BRIEFING
EU Legislation in Progress

European Parliament

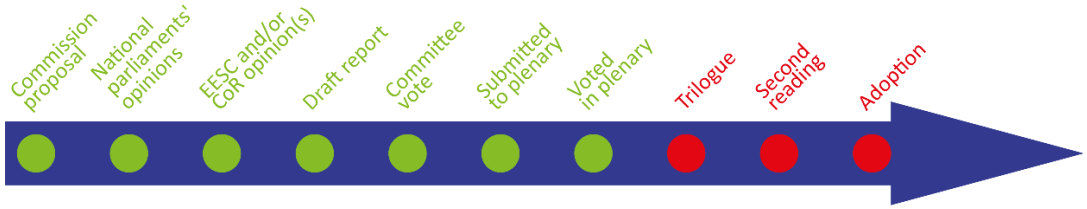
Unitary supplementary protection certificate for plant protection products

OVERVIEW

The supplementary protection certificate (SPC) is a specific intellectual property right that extends the basic patent's market exclusivity for plant protection products. The unitary patent became operational in the EU on 1 June 2023, unifying patent protection in all participating Member States. Despite this significant change, SPCs, which are inseparable from patent protection, remain regulated at national level. This fragmented regulatory approach has proven ineffective, leading to excessive administrative costs for SPC applicants, who have to navigate the national laws of each Member State where they seek SPC protection. To address this issue, on 27 April 2023 the Commission submitted a proposal for a regulation introducing a unitary SPC for plant protection products as a complement to the protection offered by the unitary patent. This proposal, coupled with a parallel proposal for an SPC for plant protection products of the same date, seeks to harmonise the process of granting SPCs for plant protection products in the single market.

In Parliament, the proposal was assigned to the Committee on Legal Affairs (JURI), with Tiemo Wölken (S&D, Germany) as rapporteur. Following the approval of the reports on the two proposals by the Parliament plenary at first reading, Parliament adopted its position for the interinstitutional negotiations. The Council has yet to agree on its negotiating mandate.

Proposal for a regulation of the European Parliament and of the Council on the unitary supplementary protection certificate for plant protection products and for a regulation of the European Parliament and of the Council on the supplementary protection certificate (recast).		
Committee responsible:	Legal Affairs (JURI)	COM(2023)221 27.4.2023
Rapporteur:	Tiemo Wölken (S&D, Germany)	2023/0126(COD)
Shadow rapporteurs:	Javier Zarzalejos (EPP, Spain) Adrián Vázquez Lázara (Renew, Spain) Marie Toussaint (Greens/EFA, France) Emmanuel Maurel (GUE/NGL, France)	COM(2023)223 27.4.2023 2023/0128(COD) Ordinary legislative procedure (COD) (Parliament and Council on equal footing – formerly 'co-decision')
Next steps expected:	Trilogue negotiations	



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Introduction

In 2023, the European Commission submitted the patent legislative package, which consisted of six proposals aimed at reforming the supplementary protection certificates (SPCs) for patented medicinal and plant protection products, the standard essential patents and the EU's compulsory licensing regime. The main goals of the package were to establish a more transparent, effective and futureproof intellectual property rights framework, eliminate the remaining barriers within the single market, reduce red tape for businesses, enhance efficiency and complement the unitary patent system, effective since 1 June 2023.

The patent legislative package includes two proposals on SPCs for plant protection products (PPPs): a proposal for a regulation on the unitary supplementary protection certificate and a parallel proposal for a regulation on the supplementary protection certificate (a recast of Regulation (EC) No 1610/96 of the European Parliament and of the Council on the supplementary protection certificate for plant protection products). These proposals aim to reinforce the single market for agrochemicals and support the twin digital and green transitions. They seek to establish a unified SPC granting procedure and introduce a unitary SPC. These goals were set in the Commission work programme for 2024.

