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Kopia:	Carl Johan Sundqvist; Marie Häggkvist; Anders Olin; Ju Registrator
Ämne:	Remiss EU-kommissionens patentpaket Ju2023/01196
Bifogade filer:	Remisslista patentpaketet.pdf; SEP - COM(2023) 232 final.pdf; tilläggsskydd - COM(2023) 221 final.pdf; tilläggsskydd - COM(2023) 222 final.pdf; tilläggsskydd - COM(2023) 223 final.pdf; tilläggsskydd - COM(2023) 231 final.pdf; tvångslicenser - COM(2023) 224 final - annex.pdf; tvångslicenser - COM(2023) 224 final.pdf
Uppföljningsflagga:	Följ upp
Flagga:	Har meddelandeflagga
Kategorier:	Björn
AppServerName:	p360_prod
DocumentID:	RR 2023-128:01
DocumentIsArchived:	-1

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EU-kommissionen har den 27 april 2023 lagt fram det s.k. patentpaketet. Patentpaketet innehåller förslag om nya regler för tilläggsskydd för läkemedel och växtskyddsmedel, tvångslicenser och standardessentiella patent (SEP) och avser följande förordningar:

- Europaparlamentets och rådets förordning om ett enhetligt växtskyddsmedel (COM(2023) 221 final),
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Remissvaren ska ha kommit in till Justitiedepartementet **senast den 22 juni 2023**. Svaren bör lämnas per e-post till ju.remissvar@regeringskansliet.se och med kopia till ju.l3@reginskanliet.se. Ange diarienummer Ju2023/01196 och remissinstansens namn i ämnesraden på e-postmeddelandet.

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Anders Olin
Departementsråd

[1] Se https://ec.europa.eu/commission/presscorner/detail/en/ip_23_2454.

Regeringskansliet

Remiss

2023-05-12
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Anders Olin
Departementsråd

Council of the European Union

Brussels, 28 April 2023
(OR. en)

8851/23

Interinstitutional File: 2023/0126(COD)

PI 53
PHARM 65
COMPET 378
MI 346
IND 201
IA 85
CODEC 735

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	27 April 2023
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2023) 221 final
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the unitary supplementary protection certificate for plant protection products

Delegations will find attached document COM(2023) 221 final.

Encl.: COM(2023) 221 final

EUROPEAN
COMMISSION

Brussels, 27.4.2023
COM(2023) 221 final

2023/0126 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the unitary supplementary protection certificate for plant protection products

(Text with EEA relevance)

{SEC(2023) 172 final} - {SWD(2023) 117 final} - {SWD(2023) 118 final} -
{SWD(2023) 119 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

Supplementary protection certificates (SPCs) are *sui generis* intellectual property (IP) rights that extend the 20-year term of patents for medicinal or plant protection products (PPPs) by up to 5 years[1]. They aim to offset the loss of effective patent protection due to the compulsory and lengthy testing required in the EU for the regulatory marketing authorisation of these products.

The unitary patent will enter into force on 1 June 2023, allowing for a single patent that covers all participating Member States in a unitary manner[2].

This proposal aims to simplify the EU's SPC system, as well as improve its transparency and efficiency, by creating a unitary certificate for plant protection products. This initiative was announced in the Commission work programme for 2022 as initiative number 16 under Annex II (REFIT initiatives)[3].

Regulation (EC) No 1610/96 provides for SPCs for plant protection products ('PPPs'), at a national level, to be granted by national patent offices on the basis of national applications, on a country-by-country basis. Similarly, Regulation (EC) No 469/2009 provides for SPCs for medicinal products. Together these two measures constitute the EU's SPC regime.

As confirmed by the evaluation carried out in 2020 (SWD(2020)292 final), today's purely national procedures for granting SPCs involve separate examination proceedings (in parallel or subsequent) in Member States. This entails duplication of work, resulting in high costs and more often discrepancies between Member States in decisions to grant or refuse SPCs including in litigation before national courts. Inconsistency between Member States in decisions to grant or refuse SPCs is the single reason most often cited by national courts for preliminary references to the Court of Justice of the European Union on the application of the EU's SPC regime. The current purely national procedures, therefore, lead to significant legal uncertainty.

The Commission's intellectual property action plan of November 2020 (COM(2020) 760 final), which builds on the SPC evaluation, highlighted the need to tackle the remaining fragmentation of the EU's intellectual property system. The plan noted that, for medicinal products and PPPs, SPC protection is only available at national level. At the same time, there is a centralised procedure for granting European patents.

In addition, many of the arguments made in the pharmaceutical strategy for Europe (COM(2020) 761 final) as regards SPCs for medicinal products are also applicable to SPCs for plant protection products. That Strategy emphasised the importance of investing in R&D

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1 An additional 6-month period of protection is available, subject to specific conditions, for medicinal products for use in the paediatric population, as defined by Regulation (EC) 1901/2006.

2 The unitary patent (UP) is a legal title that will provide uniform protection across all participating countries on a one-stop-shop basis. As of April 2023, 17 Member States are expected to participate in the UP system. For updates and more information, see: https://ec.europa.eu/growth/industry/strategy/intellectual-property/patent-protection-eu/unitary-patent_en.

3 European Commission, Annexes to Commission communication – Commission work programme 2022, COM(2021) 645 final, 2021, p. 9 (https://eur-lex.europa.eu/resource.html?uri=cellar%3A9fb5131e-30e9-11ec-bd8e-01aa75ed71a1.0001.02/DOC_2&format=PDF#page=9).

to create innovative medicines. The strategy stressed, however, that the differences between Member States in the implementation of intellectual property regimes, especially for SPCs, lead to duplications and inefficiencies that affect the competitiveness of the pharmaceutical industry. Both the Council[4] and the European Parliament[5] have called on the Commission to correct these deficiencies.

Additionally, there is a clear need to complement the unitary patent ('European patent with unitary effect') by a unitary SPC. Indeed, while a unitary patent may be extended by national SPCs, this approach is not optimal in the sense that the unitary protection conferred by a unitary patent would then, after patent expiry, be complemented by a plurality of legally independent national SPCs, without any unitary dimension anymore.

The grant of a unitary SPC could be requested by filing an application that would then be subjected to the same centralised examination procedure also applicable to 'centralised SPC applications' defined in a parallel proposal (COM(2023) 223) with a view to the grant of national SPCs in the Member States designated in the centralised applications. An applicant will have the possibility of filing a 'combined' centralised SPC application in which he/she would request the grant of both a unitary SPC (for those Member States in which the basic patent has unitary effect) and national SPCs (for other Member States).

- **Consistency with existing policy provisions in the policy area**

The core substantive provisions applicable to the unitary certificates to which this proposal relates – i.e. the conditions for obtaining a unitary certificate – are the same as those of the existing SPC regime, while this proposal creates a unitary SPC to be granted following examination by a central authority, which relies on the same substantive rules, with minor modifications, as the centralised procedure for the grant of national certificates established in the parallel proposal COM(2023) 223. This ensures consistency across the whole SPC reform package, especially in the event of a 'combined' application requesting the grant of both a unitary certificate and national certificates, as explained below.

In addition to this proposal, parallel proposals are being made to create a centralised procedure for the grant of national certificates for medicinal products (COM(2023) 231), a centralised procedure for the grant of national certificates for plant protection products (COM(2023) 223), and a unitary certificate for medicinal products (cf. COM(2023) 222). Applications for all of these certificates would undergo the same centralised examination procedure described in this proposal, especially in the event of 'combined' applications that request both a unitary certificate and national certificates, as explained below. This ensures complete consistency across the whole SPC reform package.

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4 Council conclusions on intellectual property policy of 10 November 2020 https://www.consilium.europa.eu/media/46671/st-12750-2020-init.pdf.

5 European Parliament, Committee on Legal Affairs, Report on an intellectual property action plan to support the EU's recovery and resilience (2021/2007(INI)), https://www.europarl.europa.eu/doceo/document/A-9-2021-0284_EN.html.

This table explains the purposes of the four related proposals:

Medicinal products		**Plant protection products**
PROPOSAL 1 Regulation on the SPC for medicinal products (recast)	← Art. 114 TFEU →	**PROPOSAL 2** Regulation on the SPC for plant protection products (recast)
PROPOSAL 3 Regulation on the unitary SPC for medicinal products	← Art. 118 TFEU →	**PROPOSAL 4** Regulation on the unitary SPC for plant protection products

In contrast to the proposal regarding the unitary SPC for medicinal products, this proposal foresees some minor differences as regards the conditions for grant and introduces some changes made necessary by specific features of the marketing authorisations for plant protection products.

The proposed creation of a unitary SPC will be fully compatible with the unitary patent system, under Regulation (EU) No 1257/2012 and the Agreement on a Unified Patent Court (UPCA).

In addition, as this was also the case for Regulation (EC) No 1610/96, this proposal is compatible with the agrochemical EU legislation.

Finally, this proposal is part of the 'EU patent package' announced in 2023 which, besides the revision, modernisation and introduction of a system for unitary SPCs, includes a new initiative on compulsory licensing and legislation on standard-essential patents. The proposal also complements the unitary patent system, which is a major step towards the completion of the single market for patents.

- **Consistency with other Union policies**

The proposed centralised procedure is fully consistent with the existing legislation relating to agrochemical products and with other relevant legislation. This includes the *European patent with unitary effect* ('unitary patent') as set out in Regulation (EU) No 1257/2012, and the related UPCA. The unitary patent system will enter into force on 1 June 2023.

Finally, the SPC reform and the other initiatives listed in the intellectual property action plan contribute to the broader innovation strategy of the EU.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- **Legal basis**

The current proposal is based on the first subparagraph of Article 118 of the Treaty on the Functioning of the European Union, which is the only treaty provision suitable for the creation of unitary IP rights as it allows for measures for the creation of European intellectual property rights to provide uniform protection of intellectual property rights throughout the Union and for the setting up of centralised Union-wide authorisation, coordination and supervision arrangements.

Article 118 was introduced by the Treaty on the Functioning of the European Union (TFEU) and provides an express legal base for EU-wide intellectual property rights. It is also the legal basis for Regulation (EU) No 1257/2012 of the European Parliament and of the Council implementing enhanced cooperation in the area of the creation of unitary patent protection.

