 November 2020, the Council of the EU encouraged the Commission to ‘swiftly present the announced IP action plan, with initiatives to make IP protection more effective, including with regard to the supplementary protection certificate system, and more affordable, especially for small and medium-sized EU enterprises...’ (paragraph 7 of the Council conclusions). In its resolution of 11 November 2021 on an intellectual property action plan to support the EU’s recovery and resilience, the European Parliament urged the Commission to address the fragmented implementation of the SPC regime across the Member States, including by legislative proposals based on an impact assessment. It asked the Commission to ensure coherence between the (upcoming) unitary patent and current SPC regimes within the EU by clarifying that national SPCs may be granted by national patent offices (NPOs) on the basis of a unitary patent (see paragraphs 9 to 14 of the resolution).

According to the IA, one in four SPC applications covering the same product result in divergent decisions in Member States; some Member States grant SPCs for a certain product while equivalent applications are refused in others, or granted with a different scope. Follow-on producers face uncertainty about the status of SPC protection, resulting in high costs in monitoring SPC protection in the single market. Multiple parallel procedures before NPOs are necessary to obtain SPC protection, which causes administrative costs (e.g. for translations of applications, exchanges with NPOs, administrative fees payable to each NPO). High maintenance fees for the prolongation of SPC rights in each jurisdiction create burdens for companies, especially for SMEs (one in five SPC applicants is an SME).

The IA defines the main problems to be tackled by the present initiative, namely: legal uncertainty about the SPC status; cumbersome monitoring of SPC protection; high cost and burden of seeking and maintaining SPCs. The IA identifies and explains the following problem drivers, which are described in two blocks.

- **Divergent national practices on SPCs:** The outcome of national procedures is uncertain, it can happen that the same product may be protected by an SPC in one Member State while not or only partly in another Member State and/or for a different period. The duration of the granting procedure varies in each Member State. Opportunities for affected third parties to get involved in the granting procedure are regulated differently in the Member States.

- **Lack of transparency** of SPC-related information on details of SPC protection: SPC information (e.g. content of application, public accessibility, updates of the SPC-specific data bases, information in English) is inconsistent across the Member States and it is not or not easily accessible.

The IA also mentions some ‘out of scope’ problems, e.g. differences in pricing and reimbursement schemes for medicines in the EU and worldwide that affect the pharmaceutical market (IA, p. 17).

The IA substantiates its findings with references to several sources, in particular the Commission’s evaluation of the current EU legislation, the consultation activities in the preparation of the IA, desk research and monitoring of the SPC market situation of the pharmaceutical and agrochemical industries. It provides a well-structured analysis of the existing situation (IA, Annex 5, pp. 96-101). It includes a separate annex (IA, Annex 5) where it describes the SPC market, including recent statistical data on SPCs in relation to the identified problems and problem drivers (IA, pp. 102-116). It examines the nature and scale of the problems, as well as who they would affect (e.g. originator companies, innovators and follow-on manufacturers, customers, lawyers, NPOs, other public authorities) and how (IA, Annex 3). With the aid of a problem tree, the IA illustrates the drivers behind the problems and the consequences deriving from them, including limited attractiveness of the EU as a venue to develop, manufacture and sell novel medicines and PPPs, and hampered joint cross-country public procurement of medicines (IA, p. 14). The IA explains the problem drivers in a comprehensive manner (IA, pp. 18-23). It describes the views of stakeholders on the problem drivers regarding the different approaches of NPOs to implement SPC procedures.
**Subsidiarity / proportionality**