Context

Supplementary protection certificates (SPCs) are *sui generis* intellectual property (IP) rights that provide exclusive rights for the active substance or combination of active substances in a plant protection product (PPP) available in the EU. These rights constitute a separate and distinct title of legal protection. The current SPC regime for PPPs in EU is outlined in Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products.

The main purpose of SPCs is to extend the legal protection of a patent for a PPP that has been authorised by regulatory authorities. This extension is seen as a way to prevent market failure, as the standard 20-year term of plant protection may not be sufficient. An additional incentive for the existence of an SPC regime in the Member States is the fact that other countries, such as the USA, Canada, Israel, Japan and Korea, have various models for extending patent protection.

SPCs are at an intersection between economic and societal interests. Furthermore, they influence the availability of PPPs in the agricultural sector, as well as companies' competitiveness and incentives to invest in the research and development (R&D) of PPPs.

SPCs are designed to compensate for the substantial time loss in patent protection for PPPs as a result of the compulsory lengthy testing and trials required before regulatory marketing approval for these products is obtained. A valid marketing authorisation for a PPP grants the right to place it on the EU market. This process usually takes several years and consumes a significant portion of a patent's lifespan. Therefore, the EU legislator designed SPCs as an additional form of market exclusivity to compensate for the investments made in PPPs. The SPC term is calculated as the time between the date on which the application for a patent was lodged and the date of the first market authorisation minus a period of 5 years. An SPC can last for up to 5 years. The exclusivity attached to IP protection serves as compensation for the investment. The period covered by an SPC is of significant economic importance to inventors.[1] The main objectives of SPCs include encouraging global R&D in the area of new active ingredients of PPPs, attracting R&D centres and jobs to the EU, preventing R&D relocation, and fostering common regulatory standards.

The scope of the SPC Regulation is limited to products that are protected by a European patent with unitary effect ('basic patent') and are subject to an administrative market authorisation procedure in the individual Member States prior to being marketed. Therefore, the SPC is inseparable from the patent to which it relates, meaning the grant of a SPC is contingent on the existence of a basic patent. A patent is a legal title that can be granted for any invention with a technical character,

provided it is new, involves an 'inventive step' and is industrially applicable. A patent can cover how things work, what they do, what they are made of and how they are made. The individual or entity with a patent possesses the exclusive right to prevent others from creating, employing or marketing the invention without their explicit consent.

SPCs are distinct IP rights granted specifically for patented PPPs. SPC protection confers the same rights and obligations as the basic patent. However, unlike the basic patent, an SPC does not extend the protection conferred across the entire scope of the patent claims but will only protect the product covered by the authorisation to place the corresponding medicinal product (or plant protection product) on the market and any use of that product as a medicinal product (or plant protection product) that has been authorised before the expiry of the SPC.'[2]

Plant protection products (PPPs)[3] are active substances and preparations containing one or more active substances intended to protect plants (or plant products) against harmful organisms or to prevent the action of such organisms. They can also influence the life processes of plants, preserve them, destroy undesirable plants or parts of plants, and check or prevent undesirable growth of plants. They play a vital role in safeguarding crops and plants throughout various stages of production, storage and transportation. As a subgroup of pesticides, PPPs are designed to shield crops and desirable plants in agricultural, forestry, horticultural and home garden settings. These products contain active substances that control pests or diseases, influence plant life processes, preserve plant products or deter undesired plant growth.

Before being integrated into PPPs within the EU, active substances undergo rigorous evaluations and peer reviews by Member States and the European Food Safety Authority to ensure compliance with EU regulations. This approval process highlights the importance of safety and efficacy in agricultural practices. While the terms 'pesticide' and 'plant protection product' are often used interchangeably, pesticides encompass a broader spectrum, including non-plant or crop uses such as biocides. In essence, PPPs represent a specialised category within the realm of pesticides, specifically tailored to meet the demands of modern agricultural practices and environmental sustainability.