Together with the parallel proposal relating to a centralised procedure for the grant of national certificates (COM(2023) 223), this proposal addresses the fragmentation of the existing SPC regime, implemented at a purely national level: despite the fact that SPCs are already harmonised – and indeed defined – by EU law, there are still cases where some Member States have granted SPCs while identical applications have been refused in others, or been granted with a different scope. SPC applicants thus face diverging decisions across the EU on the same product, while incurring costs for applying and maintaining SPCs in several Member States. Consequently, further EU action is needed to address these issues and can, unlike national intervention by Member States, ensure a consistent EU-wide framework, and reduce the total costs and burden of fees to be paid in multiple Member States. Further EU-level action would strengthen the integrity of the single market by providing a centralised, balanced and transparent SPC system across the EU, and mitigate the negative consequences of redundant and potentially diverging procedures that applicants face[6]. Hence, by its nature, action at EU level is also justified to ensure the smooth functioning of the single market for innovative plant protection products that are subject to marketing authorisations. EU-level action would also allow innovative and follow-on manufacturers to reap the benefits of an efficient intellectual property framework in the relevant product markets.

- **Subsidiarity**

EU action is necessary to provide a unitary SPC for the unitary patent. An EU IP right (such as a unitary SPC) can only be created by the EU. National legislation cannot achieve this objective, as it is not able to provide for unitary protection, and the objectives underlying this proposal can thus only be achieved at Union level. The Union-wide approach implemented by the centralised procedure for the grant of national certificates and unitary SPCs will ensure that the applicable rules and procedures are consistent across the Union — at least insofar as the Member States participating in the unitary patent system are concerned —, ensuring legal certainty for all relevant market participants. Moreover, the unitary SPC is an autonomous IP right, applying independently of any national system. Consequently, EU action is needed to create a new unitary SPC complementing the unitary patent.

- **Proportionality**

This initiative does not go beyond what is necessary to achieve the identified objectives. Its scope is limited to those aspects that Member States cannot achieve satisfactorily on their own and where EU action can produce better results, e.g. in terms of consistent decisions on SPC applications to reduce administrative burdens and costs, and improve transparency and legal certainty.

- **Choice of the instrument**

The instrument choice is an EU regulation establishing a unitary SPC. No other instrument can be envisioned for creating a unitary IP right.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Ex-post evaluations and fitness checks of existing legislation**

An evaluation of the SPC regime was carried out in 2020 (SWD(2020) 292). It found that SPCs promote innovation and the availability of new medicines and PPPs because they help

[6] Case C-58/08 ECLI:EU:C:2010:321.

companies recoup their R&D investments. Although the SPC Regulations provide a common framework within the EU, they are administered at a national level. This fragmentation leads to high costs and imposes an administrative burden on applicants (especially SMEs) and national administrations. It also leads to legal uncertainty, as the scope of protection can differ across the EU. This has a negative impact on SPC users and makers of follow-on products. These negative effects are amplified by a lack of transparency, especially from a cross-border perspective, making it difficult to trace what SPC protection exists for which products in which Member States. This affects both SPC holders and manufacturers of follow-on products.

- **Stakeholder consultations**

The Commission conducted a public consultation during the evaluation (between 12 October 2017 and 4 January 2018). In addition, the Max Planck Institute study mentioned below included a survey of stakeholders in the Member States, conducted in 2017 by the Allensbach Institute ('the Allensbach survey'), which included several questions on the operation of the current (national) SPC regimes. Moreover, from 8 March to 5 April 2022 interested parties could provide feedback to Commission's Call for Evidence. For further information, see Annex 2 of the impact assessment (SWD(2023) 118).

Most of the respondents to the Allensbach survey consultation (conducted by the Allensbach Institute and included in the 2018 study by the Max Planck Institute (MPI))[7] and to the public consultation organised by the Commission endorse the creation of a Unitary SPC. Answers to Question 69 of the Allensbach survey show that there is wide support for a unitary SPC, and that from all categories of respondents. The same can be said of the replies to the questions relating to the unitary SPC included in the public consultation 'on Supplementary Protection Certificates and patent research exemption for sectors whose products are subject to regulated market authorisations' that was conducted from 12 October 2017 to 4 January 2018.[8]

Moreover, from 8 March to 5 April 2022 interested parties could provide feedback to Commission's Call for Evidence. For further information, see Annex 2 of the Impact Assessment.

- **Collection and use of expertise**

The study[9] carried out in 2018 by the Max Planck Institute on the legal aspects of SPCs in the EU (especially Chapter 22) provides key findings on the operation of the current SPC regime (for medicinal products). In particular that study included a survey among stakeholders in the EU Member States (2017), conducted by the Allensbach Institute[10], which included several questions relating to a possible unitary SPC in addition to the many questions relating to the operation of the current (national) SPC regimes.

- **Impact assessment**

An impact assessment was carried out and submitted to the Regulatory Scrutiny Board in late 2022 and, after resubmission, received a positive opinion on 16 December 2022 (SWD(2023) 118).

The following options were identified:

– Option 0: No policy change.

[7] https://ec.europa.eu/docsroom/documents/29524
[8] https://ec.europa.eu/docsroom/documents/29464
[9] https://ec.europa.eu/docsroom/documents/29524
[10] https://ec.europa.eu/docsroom/documents/29524/attachments/4/translations/en/renditions/native

– Option 1: Guidelines for the application of the current SPC regimes. This option would provide common guidelines/recommendations to national patent offices (NPOs) on the application of the SPC Regulation, building on their experience and the case law of the Court of Justice of the European Union (CJEU). These guidelines would also recommend common rules for the publication and accessibility of SPC information in national registers.

– Option 2: Mutual recognition of national decisions. This would enable applicants to file an SPC application with a designated NPO, known as the reference office, whose decision would be recognised by all other NPOs.

– Option 3: Centralised filing and examination of SPC applications, resulting in a non-binding opinion. This would create a central authority for filing SPC applications in the EU, which would examine applications and issue an opinion on whether or not to grant an SPC. NPOs could follow this opinion or, alternatively, conduct their own examination. Therefore, the decision on granting SPC protection would be kept at the national level. Only holders of a European patent – and, for medicinal products, of a centralised marketing authorisation – could use this system.

– Option 4: Centralised filing and examination of SPC applications, resulting in a binding opinion. This is identical to option 3, 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 a central authority.

– Option 5: A 'unitary SPC' complementing the unitary patent. The central authority, in addition to examining applications, would grant a 'unitary SPC' to applicants with a European patent with unitary effect. The unitary SPC would be valid only in the territory of the (initially 17) Member States party to the UPCA.

These options would not replace national SPCs, but would provide alternative routes to obtaining SPC protection across the EU.

A combination of options 4 and 5 constitutes the preferred choice. It would provide for a centralised procedure that could result in the grant of national SPCs in some or all Member States, and/or of a unitary SPC (covering those Member States in which the basic unitary patent has effect). When deciding on who should act as the examination authority, several criteria were considered: accountability (in particular, to the European Parliament), alignment with the EU's overarching political values and current policy priorities, and experience with substantive SPC assessment. It is therefore proposed that the EU Intellectual Property Office (EUIPO) should become the central examination authority, supported by national offices.

Option 1, on guidelines for examining national SPC applications, would not be sufficient alone to overcome discrepancies between national practices, as the guidance would be non-binding. Nevertheless, in the context of the preferred options 4 and 5, EUIPO should develop guidelines that reflect its practice. These guidelines would be of practical use both to officials in charge of the SPC-related procedures and to their users, including professional advisers who assist applicants (e.g. by offering examples). This guidance would take stock of the practices developed by the examination panels, especially since they will include examiners from several different Member States, to improve consistency between examination practices under the new centralised procedure. Moreover, national offices may also benefit from guidelines developed by the examination authority for their own (national) examination procedures.

Option 2 may not provide enough predictability, as some reference offices could be more lenient than others, thus leading to 'forum shopping', while Option 3 alone would allow offices to re-examine the SPC application, and has thus the potential to result in divergences on the decision to grant or refuse an SPC, leading to further fragmentation in the single market.

- **Regulatory fitness and simplification**

Enabling unitary patent holders to obtain through a single procedure a unitary SPC able to be enforced centrally in all relevant Member States represents a considerable simplification compared to the current situation in which national SPCs need to be applied for and enforced separately in each Member State, while noting that SPCs based on European patents (also non-unitary ones) will be able to be enforced before the Unified Patent Court ('UPC') once it is operating[11].

- **Fundamental rights**

This proposal will have no impact on fundamental rights, especially since it is not proposed to alter the substantive features of the existing SPC regimes (e.g. conditions for grant, scope, effects). The initiative is consistent with the Charter of Fundamental Rights, as it offers greater legal certainty to applicants for unitary certificates, and where necessary for third parties, by providing for the procedural conditions for the examination, opposition, appeal and invalidity actions before the centralised authority.

In particular, where a centralised examination opinion is negative, the applicant may file an appeal before the Boards of Appeal of the EUIPO.

Moreover, examiners from national offices will play a key role in the centralised examination procedure and participate in the substantive examination of the application, as well as may take part in opposition and invalidity proceedings.

On the other hand, third parties will be able to submit observations during the examination of a centralised application, and to initiate an opposition against an examination opinion. After a unitary SPC is granted by the Office, third parties will also be able to challenge its validity before the Office. Counterclaims for a declaration of invalidity may be raised in the competent court of a Member State.

4. BUDGETARY IMPLICATIONS

This proposal will have no impact on the EU budget, since the system will remain fully self-funded by applicants' fees, as is already the case for the existing SPCs regimes governed by Regulations (EC) No 469/2009 and (EC) No 1610/96, and will be implemented by the examination authority, the EUIPO. The necessary set-up costs of the tasks conferred to the EUIPO, including the costs of new digital systems, will be financed from the EUIPO's accumulated budgetary surplus. A breakdown of the budgetary impact on the examination authority is provided in Annex 5D of the impact assessment.