The two *recast regulations* for medicinal and plant protection products are based on *Article 114* (approximation of laws in the single market) and the two *unitary SPC regulations* for medicinal and plant protection products are based on *Article 118* (uniform protection of IP rights) of the Treaty on the Functioning of the European Union (TFEU). The unitary patent, governed by *Regulation 1257/2012*, is already based on Article 118 TFEU (see IA, pp. 96-97). The IA includes a section on subsidiarity (IA, pp. 28-29), where it describes the legal basis and explains the necessity and added value of EU action. According to the IA, EU action is necessary to provide a ‘unitary SPC’ for the unitary patent, and this can only be done at EU level. The IA states that although SPCs are already harmonised by EU law, ‘there are still cases where some Member States have granted SPCs while identical applications have been refused in others, or granted with a different scope. SPC applicants thus face diverging decisions across the EU concerning the same application’ (IA, pp. 28-29). The new introduction of a centralised and transparent SPC system would enhance the integrity of the internal market and would allow for cost savings, in particular reduced financial and administrative costs for applicants. It would also mitigate the negative consequences that result from diverging procedures. As recommended by the *Task force on subsidiarity, proportionality and ‘doing less more efficiently’*, a separate *subsidarity grid* accompanies the IA, which also covers *proportionality*. According to the IA, the initiative is limited to what is necessary to achieve the initiative’s objectives (subsidarity grid, p. 6). The deadline for the subsidiarity check by national parliaments was 23 October 2023,4 with the exception of the regulation for medicinal products proposal, for which the deadline was 27 October. No reasoned opinions had been submitted at the time of writing.

**Objectives of the initiative**

The IA identifies one general and three specific objectives of the initiative (IA, pp. 29-30). The *general objective* is to improve the availability of novel medicinal products for EU patients, and of plant protection products for agriculture, and to incentivise firms to develop those products in the EU. The *specific objectives* outlined by the IA are to: i) increase predictability and legal certainty of SPC protection in the EU; ii) facilitate the monitoring of SPCs in the single market, preferably by offering a single point of access to information about the status of SPCs in the EU, as well as access to structured data; iii) reduce the cost and burden of seeking and maintaining SPC protection by investigating possible administrative cost reductions, and improve the access to procedures to all stakeholders, especially SMEs.

The objectives correspond to the problems and the problem drivers identified in the IA. The IA uses an ‘objectives tree’ to depict the links between the general objective and the specific objectives (IA, p. 29). The specific objectives are distinct from and more specific than the general one. With regard to the S.M.A.R.T. criteria (specific, measurable, achievable, relevant and time-bound), the specific objectives appear to be specific, measurable, achievable and relevant, but not time-bound (see Better Regulation Toolbox, Tool #15). However, although the IA does not define more detailed operational objectives as laid out in the Better Regulation Guidelines, it instead links monitoring indicators directly to the specific objectives (see the section on ‘Monitoring and evaluation’ below).

**Range of options considered**

The IA screens policy options for the three specific objectives. It identifies *five policy options* (POs) in addition to the *baseline scenario* (‘no policy change’). The IA provides a broad range of options, with one option (PO1) envisaging non-legislative measures. Two options are identical (PO3 and PO4) except for the ‘key distinguishing feature that the examination authority would issue a *binding opinion* on the validity of a centralised SPC application’ in PO4 (IA, p. 33; PO3 includes a non-binding opinion). The policy options would not replace national SPCs, but would provide alternative routes to obtaining SPC protection across the EU. The policy options are summarised in Table 1.
### Table 1 – Overview of policy options