Existing situation

An SPC should effectively extend a patent right for a maximum of 5 years. Therefore, the holder of both a patent and an SPC should be able to enjoy a maximum of 15 years of exclusivity from the time the PPP in question first obtains authorisation to be placed on the market in the EU.

The introduction of a unitary patent system in 2023, designed to serve as a centralised platform for patent protection and enforcement within the EU, has brought to light the limitations of the national nature of SPCs. Currently, SPCs are national, territorially restricted rights granted by national offices. This means that there is no unitary SPC that complements a patent with a unitary effect (unitary patent). Therefore, a unitary patent can only be extended through national SPC protection. The discrepancy between the newly introduced unitary patent system and the approach of granting SPCs nationally prevents the unitary patent holder from obtaining unitary protection during the combined protection period conferred by the unitary patent and the (national) SPCs. Consequently, an applicant seeking to extend the protection offered by a unitary patent must go through the national procedure in each Member State.

In the 2020 intellectual property action plan, the European Commission acknowledged that the fragmented (national) nature of the regulatory framework governing SPCs undermines their effectiveness. This fragmentation also generates legal uncertainty, red tape and extra costs for businesses, particularly small and medium-sized enterprises (SMEs). Additionally, national examination and authorisation procedures further added to the additional administrative burdens faced by businesses.

The European Commission calculated that 'to obtain SPC protection in the whole EU for the maximum term of 5 years, applicants need to comply with 27 different procedures at national patent offices and pay various national application and maintenance fees totalling €192 000'. Historically, approximately a quarter of applications for the same product resulted in different decisions regarding SPCs. Therefore, the current fragmented SPC regime leads to complex and costly application procedures and legal uncertainty, as one Member State may grant the SPC while another rejects the application.

Currently, certificates are granted by the national patent offices (NPOs) and litigated before the national courts. The jurisdiction of the Court of Justice is limited to the proceedings envisaged under Article 267 of the Treaty on the Functioning of the European Union (TFEU).

Parliament's starting position

In November 2021, Parliament stressed that the SPC regime in the EU was suffering from fragmented implementation across the Member States. It therefore asked the Commission to issue guidelines for the Member States and to propose legislation that could help to address this fragmentation and the resulting legal uncertainty. This request came after a full impact assessment had been conducted. The same year, through another resolution, Parliament called on the Commission 'to evaluate the added value of the SPC' system for the medical sector. Highlighting the existing differences in the validity of patents and SPCs among the Member States, Parliament called on the Commission: 'to revise the use of SPCs on the basis of technological and scientific advances'. Additionally, Parliament requested an evaluation of the potential impact that a proposal for a unitary SPC would have on the market entry of generic and biosimilar medicines. Following this valuation, Parliament suggested proposing a unitary SPC where appropriate.

Council starting position

The patent package was presented to the Council Working Party on Intellectual Property in May 2023. In June 2023, the European Council welcomed 'the entry into force of the Unified Patent Court Agreement for the participating Member States, and the consequent entry into operation of the unitary patent, which will help boost innovation and competitiveness'.

In 2020, the Council adopted conclusions on intellectual property policy and the revision of the industrial designs system in the EU. The Council invited the Commission to put forward initiatives to enhance the protection of intellectual property 'including with regard to the supplementary protection certificate system'. Additionally, the Council emphasised the importance of creating affordable procedures tailored to SMEs in particular.

Preparation of the proposal

In 2018, the **Max Planck Institute for Innovation and Competition** conducted a study on the legal aspects of SPCs in the EU for medicinal and plant protection products. The study's main conclusion was that stakeholders and national patent offices (NPOs) agree that the system 'fulfils its purposes'. However, there are legal uncertainties that could jeopardise the smooth functioning of the SPC regime. Specifically, inconsistencies and unclear interpretations by the Court of Justice regarding key provisions in two SPC regulations – on medicinal and plant protection products – pose challenges for NPOs in aligning their practices with evolving case law that substantially influences the protection afforded by the regulations (these ambiguities occur, for instance, through the provision of broad definitions of what exactly is covered by the SPC regimes and the provision of clarity on the various exemptions in the SPC regimes and the duration of the certificate). As companies align their practices with evolving case law, this may result in discrepancies with past practices or those of other NPOs. Originator companies express confidence that the system would self-correct over time, while generic manufacturers argue for a comprehensive overhaul to achieve a more balanced approach. The latter group underscores the need for a rebalancing due to