The financial impacts on Member States (national offices) will also remain low. Indeed, while the number of SPCs applied for each year is likely to increase, it is quite low for the time being, even in large Member States. For instance, in 2017, 70 SPC applications were filed in Germany and 72 in France. The largest number of applications (95) were filed in Ireland. The average cost varies by country. Based on current average coverage (20 Member States) and

[11] To some extent at least, during the transitional period during which non-unitary European patents will still be able to be litigated before national courts.

duration (3.5 years), SPC protection for a given product would cost around EUR 98 500 on average. In order to cover all 27 Member States for 5 years one would pay nearly EUR 192 000 in total (not including any fees charged by patent lawyers). For a breakdown of the costs, see Annex 5B of the impact assessment (SWD(2023) 118).

Moreover it may be expected that only some plant protection products will be eligible for a unitary certificate in the first years of operation of the unitary patent system, considering that not all European patents will have unitary effect (which will be a prerequisite for applying for a unitary certificate).

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

It is envisaged that an evaluation will be carried out every 5 years.

- **Detailed explanation of the specific provisions of the proposal**

Overall structure of the proposal

The proposal is structured similarly to the current SPC Regulations and in particular to a parallel proposal relating to the unitary certificate for medicinal products (COM(2023) 222). It first sets out general provisions on SPCs followed by procedural provisions.

Coherence with the parallel proposal relating to medicinal products

This proposal is similar to the one presented in parallel regarding unitary SPCs for medicinal products (COM(2023) 222), with a limited number of adaptations directly linked to the intrinsic differences between medicinal products and plant protection products, regarding in particular marketing authorisations (as there are no centralised marketing authorisations for plant protection products). Moreover the 'SPC manufacturing waiver' introduced into Regulation (EC) No 469/2009 by Regulation (EU) 2019/933 only applies to SPCs for medicinal products and therefore does not need to be reflected in this new Regulation.

Basic patent

It is proposed that a unitary SPC must be based on a European patent with unitary effect only (as the 'basic patent'), which would ensure that its claims are identical for all Member States it covers, and would avoid the risk of the basic patent being revoked, or lapsing, for one or some of these Member States. In this respect it should be noted that paragraph 28 of the explanatory memorandum of the proposal for a European Parliament and Council Regulation (EC) concerning the creation of a supplementary protection certificate for plant protection products (COM(94)579) already envisaged that '*when use is made of the European procedure to obtain a Community patent, it will be all the more necessary for the certificate to apply equally to plant protection products protected by a Community patent'* (now referred to as a 'European patent with unitary effect' or, more informally, a 'unitary patent').

Allowing unitary SPCs to be based on national patents, or even on non-unitary European patents, would be more demanding insofar as the examination of such applications would be concerned, as it would be required to examine separately, for each of the Member States concerned, if the product concerned is indeed protected. This would also raise language issues, and affect legal certainty.

Examination/granting authority

Under this proposal, a central examination authority will carry out a substantive examination of a unitary SPC application, especially as regards the conditions for grant defined in Article 3 of the existing SPC Regulations. The Commission proposes that the EUIPO should be the

central examination authority, in particular because it is an EU agency and therefore part of the EU legal order.

After assessing the formal admissibility of the unitary SPC application, the central examination authority would entrust the substantive examination of the application to a panel. This panel would be made up of a member of that central authority and two qualified examiners, experienced in SPC matters, from two different national patent offices in Member States. Before designating examiners qualified to examine SPC issues, these national patent offices will have agreed, through an ad hoc agreement with the central examination authority, to participate in this centralised examination system. Competencies and skills in SPC matters are scarce and qualified SPC examiners can be found today in national patent offices. Moreover, the relatively low number of products for which SPC applications are made each year (less than 100) justifies making recourse to existing qualified examiners in Member States, as opposed to creating an entirely new body of experts. During the examination, third parties may submit their observations on the validity of a certain unitary SPC application after its publication.

Examination procedure and remedies

After examining the application, the central examination authority will issue an examination opinion stating whether the application fulfils the applicable criteria (and in the first place those defined in Article 3). The applicant can file an appeal against a negative opinion (as further explained below).

In order to account for the need to have a complete system of remedies and avoid the need for third parties challenging a positive examination opinion in national courts which would then in turn have to make reference to the EU Courts, third parties will be able to challenge a positive (or partly positive) opinion by initiating an opposition procedure during 2 months after the publication of the examination opinion. Such an opposition may result in the examination opinion being amended.

Challenges against the examination opinion can be appealed to the Boards of Appeal, and subsequently to the General Court and, possibly, ultimately before the Court of Justice subject to the system of leave to appeal under Articles 170a and following of the Rules of Procedure of the Court of Justice, or under the review procedure in accordance with Article 256, paragraph 2, TFEU, Article 62 of the Statute of the Court and Articles 191 and following of the Rules of Procedure of the CJEU.

On the basis of the examination opinion (as possibly amended following an opposition), the EUIPO will either grant a unitary SPC, or reject the application for it, subject to the outcome of any appeal before the Boards of Appeal of the EU courts.

After the grant of a unitary SPCs, third parties will be able to initiate invalidity proceedings (actions for a declaration of invalidity) before the Office. Here as well, related decisions may be appealed to the Boards of Appeal, and may end up before the General Court.

Counterclaims for a declaration of invalidity could be raised in the competent court of a Member State (including the Unified Patent Court where the applicable conditions are met, subject to a suitable amendment of the UPCA).

Marketing authorisations concerned

Given that there is a zonal system of marketing authorisations for PPPs in the EU and that only national marketing authorisations exist for PPPs, the requirement for a centralised authorisation, included in the parallel proposal (COM(2023) 222) creating a unitary certificate

for medicinal products, cannot be applied in this Regulation. Therefore, national marketing authorisations will be allowed to serve as basis for the grant of unitary certificates for PPPs.

Since the marketing authorisations granted in respect of a given plant protection product may have slightly different scopes in different Member States, it will be important to clarify that a unitary certificate will confer protection to the product identified in the related application only to the extent that the product is duly covered by the marketing authorisations granted in each of the relevant Member States (i.e. those in which the basic patent has unitary effect).

Moreover, since marketing authorisations for a given plant protection product are usually granted at different dates in different Member States, it may happen that, at the date of filing the unitary certificate application[12], authorisations have been granted in some of the Member States in which the basic patent has unitary effect, but not in all of them. Since this situation is expected to be frequent, the traditional requirement for the availability of valid authorisations at the date of filing of the application would often make it impossible to fulfil the conditions for the grant of a unitary certificate on a PPP.

To address this situation, it is proposed to allow the grant of a unitary certificate for a PPP provided that two conditions are fulfilled in respect of marketing authorisations, as a derogation from the above-mentioned traditional requirement:

– at the date of filing of the application, it is only required that marketing authorisations have been *applied for* in each of the Member States in which the basic patent has unitary effect, but

– before the end of the examination process, marketing authorisations must have been *granted* in each of these Member States. At the same time it would be required that the examination process does not end earlier than 18 months from the filing of the application, to increase the likelihood that the 'missing' marketing authorisations may have been granted by then.

In addition, it is necessary to consider that in certain cases marketing authorisations may still not be available (granted), before the end of the examination process, in all of the Member States in which the basic patent has unitary effect – which is a real risk considering the complexity and thus duration of the authorisation procedures.

In such a case it is proposed that a unitary certificate will be granted, but will not have effect in a Member State (in which the basic patent has unitary effect) in which no authorisation was granted before the end of the examination process. In such an exceptional situation, the suspended effect in a certain Member State could resume where a 'missing' authorisation would be granted after the grant of the unitary certificate but – for legal certainty reasons – before the expiry of the basic patent, subject to a proper re-examination of that authorisation by the Office.

[12] or of filing a 'combined' application including a request for the granting of a unitary certificate in addition to the designation of additional Member States.

Substantive features of the SPC regime

This reform does not intend to modify, nor further clarify in view of the relevant case law of the Court of Justice, the substantive features currently laid down in Regulation (EC) No 1610/96 for the existing national SPC regimes or the new centralised procedure, including as regards its application to unitary SPCs, since:

– the case law[13] on SPCs is progressively but effectively converging, and steadily reducing uncertainty about the interpretation of the SPC regime[14], while further amendments might trigger new fluctuations and uncertainty as regards the proper interpretation of the amended rules;

– respondents to the Allensbach survey did not call for Article 3 of the SPC Regulations to be amended (question 48) even if they consider that the case law is unclear in some respects (question 46).

That being said, considering that there are national discrepancies in the interpretation of the rule defining the duration of a European patents, which may result in a one-day difference, there is a need to clarify that rule insofar as its application to unitary SPCs is concerned.

New recitals

Certain recitals concern the conditions (as set out in Article 3) for the grant of SPCs and incorporate the case law of the Court of Justice. The aim is to assist ensure consistency. In particular the judgements in cases C- 121/17 and C-673/18 interpret Article 3(1)(a) and 3(1)(d) of the current SPC Regulation, respectively, and should be considered settled case law. This is also the case for judgement C-471/14, whereby the date of the first marketing authorisation in the Union, within the meaning of Article 13, is the date on which notification of the decision granting the authorisation was given to the addressee of the decision.

The requirement that the product should be protected by the basic patent means that the product should fall within the scope of one or more claims of that patent, as properly interpreted at the basic patent's filing date. This also includes situations where the product corresponds to a general functional definition used by one of the claims of the basic patent, and necessarily comes within the scope of the invention covered by that patent, even if it is not indicated in individualised form as a specific embodiment in the patent, provided that it is specifically identifiable from the patent.

Many general objectives set out in the Explanatory Memorandum of the proposal (COM(94)579) for what became Council Regulation (EC) No 1610/96, remain fully relevant today, and should continue to be used as a guide to interpretation, where relevant. This includes the objective that *if a certificate has already been granted for the active substance itself, a new certificate may not be granted for that active substance, whatever changes may have been made regarding other features of the plant protection product (use of a different salt, different excipients, different presentation, etc.)*.

Furthermore, as regards the rights conferred by a certificate, *the certificate confers the same protection as the basic patent, but only protects the product covered by the authorisation, for all pharmaceutical uses authorised, until the expiry of the basic patent*.