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<th>Policy Option</th>
<th>Description</th>
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<tr>
<td><strong>Baseline</strong></td>
<td>No policy change. The supplementary protection certificate system would continue to operate on the basis of the existing EU legislation and national rules.</td>
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<tr>
<td><strong>PO1</strong></td>
<td><strong>(Non-legislative) guidelines for the application of the current SPC regimes:</strong> PO1 would give the NPOs common guidelines/recommendations on applying the existing SPC Regulation (e.g. how to assess the eligibility of a product for SPC protection), building on their experience (best practices of examiners to achieve more consistency and predictability) and case law from the Court of Justice of the EU (CJEU). The guidelines would also recommend common rules for publishing SPC information in national registers and ensuring accessibility (e.g. scope of information that should be accessible to the public and stakeholders, common technical rules on data exchange, storage and publication). The guidelines (not legally-binding) would co-exist with nationally developed guidelines. They would promote data exchange between the NPOs and the European patent office (EPO, on existing European patents) and with the European Medicines Agency (EMA, on marketing authorisations).</td>
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<td><strong>PO2</strong></td>
<td><strong>Mutual recognition of national decisions:</strong> PO2 would enable SPC applicants to file an SPC application with a designated NPO (the ‘reference office’, which would have to fulfil conditions such as having sufficient resources to conduct the examination of all the conditions for granting an SPC) whose decision would be recognised by all other NPOs. Third parties would be allowed to submit their written observations concerning an ongoing SPC procedure. ‘Reference offices’ would work on the basis of common guidelines relying on the best practices and on common interpretation of EU legislation and case law (combination with PO1). Each NPO would cooperate in setting up an SPC data exchange system with features as described in PO1.</td>
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<td><strong>PO3</strong></td>
<td><strong>Centralised filing and examination of SPC applications resulting in a non-binding opinion:</strong> PO3 would create a central authority for filing SPC applications in the EU, which would examine applications and issue an opinion on whether to grant an SPC or not. NPOs would be free to either follow this opinion or conduct their own examination (the decision on granting SPC protection would be kept at national level). All interactions with the central authority should be possible in electronic form and in all EU languages. Applicants would be charged a central fee. Member States (in which the SPC in granted) could collect annual SPC maintenance fees and the submission of written observations by third parties could also be subject to fees.</td>
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<tr>
<td><strong>PO4</strong></td>
<td><strong>Centralised filing and examination of SPC applications resulting in a binding opinion:</strong> PO4 is identical to PO3, but NPOs would have to follow the opinion (therefore, while decisions on granting SPC protection would still be taken by national offices, the outcome of these decisions would be determined by the central authority).</td>
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<tr>
<td><strong>PO5</strong></td>
<td><strong>A ‘unitary SPC’ complementing the unitary patent:</strong> The central authority, in addition to examining applications, would grant a so called ‘unitary SPC’ to applicants holding a European patent with unitary effect. The unitary SPC would be valid only in the territory of the (currently 17) EU countries participating in the unitary patent system. The key features described in policy options PO3 and PO4 (centralised procedure) would apply in PO5. All administrative fees (application, annual renewal) would be paid to the central authority. A central IT system for unitary SPC data would be set-up, as described in PO3.</td>
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Source: Compiled by the author based on the IA (IA, pp. 30-36 and executive summary of the IA, p. 3)

The IA provides information about discarded options (IA, pp. 36-37). It is transparent about the reasons for discarding options at an early stage (e.g. doubts about the legal feasibility of an option where a centralised examination authority would grant national SPCs directly; an extension of the 20-year term of protection of the basic patent by up to 5 years would require fundamental system modifications in legislation and in the Member States, in particular in the NPOs). The options
retained are linked to the specific objectives and the problem drivers. Overall, the IA provides a sufficient and balanced description of the options, albeit sometimes lacking in detail, an analysis of their impacts and a comparison of their main content (IA, pp. 35-36).

**Assessment of impacts**

The IA analyses the economic, social and environmental impacts of the options qualitatively and quantitatively (IA, pp. 37-60), also mentioning stakeholders' views and indicating how representative they are, and then compares the options. In addition, the IA analyses impacts common to PO2 to PO5 on digitalisation and on biosimilar medicines and generics market entry, which is key for the pharmaceutical market and healthcare systems. With regard to social impacts, the IA provides a description of likely impacts on healthcare (budgets), healthcare stakeholders and IP attorneys. For instance, healthcare stakeholders could participate in the SPC granting procedure by submitting third-party observations. PO3, PO4 and PO5 provide for a central database for SPCs, benefiting national medicines procurement offices and cross-border joint purchases. Regarding IP attorneys, the IA expects that the creation of one central application procedure (PO2 to PO5) is likely to reduce demand for legal advice/representation before NPOs in each Member State where SPC is sought, resulting in income loss for this group.