perceived limitations in the granted rights, which it believes are too narrowly tailored for an effective response to heightened global competition challenges. The study concludes that all concerned parties concur on the need to reform the current SPC system.

In 2020, the **European Commission** released its evaluation report on existing SPC regulations. It praised the role of SPCs in research on new active ingredients and found that they remained fit for purpose. The report concluded that SPCs were coherent with patent legislation and had brought added value to the EU. However, it also stated that national SPC management undermined the effectiveness and efficiency of the SPC system. The report assessed that the national SPC system created legal uncertainty, red tape and extra costs for businesses, especially SMEs, and national administrations.

In March 2022, the **European Commission** initiated a consultation calling 'for evidence' regarding the necessity of proposing regulations governing SPCs. The consultation aimed to explore the feasibility of implementing a unitary SPC regime and/or a single ('unified') procedure for granting national SPCs. The consultation concluded in April 2022, receiving 59 valid contributions, with 30 coming from companies and business associations. The feedback indicated that while participants considered that a unitary SPC system would be effective, potential discrepancies in its management and enforcement across EU countries could lead to inefficiencies.

In August 2022, the **Max Planck Institute** released a study on the options for a unified SPC system in Europe. The study identified several shortcomings, primarily focusing on the scope of a unitary SPC, its relation to the unitary patent, and the legal protection granted by the Unified Patent Court. Additionally, the study highlighted the main reasons for reforming the SPC granting system: 1) the complexity of legislation and case law; 2) the absence of uniform expertise among the national agencies; and 3) differing approaches to examining SPCs leading to inconsistent decisions and fragmentation of the single market. The study concluded that even a moderately unified procedure, where a central body would assess regional applications and provide an opinion on SPC eligibility while NPOs would decide whether to grant or refuse the certificate, would still improve the current fragmented situation of SPC granting.

In April 2023, the **European Commission** conducted an impact assessment (IA) (with an executive summary) on a reform of the EU's SPC regime, consisting of a proposal for a regulation creating a procedure for the centralised examination of SPC applications and a proposal for a regulation creating a unitary SPC. The IA resulted in an endorsement for a centralised procedure that would grant national SPCs in some or all EU countries and/or a unitary SPC covering those EU countries where the basic unitary patent has effect. The IA also recommended that the EU Intellectual Property Office become the central examination authority for SPCs.

The most recent document addressing the adoption of the new SPC system for medical products and PPPs was a 2023 **EPRS** implementation appraisal. This briefing highlights the results of the European Commission's assessment, discrepancies in implementation among Member States, and the complexity of balancing between various interests.

The changes the proposal would bring

On 27 April 2023, the European Commission proposed a comprehensive reform of the SPC regime, consisting of two legislative proposals regarding PPPs. The first proposal would establish a **new unitary SPC** system for PPPs, while the second proposal would create a **centralised procedure for granting national SPCs** (recast) for PPPs.

The legal basis for regulating the unitary SPC for PPPs is Article 118(1) TFEU, under which the ordinary legislative procedure applies (as defined in Articles 289(1) and 294 TFEU).

The proposed unitary SPC system for PPPs aims to complement the unitary patent system, which has been effective since June 2023. Currently, a unitary patent can only be extended by a national SPC, meaning it is not done in a unitary manner. Not only does this fragmented procedure require

the applicant to file a separate SPC for PPP application in the national language of each Member State but it also poses a risk of SPCs being granted in some Member States and denied in others. The proposed regulation on a unitary SPC system centralises the granting procedure in order to achieve complete consistency. It relies on the same substantive provisions relevant for granting the national certificates introduced in the parallel recast proposal on the SPC for PPPs (COM(2023)223). In other words, the proposed changes do not aim to modify the substantive rules for acquiring SPCs but seek to introduce new, harmonised procedural provisions for the granting of SPCs.