As regards the rights conferred by a certificate, and in line with the earlier statements regarding derivatives, it is appropriate to consider that the protection conferred by a certificate

[13] For a full list of cases, see Table 5.5. of the second MPI study.

[14] Further clarifications are, however, necessary in certain areas as indicated by two referrals in 2022, cases C-119/22 and C-149/22.

on a product extends to the derivatives of that product that are equivalent to the product from a phytosanitary perspective.

Finally, it remains fully justified to require, as already stated in the Explanatory Memorandum of the proposal (COM(94)579) for what became Council Regulation (EC) No 1610/96, that *only the first authorisation to place the product on the market in the Member State in which the application is lodged is taken into account for the purposes of the Regulation*. In other words, this 'first authorisation' requirement should be applied on a country-by-country basis.

Language regime

This Regulation envisages the possibility of filing a centralised SPC application in any official EU language. In this regard, the amount of text in an SPC application is extremely small, especially compared to patents and that this would not present a burden for applicants. Certain matters would not require any translation, such as the identification of the basic patent and the relevant marketing authorisation, the relevant dates, and the identification of the applicant(s) and the product concerned. The translation costs are, therefore, expected to be considerably lower than would be the case for patent applications. See the impact assessment (SWD(2023) 118) for an exact calculation.

Appeal

Decisions of the central examination authority are subject to appeal. This also applies to a negative examination opinion issued by the central examination authority, against which the applicant may file an appeal. This also applies to other decisions of that authority; for instance, the decision relating to an opposition may be appealed by any of its parties. An appeal may result in the examination opinion being amended.

In the event of a 'combined' SPC application as referred to below – namely an SPC application which requests the grant of a unitary SPC and also of national SPCs –, such an appeal would be applicable to the (common) examination opinion relating to the combined SPC application.

The appeal would take place before the Boards of Appeal of the EUIPO. Members from the Boards of Appeal should be appointed in accordance with Article 166 (5) of Regulation 2017/1001. These members may also be national examiners, but they may not be the same examiners already involved in the examination of the centralised applications or applications for unitary certificates.

In terms of workload, SPC applications are made for less than 100 products each year on average, for both medicinal products and PPPs, and introducing third-party observations should help keep the number of appeals at a very low level.

Fees and financial transfers between the central authority and national patent offices (NPOs)

An application fee and possibly other procedural fees, such as the fee for a review or an appeal, and annual (renewal) fees, will have to be paid by applicants to the central examination authority. The level of fees to be paid to the central examination authority will be set in an implementing act.

It would be appropriate that a fraction of the renewal fees paid by unitary SPC holders be transferred to the national patent offices[15] of the Member States in which unitary SPCs have legal effect (as already planned in respect of renewal fees for unitary patents). At the same

[15] Or any other national authority competent for the grant of SPCs.

time, it is necessary to ensure that those national offices that participate in the new procedure as regards the substantive examination of unitary SPC applications are properly remunerated for their participation.

Litigation

It is intended that a unitary SPC will be able to be litigated before the body responsible under national law for the revocation of the corresponding basic patent. It is expected that the definition of SPCs present in the UPCA will be amended to include unitary SPCs as well. Such amendment may be based on Article 87(2) of the UPCA.

Centralised procedure for the grant of national SPCs

A parallel proposal (COM(2023) 223) is intended to create a centralised procedure for the filing and examination of 'centralised SPC applications', able to result in the grant (at a national level) of national SPCs in the Member States designated in that application. This procedure would be available potentially for all Member States, and only on the basis of a European patent as basic patent.

It is proposed that the procedure for the filing and examination of unitary SPC applications would be the same (mutatis mutandis) as the centralised procedure defined in the above-mentioned parallel proposal. In this manner, a 'combined' SPC application could possibly include both a request for the grant of a unitary SPC (for the Member States covered by the basic patent) and a request for the grant of national SPCs in other Member States. That 'combined' application would undergo a single examination procedure, ruling out any discrepancies, and considerably reducing costs and administrative burden for applicants.

2023/0126 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the unitary supplementary protection certificate for plant protection products

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 118, first paragraph, thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[16],

Having regard to the opinion of the Committee of the Regions[17],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Phytopharmaceutical research plays a decisive role in the continuing improvement in agriculture. Plant protection products, in particular those that are the result of long, costly research will not continue to be developed in the Union unless they are covered by favourable rules that provide for sufficient protection to encourage such research.

(2) The period that elapses between the filing of an application for a patent for a new plant protection product and the authorisation to place that product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research.

(3) Uniform patent and supplementary protection within the internal market, or at least a significant part thereof, should feature amongst the legal instruments which agrochemical undertakings have at their disposal to enhance their competitiveness.

(4) In its Communication of 25 November 2020 entitled 'Making the most of the EU's innovative potential – An intellectual property action plan to support the EU's recovery and resilience'[18], the Commission highlighted the need to tackle the remaining fragmentation of the Union's intellectual property system. In that Communication, the Commission noted that, for medicinal products and plant protection products, supplementary protection is only available at national level. At the same time, there is a centralised procedure for granting European patents. In

16 OJ C […], […], p. […].
17 OJ C […], […], p. […].
18 COM(2020)760 final.

addition, the 'unitary patent' as laid down in Regulation (EU) No 1257/2012[19] enters into force on 1 June 2023 in respect for all Member States having ratified the Agreement on a Unified Patent Court ('UPC').

(5) Regulation (EU) No 1257/2012 has created the possibility to provide unitary patents. However, Regulation (EU) No 1257/2012 does not provide for a unitary supplementary protection certificate ('unitary certificate').

(6) In the absence of a unitary certificate, a unitary patent could only be extended by applying for several national certificates in each Member State where protection is sought, preventing the holder of a unitary patent from obtaining unitary protection during the whole combined protection period conferred by that unitary patent and subsequently by these certificates. Therefore, a unitary certificate for plant protection products should be created, that would allow a unitary patent to be extended in a unitary manner. Such a unitary certificate should be applied for on the basis of a unitary basic patent and would have the same legal effects as national certificates in all Member States in which that basic patent has unitary effect. The main feature of such a unitary certificate should be its unitary character.

(7) A unitary certificate should provide uniform protection and have equal effect in all Member States where the basic patent it relies upon has unitary effect, except in the case of temporary suspension of the effect to allow for marketing authorisations granted at different times. Consequently, a unitary certificate should only be transferred or revoked, or expire, in respect of all those Member States.

(8) Regulation [COM(2023) 223] replaces Regulation (EC) No 1610/96 of the European Parliament and of the Council[20], and includes new provisions establishing a centralised procedure for the examination of supplementary protection certificates for plant protection products.

(9) Considering that certain Member States have not yet joined the unitary patent system, certificates granted by national patent offices should remain available.

(10) To avoid discrimination between applicants for certificates under Regulation [COM(2023) 223] and for unitary certificates under this Regulation, and distortions of the internal market, the same substantive rules should apply, with appropriate adaptations, to certificates under Regulation [COM(2023) 223] and to unitary certificates, in particular as regards the conditions for grant of a certificate, as well as the duration and effects of a certificate.

(11) In particular, the duration of the protection granted by a unitary certificate should be identical to the duration provided for as regards national certificates under Regulation [COM(2023) 223]*;* namely, the holder of both a unitary patent and a unitary certificate should be able to enjoy an overall maximum of 15 years of exclusivity from the time the plant protection product in question first obtains an authorisation to be placed on the market in the Union. Since the unitary certificate would take effect at the expiry of the basic patent, and in order to take into account discrepancies in national practices

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[19] Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection (OJ L 361, 31.12.2012, p. 1).

[20] 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 (OJ L 198, 8.8.1996, p. 30).

regarding the date of expiry of a patent which may result in 1-day differences, this Regulation should clarify when exactly the protection conferred by a unitary certificate should take effect.

(12) Regulation (EU) No 2017/1001 of the European Parliament and of the Council[21] has established, under its Article 2, a European Union Intellectual Property Office ('the Office'). In the interest of the internal market, and due to the autonomous nature of the unitary certificate, its examination and grant procedure should be carried out by a single examining authority. This can be achieved by giving the Office the task of examining both applications for unitary certificates in accordance with this Regulation and Regulation [COM(2023) 222] and centralised applications for certificates under Regulations [COM(2023) 231] and [COM(2023) 223].

(13) In the absence of a centralised marketing authorisation, marketing authorisations are granted at a national level. Accordingly, authorisations in respect of a given plant protection product may have a slightly different scope in different Member States. Nevertheless, a unitary certificate should confer protection to that plant protection product only to the extent that it is duly covered by the marketing authorisations granted in each of the Member States in which the basic patent has unitary effect.

(14) The fact that marketing authorisations in respect of a given plant protection product may be granted at different dates in different Member States would in many cases make the grant of a unitary certificate for a given plant protection product impossible, if it was required that authorisations must have been granted in all relevant Member States – i.e. those in which the basic patent has unitary effect – by the time of the filing of the application. An applicant should therefore be allowed to file an application for a unitary certificate where marketing authorisations have been applied for in all relevant Member States, provided that such authorisations are granted before the end of the examination process – which for that reason should not be completed earlier than 18 months from the filing of the application. Where no authorisation has been granted in a relevant Member State before the completion of the examination, the unitary certificate should not have any effect in respect of that Member State until a valid authorisation is granted in that Member State. However, that suspensory effect should be lifted where an outstanding authorisation is granted after the grant of the unitary certificate but – to ensure legal certainty – before the expiry of the basic patent, following a request to that end by the holder of the unitary certificate, subject to a verification of that request by the Office.

(15) An applicant should also be allowed to lodge a 'combined application' that would also include the designation of Member States, other than those in which the basic patent has unitary effect, in which the grant of national certificates would be requested as set out in Regulation [COM(2023) 223]. Such a combined application should undergo a single examination procedure.

(16) In such an event, double protection by both a unitary certificate and a national certificate – whether obtained on the basis of a national application or of a centralised application – should be excluded in any Member State.