Regarding environmental impacts, the policy options appear not to have a direct impact on the environment. The IA refers only generally to sustainability as a key pillar of the pharmaceutical strategy for Europe and recent initiatives, such as the sustainable use of plant protection products proposal. The options are considered to comply with the 'do no significant harm' principle. In the assessment of economic impacts, the analysis is further subdivided into sections covering the following aspects: linguistic regime for SPC procedures; impacts on NPOs (possible net loss of income for NPOs), applicants and follow-on manufacturers; choice of the examination authority. Annex 5 of the IA provides for a detailed analysis of costs and benefits. Overall the focus of the analysis is on economic impacts, while social and environmental impacts are not discussed extensively. More specifically, the estimates for the setting-up and recurrent costs of the central examination authority (one-off costs of €1.4 million, recurrent costs of €1.8 million per year), the cost impacts for applicants, and positive and negative impacts on health care systems and access to biosimilar and generic medicines could have been explained more clearly and in more detail.

In line with the Commission's Better Regulation Guidelines, the options are compared on the basis of their effectiveness in achieving the three specific objectives, their efficiency, their coherence with other policy objectives and initiatives, and their proportionality. In an effort to facilitate the assessment of the above mentioned criteria, the IA presents all options in summary tables showing how the options score and the impacts (costs and benefits) they have on the affected stakeholder groups (e.g. originators, generic/ biosimilar manufactures, healthcare sector, patients and users of PPPs, patent offices, IP agents/lawyers). According to the IA, all options comply with the proportionality principle and do not go beyond what is necessary to achieve the objectives of the initiative. The assessment of impacts and the comparison of the options is in many aspects a qualitative exercise, with a quantitative method used to assess costs and benefits of each option. After comparing the options, policy option 5 combined with policy option 4 appears to score best and it has been selected as preferred option (see Table 1 in grey).

According to the IA, the preferred option would make best use of the advantages of a one-stop-shop SPC procedure with the possibility to obtain unitary SPC protection in countries where the corresponding unitary patent takes effect. The IA estimates savings of the preferred option at €137 100 per applicant for receiving EU-wide, 5-year-long SPC protection for a given product (55% less cost than the baseline scenario). The IA comprehensively describes and explains that after comparing possible combinations of options, the combination of PO4 and PO5 was preferred (IA, pp. 66-67). It provides a clear justification – using transparent selection criteria – as to why the EUIPO was chosen as the preferred central examination authority by the Commission, although this was
not supported by the majority of the stakeholders who were asked in the public consultation on the evaluation of the existing SPC legislation (IA, pp. 42-44).

On the impacts on **fundamental rights**, the IA mentions [Article 35](https://ec.europa.eu/justice/en/crpl/charter/article-35) (health care) of the Charter of Fundamental Rights of the European Union (CFEU) when discussing the consistency of the initiative with other EU policies, without going into details. Regarding the impacts of the preferred option on the **Sustainable Development Goals** (SDGs), the IA mentions SDG3 (good health and well-being) as relevant and describes – in fairly general terms – the expected progress towards the goal (better access to SPC for innovators might have a positive effect on more R&D expenditures for complex novel medicines). The impacts both on fundamental rights and on the SDGs could have been analysed in more detail in the IA.