A unitary SPC should provide **uniform protection** and have an equal effect in all Member States where the patent it relies upon has unitary effect. Being an object of property right, a unitary certificate should be treated as a national certificate of the Member State determined by the law governing the basic patent, in its entirety and in all Member States in which it takes effect. Therefore, the unitary SPC should effectively complement the unitary patent.

The new (harmonised) regulatory regime would allow applicants to file a **combined application** for a unitary SPC and a national SPC. It would be possible to file the application in any official EU language. If the SPC examination is successful, the procedure would result in the granting of both a unitary SPC (currently applicable in 17 Member States) and a national SPC for those Member States not covered by the unitary patent. However, it would not be possible for a single product to be protected by both a national SPC and a unitary SPC in the same Member State.

The unified procedure should significantly reduce administrative burden and costs, such as application, renewal and translation fees. At the same time, the revamped SPC system would increase transparency and provide more predictability, ensuring manufacturers are better informed about the protection status of their products across the EU. Combining the unitary SPS and unitary patent should encourage innovation and promote growth and jobs in affected sectors. Thus, the SPC reform is anticipated to boost the utilisation of the unitary patent.

The proposed regulation identifies the **European Union Intellectual Property Office** (EUIPO) as the central examination authority to assess the formal admissibility of the unitary SPC. The EUIPO panels would review applications. The proposed procedure would involve close cooperation between EUIPO and Member States' national IP offices, as each panel would consist of a member from EUIPO and two qualified examiners, who are experienced in SPC matters, from two NPOs in the Member States.

The first step in evaluating an application for a unitary SPC certificate would involve assessing its **formal admissibility**.[4] If it meets these requirements, the EUIPO will publish the application in a register. This register would serve as a single access point providing information on applications for unitary certificates, granted unitary certificates, and their status. The register should be available in all official languages of the EU.

Within 3 months of the application's publication, i.e., in the early stages of the process, third parties (any natural or legal persons) would be able to submit **written observations** to the EUIPO regarding the eligibility for supplementary protection of the product to which the application relates in one or more of the Member States where the basic patent has unitary effect.

Subsequently, the EUIPO would assign the **substantive examination of the application** to a panel. This panel would be composed of an EUIPO member and two qualified examiners, experienced in SPC matters, from two different national patent offices in the Member States.

The unitary SPC would be granted on the basis of a basic patent, if in each of the Member States where that basic patent has unitary effect, at the date of the application, all of the following conditions are met:[5] a) the product is protected by the basic patent in force; b) a valid authorisation to place the product on the market as a plant protection product has been granted in accordance with Regulation (EC) No 1107/2009; c) the product has not already been the subject of a certificate nor a unitary certificate; d) the authorisation referred to in point b) is the first authorisation to place the product on the market as a plan protection product.

After examining the application, the EUIPO would issue **an examination opinion** stating whether the application meets the applicable criteria. After the final decision on the merits, the EUIPO would either grant a unitary SPC or reject the application.

Any person could file a notice of **opposition** to the examination opinion regarding an application for a unitary certificate with the EUIPO within 2 months of its publication. Opposition could be based on one or more conditions not being met for one or more Member States where the basic patent has a unitary effect. The various EUIPO examination panels would review the opposition within 6 months.

Once the deadline for filing an appeal or opposition may be filed has passed without any submissions, or after a final decision on the merits has been made, the EUIPO would either grant a unitary certificate or reject the application for a unitary certificate.