(17) One of the conditions for the grant of a certificate should be that the product should be protected by the basic patent, in the sense that the product should fall within the scope

[21] Regulation (EU) 2017/1001 of the European Parliament and of the Council of 14 June 2017 on the European Union trade mark (OJ L 154, 16.6.2017, p. 1).

of one or more claims of that patent, as interpreted by the person skilled in the art by the description of the patent on its filing date. This should not necessarily require that the active substance of the product be explicitly identified in the claims. Or, in the event of a preparation, this should not necessarily require that each of its active substances be explicitly identified in the claims, provided that each of them is specifically identifiable in the light of all the information disclosed by that patent.

(18) To avoid overprotection, it should be provided that no more than one certificate, whether national or unitary, may protect the same product in a Member State. Therefore it should be required that the product, or any derivative such as salts, esters, ethers, isomers, mixtures of isomers, or complexes, equivalent to the product from a phytosanitary perspective, should not have already been the subject of a prior certificate, either alone or in combination with one or more additional active ingredients, whether for the same application or for a different one.

(19) Within the limits of the protection conferred by the basic patent, the protection conferred by a unitary certificate should extend only to the product, namely the active substance or combinations thereof, covered by the authorisation to place it on the market and for any use of the product as a plant protection product that has been authorised before the expiry of the unitary certificate.

(20) To ensure balanced protection, however, a unitary certificate should entitle its holder to prevent a third party from manufacturing not only the product identified in the unitary certificate but also derivatives of that product, such as salts, esters, ethers, isomers, mixtures of isomers, or complexes, equivalent to the product from a phytosanitary perspective, even where such derivatives are not explicitly mentioned in the product description on the unitary certificate. There is therefore a need to consider that the protection conferred by the unitary certificate extends to such equivalent derivatives, within the limits of the protection conferred by the basic patent.

(21) As a further measure to ensure that no more than one certificate may protect the same product in any Member State, the holder of more than one patent for the same product should not be granted more than one certificate for that product. However, where two patents protecting the product are held by two holders, one certificate for that product should be allowed to be granted to each of those holders, where they can demonstrate that they are not economically linked. Furthermore, no certificate should be granted to the proprietor of a basic patent in respect of a product which is the subject of an authorisation held by a third party, without that party's consent.

(22) As regards unitary certificate applications for plant protection products, the condition for grant relating to the authorisation being the first one should be fulfilled on a country-by-country basis.

(23) To ensure alignment with the rules applicable to unitary patents, a unitary certificate as an object of property should be dealt with, in its entirety and in all Member States in which it has effect, as a national certificate of the Member State determined in accordance with the law that applies to the basic patent.

(24) To guarantee a fair and transparent process, ensure legal certainty and reduce the risk of subsequent validity challenges, third parties should have the possibility, after the publication of the unitary certificate application, to submit within 3 months observations to the Office while the centralised examination is being performed. These third parties allowed to submit observations should also include Member States. This, however, should not affect the rights of third parties to initiate subsequent invalidity

proceedings before the Office. These provisions are necessary to ensure involvement of third parties both before and after the grant of certificates.

(25) The examination of an application for a unitary certificate should be conducted, under supervision of the Office, by an examination panel including one member of the Office as well as two examiners employed by the national patent offices. This would ensure that optimal use be made of expertise in supplementary protection certificates matters, located today at national offices only. To ensure an optimal quality of the examination, suitable criteria should be laid down in respect of the participation of specific examiners in the procedure, in particular as regards qualification and conflicts of interest.

(26) The Office should examine the application for a unitary certificate and issue an examination opinion. That opinion should state the reasons for which it is positive or negative.

(27) To safeguard third parties' procedural rights and ensure a complete system of remedies, third parties should be able to challenge an examination opinion, by initiating opposition proceedings within a short duration following the publication of that opinion, and that opposition may result in that opinion being amended.

(28) After the completion of the examination of a unitary certificate application, and after the time limits for appeal and opposition have expired, or, the case being, after a final decision on the merits has been issued, the Office should implement the examination opinion by granting a unitary certificate or rejecting the application, as applicable.

(29) Where the applicant or another party is adversely affected by a decision of the Office, the applicant or that party should have the right, subject to a fee, to file within 2 months an appeal against the decision, before a Board of Appeal of the Office. This also applies to the examination opinion, that may be appealed by the applicant. Decisions of that Board of Appeal should, in turn, be amenable to actions before the General Court, which has jurisdiction to annul or to alter the contested decision. In case of a combined application including the designation of additional Member States with a view to the grant of national certificates, a common appeal may be filed.

(30) When appointing members of the Boards of Appeal in matters regarding applications for unitary certificates, their prior experience in supplementary protection certificate or patent matters should be taken into account.

(31) Any person may challenge the validity of a unitary certificate by lodging with the Office an application for a declaration of invalidity.

(32) The Office should have the possibility to charge a fee for the application for a unitary certificate, as well as other procedural fees such as those for oppositions, appeals and invalidity. The fees charged by the Office should be laid down by an implementing act.

(33) Annual fees in respect of unitary certificates (also known as renewal fees) should be paid to the Office, which should retain a part of them to cover the expenses generated by carrying out tasks in relation to the grant of unitary certificates while the remaining part would be shared with those Member States in which unitary certificates have effect.

(34) To ensure transparency, a register should be set up that can serve as a single access point providing information on applications for unitary certificates as well as granted

unitary certificates and their status. The register should be available in all official languages of the Union.

(35) For the tasks conferred on the Office under this Regulation, the languages of the Office should be all official languages of the Union, to enable actors across the Union to easily apply for unitary certificates or submit third party observations and result in optimal transparency for all stakeholders across the Union. The Office should accept verified translations, into one of the official languages of the Union, of documents and information. The Office may, if appropriate, use verified machine translations.

(36) Financial provision should be made to ensure that competent national authorities that participate in the centralised procedure are adequately remunerated for their participation.

(37) The necessary set-up costs related to the tasks conferred to the Office, including the costs of new digital systems, should be financed from the Office's accumulated budgetary surplus.

(38) In order to supplement certain non-essential elements of this Regulation, the power to adopt acts, in accordance with Article 290 of the Treaty on the Functioning of the European Union, should be delegated to the Commission in respect of: (i) specifying the content and form of the notice of appeal and the content and the form of the Boards of Appeal's decision, (ii) specifying the details concerning the organisation of the Boards of Appeal in proceedings relating to certificates, (iii) specifying the rules on the means of communication, including the electronic means of communication, to be used by the parties to proceedings before the Office and the forms to be made available by the Office, (iv) setting out the detailed arrangements for oral proceedings, (v) setting out the detailed arrangements for the taking of evidence, (vi) setting out the detailed arrangements for notification, (vii) specifying the details regarding the calculation and duration of time limits and (viii) setting out the detailed arrangements for the resumption of proceedings. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016.[22] In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

(39) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards: (i) the application forms to be used; (ii) rules on procedures relating to the filing, and procedures regarding the way in which examination panels examine centralised applications and prepare examination opinions, as well as the issuance of examination opinions by the Office, (iii) the criteria in the ways the examination panels are to be set up, and the criteria for the selection of examiners, (iv) the amounts of the applicable fees to be paid to the Office, (v) specifying the maximum rates for costs essential to the proceedings and actually incurred by the successful party, and (vi) rules on the financial transfers between the Office and Member States, the amounts of these transfers, and the remuneration to be paid by the Office regarding the participation of

[22] Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making (OJ L 123, 12.5.2016, p. 1).

competent national authorities. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[23].

(40) The Commission should regularly report on the operation of this Regulation, in coordination with that required in Regulation [COM(2023) 223].

(41) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union ('the Charter'). The rules in this Regulation should be interpreted and applied in accordance with those rights and principles. In particular, this Regulation seeks to ensure full respect for the right to property and the right to health care and the right to an effective remedy in Articles 17 and 47 of the Charter.

(42) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States but can rather, by reason of the autonomous nature of the unitary SPC being independent from national systems, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

(43) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725[24] and delivered an opinion on XXX *[OP, please add reference once available]*.

(44) Provision should be made for appropriate arrangements to facilitate a smooth implementation of the rules provided for in this Regulation. To allow for sufficient time for the Office to prepare the operational set-up and launch of the procedure to be used for the grant of unitary certificates, as set out in this Regulation, the application of this Regulation should be deferred,

HAVE ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation lays down rules on the unitary supplementary protection certificate ('unitary certificate') for plant protection products protected by a European patent with unitary effect and subject, prior to being placed on the market as a plant protection product, to an administrative authorisation procedure as laid down in Regulation (EC) No 1107/2009 of the European Parliament and of the Council[25].

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23 Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

24 Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

25 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309 24.11.2009, p. 1).

Article 2

Definitions

For the purposes of this Regulation, the following definitions shall apply:

(1) ‘plant protection products’ means active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to:

(a) protect plants or plant products against all harmful organisms or prevent the action of such organisms, in so far as such substances or preparations are not otherwise defined below;

(b) influence the life processes of plants, other than as a nutrient (e.g. plant growth regulators);

(c) preserve plant products, in so far as such substances or products are not subject to special Council or Commission provisions on preservatives;

(d) destroy undesirable plants;

(e) destroy parts of plants, check or prevent undesirable growth of plants;

(2) ‘substances’ means chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing process;

(3) ‘active substances’ means substances or micro-organisms including viruses, having general or specific action:

(a) against harmful organisms;

(b) or on plants, parts of plants or plant products;

(4) ‘preparations’ means mixtures or solutions composed of two or more substances, of which at least one is an active substance, intended for use as plant protection products;

(5) ‘plants’ means live plants and live parts of plants, including fresh fruit and seeds;

(6) ‘plant products’ means products in the unprocessed state or having undergone only simple preparation such as milling, drying or pressing, derived from plants, but excluding plants themselves;

(7) ‘harmful organisms’ means pests of plants or plant products belonging to the animal or plant kingdom, and also viruses, bacteria and mycoplasmas and other pathogens;

(8) ‘product’ means the active substance or combination of active substances of a plant protection product;

(9) 'European patent' means a patent granted by the European Patent Office (‘EPO’) under the rules and procedures laid down in the European Patent Convention[26] ('EPC');

(10) ‘unitary patent’ means a European patent which benefits from unitary effect in the Member States participating in the enhanced cooperation laid down in Regulation (EU) No 1257/2012;

[26] Convention on the Grant of European Patents of 5 October 1973, as revised on 17 December 1991 and on 29 November 2000.