**SMEs / Competitiveness**

The present initiative is considered relevant for small and medium-sized enterprises (SMEs) and was listed by the SME envoys network in the SME filter. In line with the Better Regulation Guidelines (see also [Better Regulation Toolbox, Tool #23](https://ec.europa.eu/health/better-regulation-toolbox/index_en)), an SME test was carried out, the main findings of which are described in detail in a separate annex (IA, Annex 6, pp. 146-151). Evidence was gathered through consultations, for instance the Commission’s open public consultation supporting the evaluation of the existing SPC regime, bilateral meetings of the Commission with the pharmaceutical and agrochemical industries, analysis of position papers of the pharmaceutical and agrochemical associations that also represent the interests of SMEs. However, it appears that no targeted SME consultation was conducted and it is not clear how the received input was taken into consideration. The IA provides for a comprehensive overview of the impacts of each policy option on SMEs (originators and biosimilar/generic SMEs) in a separate table (IA, p. 150). According to the IA, SMEs would benefit from lower SPC application and maintenance fees. Other savings would include less spending on legal advice and translation. SMEs in the biosimilar and generic sectors would benefit from easier access to SPC information and a lower burden of monitoring SPC protection in the EU. However, the IA does not provide evidence or clear assumptions regarding how many SMEs will seek SPC protection.

The IA does not discuss **competitiveness** in detail, although the IA states that ‘the pharmaceutical and agrochemical sectors are global and highly competitive’ (IA, p. 9). However, some analysis is given in the context of the EU’s attractiveness for medicines and PPP development (IA, p. 23-25). According to the IA, EU based pharmaceutical firms face a much more fragmented home-base than is the case for their main global competitors originating from jurisdictions with harmonised protection systems (IA, p. 24).

**Simplification and other regulatory implications**

The IA includes a short chapter on simplification and improved efficiency (REFIT) in which the cost savings of the preferred option are described (IA, p. 72). The 27 national SPC procedures would be replaced by a central one with lower fees and the need for just one legal representative across the EU, which would bring a reduction in SPC application costs amounting to €11.5 million. The reduction in monitoring costs for follow-on producers and the health sector would bring cost savings of €13 million. In light of the ‘one-in, one-out’ approach, the IA identifies annual savings of €52 000 on legal advice and €4 000 on translation for approximately 100 SPC applicants per year. According to the IA, the initiative is fully coherent with existing EU rules, including legislation concerning public health, including the recently proposed general pharmaceutical legislation, and food safety (as regards PPPs). The IA does not, however, appear to offer a clear analysis or description of the expected links with the proposals revising the EU’s general pharmaceutical legislation.

**Monitoring and evaluation**

For the purpose of monitoring the proposal’s operation, the IA presents a set of monitoring indicators linked to the specific objectives. They appear relevant to achieving the specific objectives,
for instance: duration of the protection, as defined in the specific SPC decision; number of negative granting decisions; number of countries covered by an SPC for a given product; number of ‘unitary SPCs’; quality and timeliness of the data in the databases; number of SPCs submitted and granted following the centralised procedure; duration of the SPC procedure; and cost of the SPC protection (IA, pp. 73–74). The IA envisages an evaluation by the Commission every 5 years.

Stakeholder consultation

The IA provides a description of the stakeholder consultations in a separate annex as required in the Better Regulation Guidelines (IA, Annex 2). The Commission carried out an open public consultation (OPC) from 12 October 2017 to 4 January 2018 supporting the evaluation of the existing SPC legislation (231 replies). The Commission conducted a targeted survey among Member States (NPOs) in 2020 on SPC transparency that showed the variety of transparency practices (e.g. accessibility of databases, language availability) in the Member States (IA, p. 80). A call for evidence for an impact assessment was conducted from 8 March to 5 April 2022 (59 replies were submitted). The Commission organised a meeting of the Commission expert group on industrial property policy (GIPP) on 18 November 2022 to discuss the SPC reform. In that context the IA provides information about the preliminary support of the participating Member States for the policy options (IA, p. 87).

The IA gives a comprehensive outline of stakeholder groups’ views on the problems, the problem drivers, the objectives and the policy options (on the latter see IA, p. 88). However, no public consultation was carried out in the preparation of this IA. The IA describes the expected impacts of the preferred option on the stakeholder groups identified as being most affected. Diverging views of the different stakeholder groups are presented in a transparent manner. It appears that the views of stakeholders were taken broadly into account.