Any party involved in the proceedings who is adversely affected by a decision of the EUIPO, including the adoption of an examination opinion, would be able to challenge a negative opinion before the **EUIPO's Board of Appeal.** Filing an appeal would have a suspensive effect and would have to be done in writing within 2 months of the decision's notification date. Where an appeal results in a decision that is not in line with the examination opinion, the EUIPO Board of Appeal may, through its decision, annul or modify the opinion.

Subsequently, an action might be brought before the **General Court** against a decision of the EUIPO Board of Appeal in relation to appeals within 2 months of the date of notification of that decision. This action can be based on grounds such as infringement of an essential procedural requirement, infringement of the TFEU rules, infringement of the proposed regulation or of any rule of law related to their application, or misuse of power. The action would be available to any party involved in proceedings before the EUIPO Board of Appeal who has been adversely affected by its decision. The General Court would have the authority to annul or modify the contested decision.

Ultimately, under Article 256(2) TFEU, the General Court's decision might be exceptionally subject to a review by the Court of Justice under the conditions and within the limits laid down by the Rules of Procedure of the Court of Justice.

Advisory committees

The European Economic and Social Committee (EESC) issued its opinion on the proposed regulation and the other Commission proposals included in the patent package on 25 September 2023. The EESC report generally supported the Commission's initiative to establish a centralised SPC for both European and unitary patents, considering them essential for establishing a more harmonised patent system within the EU. However, the report also mentioned several potential complications of the proposal. Most importantly, it considered the proposed 'all EU languages' regime for centralised SPC applications enormously challenging. Additionally, the report considered the processes that involve assessing the scope of protection of a given patent to determine whether a product falls under a basic patent (for SPCs) difficult to execute. Given the technical nature, high level of sophistication, and insufficient number of experts, this language system would increase the complexity of implementing the proposed regulation.

National parliaments

The deadline for submitting reasoned opinions on subsidiarity was 23 October 2023. The **Czech Chamber of Deputies** examined four proposals and supported the Czech government's position on the issue. The **Irish Houses of Oireachtas** considered that the proposal did not warrant further scrutiny. The Committee on Rural Affairs of the **Lithuanian Seimas** concluded that the proposal complied with the subsidiarity principle. The **Slovenian National Assembly** was generally in favour of the proposal but recommended a balanced approach. It furthermore advocated 'a non-binding regulation [for] the participation of national examiners in the centralised procedure for testing the

conditions for the grant of SPCs'. It argued that a binding regime would overload the Slovenian Intellectual Property Office.

Stakeholder views[6]

In June 2023, the **European Data Protection Supervisor** (EDPS) released an opinion under Article 42(1) of Regulation 2018/1725, which states that the Commission must consult the EDPS when a proposal for a legislative act impacts the protection of individuals' rights and freedoms regarding the processing of personal data. The EDPS acknowledged that launching an application for an SPC or a unitary SPC involved the processing of personal data. Therefore, the opinion focused 'on the provisions requiring publication of personal data, as well as the proposed storage duration'. Among other things, the EDPS requested clarification on the purposes for which personal data may be disclosed and the mechanism for accessing them. The opinion recommended clearly articulating the specific purposes for which personal data may be made available and considering providing a mechanism that allows access only to parties that have demonstrated a legitimate interest linked to the proposal's objectives (i.e., this data should not be publicly available). Additionally, the EDPS provided observations regarding the retention period for all entries in the register and an administrative database.

The proposals on the SPC for PPPs have been **the least controversial parts of the patent package**, especially when compared to the proposals dealing with the SPC for medical products or even more so, to the compulsory licencing regime. This lack of controversy is evidenced by the limited number of studies and research articles on the topic. Currently, none of the stakeholders have opposed the stated aims of the SPC for PPPs proposals: to simplify and harmonise the current framework around SPCs, increase transparency, and address the omission of a unitary SPC from the unitary patent system. The SPC for PPPs proposals have been broadly welcomed by stakeholders and are expected to progress relatively smoothly through the legislative process. It remains to be seen how the proposed changes to the provisions of the basic SPC Regulation will affect the scope of rights available under SPCs for PPPs (and how national patent offices and courts will interpret these rights following such changes).