(11) 'basic patent' means a unitary patent which protects a product as such, a preparation, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a unitary certificate;

(12) 'centralised application' means an application made before the European Union Intellectual Property Office ('the Office') pursuant to Chapter III of Regulation [COM(2023) 223] with a view to the grant of certificates, for the product identified in the application, in the designated Member States;

(13) 'competent national authority' means the national authority that is competent, in a given Member State, for the grant of certificates and for the rejection of applications for certificates.

Article 3

Conditions for obtaining a unitary certificate

1. A unitary certificate shall be granted by the Office on the basis of a basic patent if, in each of the Member States in which that basic patent has unitary effect, at the date of the application, all of the following conditions are fulfilled:

   (a) the product is protected by that 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 of 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.

2. The holder of more than one patent for the same product shall not be granted more than one certificate or unitary certificate for that product for any given Member State.

   Where two or more applications, whether national or centralised applications for certificates, or applications for unitary certificates, concerning the same product and submitted by two or more holders of different patents are pending for a given Member State, one certificate or unitary certificate for that product may be granted to each of those holders, where they are not economically linked, by a competent national authority or by the Office, as applicable.

3. A unitary certificate shall also be granted for a given plant protection product if the following conditions are fulfilled:

   (a) at the date of the application, in each of the Member States in which the basic patent has unitary effect, an authorisation to place the product on the market as a plant protection product has been applied for in accordance with Regulation (EC) No 1107/2009, but an authorisation has not yet been granted in at least one of these Member States;

   (b) before the examination opinion is adopted, valid authorisations have been granted in each of the Member States in which the basic patent has unitary effect.

4. Where the condition set out in paragraph 3, point (a), is fulfilled, the examination opinion shall not be adopted earlier than 18 months after the application was filed.

5. By way of derogation from paragraph 3, where only the condition set out in paragraph 3, point (a), is fulfilled in respect of a Member State in which the basic patent has unitary effect, a unitary certificate shall be granted, but shall not have effect in that Member State.

Where a unitary certificate is granted in accordance with the first subparagraph, the applicant may submit to the Office a marketing authorisation subsequently granted in that Member State before the expiry of the basic patent, together with a request for the effect of the unitary certificate to resume in that Member State. The Office shall assess whether the conditions set out in paragraph 1 are fulfilled in respect of that Member State, and shall issue a decision on whether the effect shall resume.

Article 4

Scope of the protection

Within the limits of the protection conferred by the basic patent, the protection conferred by a unitary certificate shall extend only to the product covered, in each of the Member States in which that basic patent has unitary effect, by an authorisation to place the corresponding plant protection product on the market and for any use of the product as a plant protection product that has been authorised before the expiry of the unitary certificate.

Article 5

Effects of the unitary certificate

1. The unitary certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations, in all Member States in which the basic patent has unitary effect.

2. A unitary certificate shall have a unitary character. It shall provide uniform protection and shall have equal effect in all Member States in which the basic patent has unitary effect. The unitary certificate may only be limited, transferred or revoked, or lapse, in respect of all those Member States.

Article 6

Entitlement to the unitary certificate

1. The unitary certificate shall be granted to the holder of the basic patent or to the successor in title of that holder.

2. Notwithstanding paragraph 1, where a basic patent has been granted in respect of a product that is the subject of an authorisation held by a third party, a unitary certificate for that product shall not be granted to the holder of the basic patent without the consent of that third party.

Article 7

The unitary certificate as an object of property

A unitary certificate or an application for a unitary certificate as an object of property shall be treated in its entirety, in each Member State in which the basic patent has unitary effect, in accordance with the national law applicable to the basic patent as an object of property.

Article 8

Application for a unitary certificate

1. The application for a unitary certificate shall be lodged within 6 months of the date on which the first authorisation referred to in Article 3(1), point (b), to place the product on the market as a plant protection product was granted in one of the Member States in which the basic patent has unitary effect.

2. Notwithstanding paragraph 1, where an authorisation to place the product on the market are granted in a Member State in which the basic patent has unitary effect, before unitary effect is attributed to the basic patent, the application for a unitary certificate shall be lodged within 6 months of the date on which unitary effect is attributed to the basic patent.

Article 9

Content of the application for a unitary certificate

1. The application for a unitary certificate shall contain the following:

   (a) a request for the grant of a unitary certificate, stating the following information:

      (i) the name and address of the applicant;

      (ii) if the applicant has appointed a representative, the name and address of that representative;

      (iii) the number of the basic patent and the title of the invention;

      (iv) the number and date of the first authorisation to place the product on the market, as referred to in Article 3(1), point (b), and, if this authorisation is not the first authorisation for placing the product on the market in the Union, the number and date of that authorisation;

   (a) a copy of the authorisation to place the product on the market, as referred to in Article 3(1), point (b), in which the product is identified, containing in particular the number and date of the authorisation and the summary of the product characteristics listed in Part A, Section 1, points 1.1 to 1.7, of Commission Regulation 283/2013[27] or Part B, Section 1, points 1.1 to 1.4.3, of that Regulation or in equivalent national laws of the Member State in which the application was lodged;

   (b) where the authorisation referred to in point (b) is not the first authorisation for placing the product on the market as a medicinal product in the Union, information regarding the identity of the product thus authorised and the legal provision under which the authorisation procedure took place, together with a copy of the notice publishing the authorisation in the appropriate official publication or, in the absence of such a notice, any other document proving that the authorisation has been issued, the date on which it was issued and the identity of the product authorised.

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[27] Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 093 3.4.2013, p. 1).

2. The application referred to in this Article shall be filed by using a specific application form.

The Commission is empowered to adopt implementing acts laying down rules on the application form to be used. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 50.

Article 10

Lodging of an application for a unitary certificate

The application for a unitary certificate shall be lodged with the Office.

Article 11

Examination of the admissibility of a centralised application for a unitary certificate

1. The Office shall examine the following:
   (a) whether the application for a unitary certificate complies with Article 9;
   (b) whether the application complies with Article 8;
   (c) whether the application fee referred to in Article 29(1) has been paid within the prescribed period.
2. Where the centralised application does not satisfy the requirements referred to in paragraph 1, the Office shall request the applicant to take the measures necessary to satisfy those requirements, and shall set a deadline for such compliance.
3. Where the fee referred to in paragraph 1, point (c), has not been paid or has not been paid in full, the Office shall inform the applicant accordingly.
4. If the applicant does not satisfy the requirements referred to in paragraph 1 within the deadline referred to in paragraph 2, the Office shall reject the application for a unitary certificate.

Article 12

Publication of the application

If the application for a unitary certificate complies with Article 11(1), the Office shall publish the application in the Register.

Article 13

Examination of the application for a unitary certificate

1. The Office shall assess the application on the basis of all the conditions in Article 3(1), for all Member States in which the basic patent has unitary effect.
2. Where the application for a unitary certificate and the product to which it relates comply with Article 3(1) for each of the Member States referred to in paragraph 1, the Office shall issue a reasoned positive examination opinion in respect of the grant of a unitary certificate. The Office shall notify that opinion to the applicant.
3. Where the application for a unitary certificate and the product to which it relates does not comply with Article 3(1) in respect of one or more of those Member States, the

Office shall issue a reasoned negative examination opinion on the grant of a unitary certificate. The Office shall notify that opinion to the applicant.

4. The examination opinion shall be translated in the official languages of all Member States in which the basic patent has unitary effect. The Office may use verified machine translation to that effect.

5. The Commission is empowered to adopt implementing acts laying down rules on procedures relating to the filing, and procedures regarding the way in which examination panels examine applications for unitary certificates and prepare examination opinions, as well as the issuance of examination opinions by the Office. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 50.

Article 14

Observations by third parties

1. Any natural or legal person may submit written observations to the Office concerning the eligibility for supplementary protection of the product to which the application relates, in one or more of the Member States in which the basic patent has unitary effect.

2. A natural or legal person that has submitted the written observations in accordance with paragraph 1 shall not be a party to the proceedings.

3. Third party observations shall be submitted within 3 months after publication of the application in the Register.

4. Any observations by a third party shall be submitted in writing in one of the official languages of the Union and state the grounds on which they are based.

5. Any observations by a third party shall be notified to the applicant. The applicant may comment on the observations within a time limit set by the Office.

Article 15

Opposition

1. Within a period of 2 months following the publication of the examination opinion in respect of an application for a unitary certificate, any person ('opponent') may file with the Office a notice of opposition to that opinion.

2. Opposition may only be filed on the grounds that one or more of the conditions set out in Article 3 are not fulfilled for one or more of the Member States in which the basic patent has unitary effect.

3. Opposition shall be filed in writing, and shall specify the grounds on which it is made. It shall not be considered as duly filed until the opposition fee has been paid.

4. The notice of opposition shall contain:

   (a) the references of the unitary certificate application against which opposition is filed, the name of its holder, and the identification of the product;

   (b) the particulars of the opponent and, where applicable, of its representative;

   (c) a statement of the extent to which the examination opinion is opposed, and of the grounds on which the opposition is based.

5. The opposition shall be examined by an opposition panel set up by the Office in accordance with the rules applicable to examination panels as referred to in Article 17. However, the opposition panel shall not include any examiner previously involved in the examination panel that examined the unitary certificate application.

6. If the opposition panel notes that the notice of opposition does not comply with paragraphs 2, 3 or 4, it shall reject the opposition as inadmissible, and communicate this to opponent, unless these deficiencies have been remedied before expiry of the opposition filing period referred to in paragraph 1.

7. The decision to reject an opposition as inadmissible shall be communicated to the holder of the unitary certificate application, together with a copy of the notice of opposition.

1. A notice of opposition shall be inadmissible where a previous appeal relating to the same subject matter and cause of action has been adjudicated on its merits by the Office, and the decision of the Office on that appeal has acquired the authority of a final decision.

9. Where the opposition is not rejected as inadmissible, the Office shall promptly transmit the notice of opposition to the applicant, and shall publish it in the Register. If several notices of opposition have been filed, the Office shall promptly communicate them to the other opponents.

10. The Office shall issue a decision on the opposition within 6 months, unless the complexity of the case requires a longer period.