Supporting data and analytical methods used

With regard to supporting data, the IA lists key sources such as: the evaluation of the SPC system for medicinal and plant protection products; publicly available and referenced studies; stakeholder consultations; databases (e.g. NPO websites); and the contribution of the Commission expert group on industrial property policy (GIPP). The IA describes the analytical methods in a separate annex (IA, Annex4), for instance the use of Eurostat data (structural business statistics) for key economic indicators, the Orbis database, and the IQVIA database containing descriptions of variables characterising the pharmaceutical market. However, the use of analytical methods used in the referenced studies and the consultations are not described in the IA, which weakens its ability to keep a clear overview. Assumptions and estimates, for instance on (one-off and recurrent) costs of the central examination authority and limitations of data could have been explained in more detail and more transparently.

Follow-up to the opinion of the Commission Regulatory Scrutiny Board

The Regulatory Scrutiny Board (RSB) initially issued a negative opinion on a draft version of the IA on 30 September 2022, where it identified significant shortcomings (nature of the problem, coherence with the revision of the general pharmaceutical legislation, net impacts and comparison of options, justification for the choice of the preferred option and the examination authority, views of different stakeholder categories). Following the submission of a revised IA report on 23 November 2022, the RSB issued a positive opinion on 16 December 2022, suggesting that the IA should do more to: clarify the drivers behind divergences in national practices on SPCs; and justify the choice of the preferred option. In its Annex 1, the IA explains how the RSB’s comments were addressed in the revised IA. It appears that the RSB’s comments were taken broadly into account.

Coherence between the Commission’s legislative proposal and IA

The proposals appear to follow the IA’s preferred option (PO4 and PO5).
The problem definition appears to be well supported by evidence. The IA provides a sufficient and balanced description of the options, albeit sometimes lacking in detail. The assessment of the options' impacts (economic, social and environmental) is qualitative and quantitative. It appears to be based on sound research and analysis. However, assumptions, estimates of costs and limitations of data could have been explained more clearly and in more detail. The IA provides a summary of the costs and benefits of the preferred option for the affected stakeholder groups (originators, follow-on manufacturers, national patent offices, IP agents/lawyers). An SME test was carried out. However, it appears that no targeted SME consultation was conducted. According to the IA, SMEs would benefit from lower SPC application and maintenance fees, and lower expenditure on legal advice and translation. SMEs in the biosimilar and generic sectors would benefit from easier access to SPC information. However, the IA is not fully clear about the estimated number of SMEs that will seek SPC protection. Competitiveness could have been discussed in more detail. The IA provides a comprehensive outline of the views of the stakeholder groups on the problems, problem drivers, objectives and policy options, obtained through several consultation activities. However, no public consultation was carried out in the preparation of the IA.

ENDNOTE

3 See IA, p. 97, on the unitary patent system, participating Member States and the applicable procedures for registration.
4 COM(2023) 231, COM(2023) 223, COM(2023) 221.
5 See IA, p. 96, for information about the regulatory context of patent systems in the EU, including European patents.
6 According to the IA, this could be the following institutions: the European Patent Office, the European Union Intellectual Property Office, the European Medicines Agency or the European Food Safety Authority.
7 See IA, p. 32: 'The Commission would set up a single entry point for filing SPC applications in the EU for holders of European patents and EU-centralised marketing authorisations. Applicants would ... select in which Member States they seek SPC protection. Such application would be examined by a dedicated central examination authority.'
8 For instance, Max Planck Institute for Innovation and Competition, Study on the options for a unified supplementary protection certificates (SPCs) system in Europe, 2022 and Study on the legal aspects of Supplementary Protection Certificates in the EU, 2018; Technopolis Group, Final report, Effects of supplementary protection mechanisms for pharmaceutical products, 2018.