Legislative process

The two proposals under examination in this briefing, one on the unitary SPC for PPPs (the unitary SPC proposal) based on Article 118 TFEU and the second one on the SPC for PPPs (the recast SPC proposal) based on Article 114 TFEU, are subject to the ordinary legislative procedure, requiring the support of both the Council of the EU and the European Parliament. In the Parliament, both proposals were referred to the **Committee on Legal Affairs (JURI)**, with Tiemo Wölken (S&D, Germany) as rapporteur.

Under Rule 56 of Parliament's Rules of Procedure, the Committees on Agriculture and Rural Development (AGRI) and on the Environment, Public Health and Food Safety (ENVI) were asked to give opinions. The AGRI committee decided not to give an opinion as the proposal would not substantially modify the existing regime for SPCs. On 29 August 2023, the ENVI committee decided not to give an opinion on these legislative files, without giving any reasons.

The rapporteur presented his draft report **on the unitary SPC proposal** on 13 October 2023. The key recommendations of the report included defining the concept of 'economically linked' for holders of multiple patents; holding applicants accountable for the accuracy of the information they submit; making it possible for the EUIPO to collectively address multiple oppositions filed against an examination opinion; appointing examiners based on expertise; prioritising expertise over geographical balance in examination panels; setting a 3-month decision deadline for the EUIPO, requiring evidence-supported appeals; ensuring expert neutrality; and obligating the Commission to report the main findings on the establishment of a central authorisation procedure to the European Parliament and the Council after 5 years.

The draft report **on the recast SPC proposal**, published on 16 October 2023, suggested minor changes, aimed at refining the text and unifying the terminology and procedures with those from the unitary SPC proposal.

The deadline for tabling amendments in the JURI committee was set for 10 November 2023. Some 98 for the first proposal and 57 amendments for the second one were tabled. Ultimately, five compromise amendments were tabled for the unitary SPC proposal. For the recast SPC proposal, three compromise amendments and one amendment were tabled. On 24 January 2024, **the JURI committee** voted **in favour of both legislative reports**, adopting all compromise positions except for amendment 47 to the recast proposal, which was rejected.

The approved reports mainly contain technical amendments, addressing various aspects, including:

- the examination of the unitary and centralised SPC applications,
- the opposition procedure,
- the role of national authorities,
- the combined applications,
- the formation of examination panels,
- the appellate process.

The reports were tabled for the February II plenary session. Parliament voted in favour of both reports, including the JURI committee's amendments, by an overwhelming majority. It thus adopted its first-reading positions for the proposals on the unitary SPC for PPPs and on the recast SPC for PPPs for the interinstitutional negotiations.

In the Council, the Working Party on Intellectual Property (Patents) is responsible for handling the proposals. On 29 September 2023, the preliminary written comments of the national delegations were distributed among the members of the Working Party. On 16 October 2023, several (non-public) working papers were distributed among the delegations. The Council held a debate on the proposal on 22 December 2023, at which the Member States shared their views. The Council has yet to agree on its mandate for negotiating with Parliament.

EUROPEAN PARLIAMENT SUPPORTING ANALYSIS

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ENDNOTES

[1] 'A. Purpose, History and Legal Character of the Certificate', in Marco Stief (ed), *Supplementary Protection Certificates (SPC): A Handbook*, Second edition (© Verlag C.H. Beck oHG; Verlag C.H. Beck oHG 2021) pp. 4-12.

[2] https://e-courses.epo.org/wbts_int/litigation/SPCs.pdf

[3] See Article 2 of the proposal on the unitary SPC for PPPs.

[4] See Articles 8, 9, and 29(1) of the proposal on the unitary SPC for PPPs.

[5] See Article 3 of the proposal on the unitary SPC for PPPs.

[6] This section does not intend to serve as an exhaustive account of all different views on the proposal.

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