11. If the opposition panel considers that no ground for opposition prejudices the maintenance of the examination opinion, it shall reject the opposition, and the Office shall mention this in the Register.

12. If the opposition panel considers that at least one ground for opposition prejudices the maintenance of the examination opinion, it shall adopt an amended opinion, and the Office shall mention this in the Register.

13. The Commission is empowered to adopt delegated acts in accordance with Article 49 to supplement this Regulation by specifying the details of the procedure for filing and examining an opposition.

Article 16

Role of competent national authorities

1. On a request made to the Office, any competent national authority may be appointed by the Office as a participating office in the examination procedure. Once a competent national authority is appointed in accordance with this Article, that authority shall designate one or more examiners to be involved in the examination of one or more applications for unitary certificates.

2. The Office and the competent national authority shall conclude an administrative agreement before that competent national authority is appointed as participating office as referred to in paragraph 1.

The agreement shall specify the rights and obligations of the parties, in particular the formal undertaking by the competent national authority concerned to comply with this Regulation as regards the examination of applications for unitary certificates.

3. The Office may appoint a competent national authority as a participating office as referred to in paragraph 1 for 5 years. That appointment may be extended for further periods of 5 years.

4. The Office shall, before appointing a competent national authority, or extending its appointment, or before any such appointment expires, hear the competent national authority concerned.

5. Each competent national authority appointed under this Article shall provide the Office with a list identifying the individual examiners who are available for participation in examination, opposition and invalidity proceedings. Each such competent national authority shall update that list in the event of a change.

Article 17

Examination panels

1. The assessments under Articles 13, 15 and 22 shall be conducted by an examination panel including one member of the Office as well as two examiners as referred to in Article 16(1) from two different participating competent national authorities, under supervision of the Office.

2. Examiners shall be impartial in the exercise of their duties and shall declare to the Office any real or perceived conflict of interest upon their designation.

3. When setting up an examination panel, the Office shall ensure the following:

   (a) geographical balance amongst the participating offices;

   (b) the respective workload of the examiners is taken into account;

   (c) no more than one examiner employed by a competent national authority making use of the exemption set out in Article 10(5) of Regulation [COM(2023) 223].

4. The Office shall publish a yearly overview of the number of procedures, including those for examination, opposition, appeal and invalidity, each competent national authority participated in.

5. The Commission is empowered to adopt implementing acts to determine the criteria in the ways the panels are to be set up, and the criteria for the selection of examiners. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 50.

Article 18

Grant of a unitary certificate or rejection of the application for a unitary certificate

After the period during which an appeal or an opposition may be filed has expired without any appeal nor opposition being filed, or after a final decision on the merits has been issued, the Office shall take one of the following decisions:

   (a) where the examination opinion is positive, the Office shall grant a unitary certificate;

   (b) where the examination opinion is negative, the Office shall reject the application for a unitary certificate.

Article 19

Duration of the unitary certificate

1. The unitary certificate shall take effect at the end of the lawful term of the basic patent, namely on the twentieth anniversary of the filing date of the application for that patent, for a period equal to the period which elapsed between the date on which the application for the basic patent was lodged and the date of the first authorisation to place the product on the market in the Union, reduced by a period of 5 years.

2. The duration of the unitary certificate may not exceed 5 years from the date on which it takes effect.

Article 20

Expiry of the unitary certificate

1. The unitary certificate shall lapse in any of the following events:

   (a) at the end of the period provided for in Article 19;

   (b) if the unitary certificate holder surrenders it;

   (c) if the annual fee laid down in accordance with Article 29(3) is not paid in time.

2. Where the authorisation to place the product on the market in accordance with Regulation (EC) No 1107/2009 is withdrawn in a Member State in which the basic patent has unitary effect, the certificate shall cease to have effect in that Member State. This may be decided by the Office of its own motion or at the request of a third party.

Article 21

Invalidity of the unitary certificate

The unitary certificate shall be invalid in any of the following events:

   (a) the certificate was granted contrary to Article 3;

   (b) the basic patent has lapsed before its lawful term expires;

   (c) the basic patent is revoked or limited to the extent that the product for which the unitary certificate was granted would no longer be protected by the claims of the basic patent or, after the basic patent has expired, grounds for revocation exist which would have justified such revocation or limitation.

Article 22

Action for a declaration of invalidity

1. Any person may file with the Office an application for a declaration of invalidity of a unitary certificate.

2. An application for a declaration of invalidity may only be filed on the grounds that one or more of the conditions set out in Article 21 are not fulfilled for one or more of the Member States in which the basic patent has unitary effect.

3. An application for a declaration of invalidity shall be filed in writing, and shall specify the grounds on which it is made. It shall not be considered as duly filed until the related fee has been paid.

4. The application for a declaration of invalidity shall contain:

(a) the references of the unitary certificate against which that application is filed, the name of its holder, and the identification of the product;

(b) the particulars of the person referred to in paragraph 1 (‘applicant’) and, where applicable, of its representative;

(c) a statement of the grounds on which the application for a declaration of invalidity is based.

5. The application for a declaration of invalidity shall be examined by an invalidation panel set up by the Office in accordance with the rules applicable to examination panels. However, the invalidation panel shall not include any examiner previously involved in the examination panel that examined the unitary certificate application, nor, the case being, any examiner involved in possible related opposition proceedings, nor in related appeal proceedings.

1. An application for a declaration of invalidity shall be inadmissible where an application relating to the same subject matter and cause of action, and involving the same parties, has been adjudicated on its merits, either by the Office or by a competent court as referred to in Article 24, and the decision of the Office or that court on that application has acquired the authority of a final decision.

7. If the invalidation panel notes that the application for a declaration of invalidity does not comply with paragraphs 2, 3 or 4, it shall reject that application as inadmissible, and communicate this to applicant.

8. The decision to reject an application for a declaration of invalidity as inadmissible shall be communicated to the holder of the unitary certificate, together with a copy of that application.

9. Where the application for a declaration of invalidity is not rejected as inadmissible, the Office shall promptly transmit that application to the holder of the unitary certificate, and shall publish it in the Register. If several applications for a declaration of invalidity have been filed, the Office shall promptly communicate them to the other applicants.

10. The Office shall issue a decision on the application for a declaration of invalidity within 6 months, unless the complexity of the case requires a longer period.

11. If the examination of the application for a declaration of invalidity reveals that the one or more of the conditions set out in Article 21 are met, the unitary certificate shall be declared invalid. Otherwise the application for a declaration of invalidity shall be rejected. The outcome shall be mentioned in the Register.

12. The unitary certificate shall be deemed not to have had, as from the outset, the effects specified in this Regulation, to the extent that it has been declared invalid.

13. The Commission is empowered to adopt delegated acts in accordance with Article 49 to supplement this Regulation by specifying the details of the procedure governing the declaration of invalidity.

Article 23

Counterclaim for the invalidity of a certificate

1. A counterclaim for a declaration of invalidity may only be based on the grounds for invalidity set out in Article 21.

2. The competent court of a Member State shall reject a counterclaim for a declaration of invalidity if a decision taken by the Office relating to the same subject matter and cause of action and involving the same parties has already become final.

3. If the counterclaim is brought in a legal action to which the holder of the unitary certificate is not already a party, that holder shall be informed thereof and may be joined as a party to the action in accordance with the conditions applicable before the competent court.

4. The competent court of a Member State with which a counterclaim for a declaration of invalidity of the unitary certificate has been filed shall not proceed with the examination of the counterclaim, until either the interested party or the court has informed the Office of the date on which the counterclaim was filed. The Office shall record that information in the Register. If an application for a declaration of invalidity of the unitary certificate had already been filed before the Office before the counterclaim was filed, the court shall be informed thereof by the Office and stay the proceedings until the decision on the application is final or the application is withdrawn.

5. Where the competent court of a Member State has given a judgment which has become final on a counterclaim for a declaration of invalidity of a unitary certificate, a copy of the judgment shall be sent to the Office without delay, either by the court or by any of the parties to the national proceedings. The Office or any other interested party may request information about such transmission. The Office shall mention the judgment in the Register and shall take the necessary measures to comply with its operative part.

6. The competent court hearing a counterclaim for a declaration of invalidity may stay the proceedings on application by the holder of a unitary certificate and after hearing the other parties and may request the defendant to submit an application for a declaration of invalidity to the Office within a time limit which it shall determine. If the application is not made within the time limit, the proceedings shall continue; the counterclaim shall be deemed withdrawn. Where the competent court of a Member State stays the proceedings it may order provisional and protective measures for the duration of the stay.

Article 24

Notification of lapse or invalidity

Where the unitary certificate lapses in accordance with Article 20(1), point (b) or (c), or Article 20(2), or is invalid in accordance with Article 21 and 22, the Office shall promptly publish a notification thereof.

Article 25

Conversion

1. Where the unitary effect of the basic patent is revoked while the application for a unitary certificate is still pending, the holder of that application may, subject to a fee, request the conversion of that application into a centralised application for certificates.

2. Where the unitary effect of the basic patent is revoked after the unitary certificate has been granted, the holder of that certificate may, subject to a fee, request the conversion of that unitary certificate into national certificates.

3. A request for conversion may be filed with the Office within 3 months after notification of the revocation of the unitary effect of the basic patent.

4. A request for conversion, as well as its outcome, shall be published in the Register.

5. The Office shall check whether the conversion requested fulfils the conditions set out in this Article, together with the formal conditions specified in the implementing act adopted pursuant to paragraph 8. If the conditions governing the request are not fulfilled, the Office shall notify the applicant of the deficiencies. If the deficiencies are not remedied within a period to be specified by the Office, the Office shall reject the request for conversion. Where the conversion fee has not been paid within the relevant period of 3 months, the Office shall inform the applicant that the request for conversion is deemed not to have been filed.

6. Where a request under paragraph 1 complies with paragraph 5, the Office shall convert the application for a unitary certificate into a centralised application for certificates designating the Member States in which the basic patent had unitary effect. In the event of a combined application, the designation of the Member States in which the basic patent had unitary effect shall be added to the designation of other Member States already included in the combined application.

7. Where a request under paragraph 2 complies with paragraph 5, the Office shall transmit the request for conversion to the competent national authorities of each Member State in which the basic patent had unitary effect and for which the request has been found admissible. The competent national authorities shall take decisions accordingly.

8. The Commission shall adopt implementing acts specifying the details to be contained in a request for conversion of the for a unitary certificate or unitary certificate into a centralised application for certificates or national certificates. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 50.

Article 26

Appeals

1. Any party to proceedings under this Regulation, adversely affected by a decision of the Office, including the adoption of an examination opinion, may appeal the decision to the Boards of Appeal.

2. The filing of the appeal shall have suspensive effect. A decision of the Office that has not been contested shall take effect on the day following the date of expiry of the appeal period referred to in paragraph 3.

3. Notice of appeal shall be filed in writing at the Office within 2 months of the date of notification of the decision. The notice shall be deemed to have been filed only when the fee for appeal has been paid. In case of an appeal, a written statement setting out the grounds of appeal shall be filed within 4 months of the date of notification of the decision.

4. Following an examination of admissibility of the appeal, the Boards of Appeal shall decide on the merits of the appeal.

5. Where an appeal results in a decision which is not in line with the examination opinion, the decision of the Boards may annul or alter the opinion.

6. An action may be brought before the General Court of the European Union against a decision of the Boards of Appeal in relation to appeals, within 2 months of the date of notification of that decision, within 2 months of the date of notification of that decision, on grounds of infringement of an essential procedural requirement, infringement of the Treaty on the Functioning of the European Union, infringement of this Regulation or of any rule of law relating to their application or misuse of power. The action shall be open to any party to proceedings before the Board of Appeal adversely affected by its decision. The General Court shall have jurisdiction to annul or to alter the contested decision.

7. The decisions of the Boards of Appeal shall take effect on the day following the date of expiry of the period referred to in paragraph 6 or, if an action has been brought before the General Court within that period, as from the date following the day of dismissal of such action or of dismissal of any appeal filed with the Court of Justice of the European Union against the decision of the General Court. The Office shall take the necessary measures to comply with the judgement of the General Court or, in the event of an appeal against that judgement, the Court of Justice.

8. The Commission is empowered to adopt delegated acts in accordance with Article 49 to supplement this Regulation by specifying the content and form of the notice of appeal referred to in paragraph 3, the procedure for the filing and examination of an appeal and the content and the form of the Boards of Appeal's decision referred to in paragraph 4.

Article 27

Boards of Appeal

1. In addition to the powers conferred upon it by Article 165 of Regulation (EU) 2017/1001, the Boards of Appeal instituted by that Regulation shall be responsible for deciding on appeals against decisions of the Office taken on the basis of Article 26(1).

2. A Board of Appeal in matters regarding unitary certificates shall consist of three members, at least two of whom are legally qualified. Where the Board of Appeal considers that the nature of the appeal so requires, it may call up to two further members for that case.

3. There shall be no Grand Board as referred to in Article 165 (2), (3) and (4), and Article 167(2) of Regulation (EU) 2017/1001 in matters regarding unitary certificates. Decisions taken by a single member as under Article 165 (2) of Regulation (EU) 2017/1001 shall not be possible.

4. Members of the Boards of Appeal in matters regarding unitary certificates shall be appointed in accordance with Article 166 (5) of Regulation (EU) 2017/1001.

Article 28

Delegation of power regarding the Boards of Appeal

The Commission is empowered to adopt delegated acts in accordance with Article 49 to supplement this Regulation by specifying the details concerning the organisation of the Boards of Appeal in proceedings relating to unitary certificates under this Regulation.

Article 29

Fees

1. The Office shall charge a fee for an application for a unitary certificate.
2. The Office shall charge a fee for appeals, for oppositions, for applications for a declaration of invalidity and for conversions.
3. The unitary certificate shall be subject to the payment of annual maintenance fees to the Office.
4. The Commission is empowered to adopt implementing acts determining the amounts of the fees charged by the Office, the time limits within which they have to be paid, and the ways in which they are to be paid. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 50.

Article 30

Combined applications

An application for a unitary certificate may be included in a combined centralised application in which the applicant also requests the grant of national certificates, in the designated Member States, in accordance with the centralised procedure under Regulation [COM(2023) 223]. In that case, Article 38 of that Regulation shall apply.

Article 31

Language

1. All documents and information sent to the Office in respect of the procedures under this Regulation shall be in one of the official languages of the Union.
2. For the tasks conferred on the Office under this Regulation, the languages of the Office shall be all the official languages of the Union in accordance with Council Regulation No 1[28].

[28] Council Regulation No 1 determining the languages to be used by the European Economic Community (OJ 17, 6.10.1958, p. 385).

Article 32

Communications to the Office

1. Communications addressed to the Office may be effected by electronic means. The Executive Director shall determine to what extent and under which technical conditions those communications may be submitted electronically.

2. The Commission is empowered to adopt delegated acts in accordance with Article 49 to supplement this Regulation by specifying the rules on the means of communication, including the electronic means of communication, to be used by the parties to proceedings before the Office and the forms to be made available by the Office.

Article 33

Register

1. As regards applications for unitary certificates for plant protection products, the Register set up under Article 35 of Regulation [COM(2023) 231][29] shall include, for each unitary certificate, or application for a unitary certificate, the following information, as applicable:

   (a) the name and address of the applicant or certificate holder;

   (b) the name and business address of the representative, other than a representative as referred to in Article 36(3);

   (c) the application as well as its date of lodging and date of publication;

   (d) whether the application relates to a medicinal product or to a plant protection product;

   (e) the number of the basic patent;

   (f) an identification of the product for which a unitary certificate is requested;

   (g) the numbers and dates of the authorisations to place the product on the market referred to in Article 3(1), point (b), and an identification of the product identified in each of them;

   (h) the number and date of the first authorisation to place the product on the market in the Union;

   (i) the date and a summary of the examination opinion of the Office in respect of each of the Member States in which the basic patent has unitary effect;

   (j) where applicable, the number and the duration of the unitary certificate;

   (k) where applicable, the filing of an opposition, and the outcome of the opposition proceedings, including where applicable a summary of the revised examination opinion;

   (l) where applicable, the filing of an appeal, and the outcome of the appeal proceedings, including where applicable a summary of the revised examination opinion;

[29] Regulation of the European Parliament and of the Council on the supplementary protection certificate for medicinal products [COM(2023) 231].

(m) where applicable, a mention that a certificate has lapsed or was declared invalid;

(n) where applicable, any decision regarding the geographical scope of the unitary certificate, in respect of a derogation under Article 3, paragraph 5 or under Article 20, paragraph 2;

(o) where applicable, the filing of an application for a declaration of invalidity and, once available, the outcome of the related proceedings;

(p) where applicable, information relating to a request for conversion, and its outcomes;

(q) information on the payment of annual fees.

2. The Register shall contain changes to the information referred to in paragraph 1, including transfers, each accompanied by the date of recording of such entry.

3. The Register and information referred to in paragraphs 1 and 2 shall be available in all official languages of the Union. The Office may use verified machine translation for the information to be published in the register.

4. The Executive Director of the Office may determine that information other than those referred to in paragraphs 1 and 2 shall be entered in the Register.

5. The Office shall collect, organise, make public and store the information referred to in paragraphs 1 and 2, including any personal data, for the purposes laid down in paragraph 7. The Office shall keep the Register easily accessible for public inspection.

6. The Office shall provide certified or uncertified extracts from the Register on request and on payment of a fee.

7. The processing of the data concerning the entries set out in paragraphs 1 and 2, including any personal data, shall take place for the purposes of:

(a) administering the applications and unitary certificates in accordance with this Regulation and the acts adopted pursuant to it;

(b) maintaining the Register and making it available for inspection by public authorities and economic operators;

(c) producing reports and statistics enabling the Office to optimise its operations and improve the functioning of the system.

8. All the data, including personal data, concerning the entries in paragraphs 1 and 2 shall be considered to be of public interest and may be accessed by any third party free of charge. For reasons of legal certainty, the entries in the Register shall be kept for an indefinite period of time.

Article 34

Database

1. In addition to the obligation to keep a Register, the Office shall collect and store in an electronic database all the particulars provided by applicants or any other third party observations pursuant to this Regulation or acts adopted pursuant to it.

2. The electronic database may include personal data, beyond those included in the Register, to the extent that such particulars are required by this Regulation or by acts

adopted pursuant to it. The collection, storage and processing of such data shall serve the purposes of:

(a) administering the applications and/or certificate registrations as described in this Regulation and in acts adopted pursuant to it;

(b) accessing the information necessary for conducting the relevant proceedings more easily and efficiently;

(c) communicating with the applicants and other third parties;

(d) producing reports and statistics enabling the Office to optimise its operations and improve the functioning of the system.

3. The Executive Director shall determine the conditions of access to the electronic database and the manner in which its contents, other than the personal data referred to in paragraph 2 of this Article but including those listed in Article 33(3), may be made available in machine-readable form, including the charge for such access.

4. Access to the personal data referred to in paragraph 2 shall be restricted and such data shall not be made publicly available unless the party concerned has given his express consent.

5. All data shall be kept indefinitely. However, the party concerned may request the removal of any personal data from the database after 18 months from the expiry of the unitary certificate or, the case being, the closure of the relevant *inter partes* procedure. The party concerned shall have the right to obtain the correction of inaccurate or erroneous data at any time.

Article 35

Transparency

1. Regulation (EC) No 1049/2001 of the European Parliament and of the Council[30] shall apply to documents held by the Office.

2. The Management Board of the Office shall adopt detailed rules for applying Regulation (EC) No 1049/2001 in the context of this Regulation.

3. Decisions taken by the Office under Article 8 of Regulation (EC) No 1049/2001 may be challenged through the European Ombudsman or form the subject of an action before the Court of Justice of the European Union, under the conditions laid down in Articles 228 and 263 TFEU respectively.

4. The processing of personal data by the Office shall be subject to Regulation (EC) No 45/2001 of the European Parliament and of the Council[31].

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30 Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

31 Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

Article 36

Representation

1. Natural or legal persons having neither their domicile nor their principal place of business or a real and effective industrial or commercial establishment in the European Economic Area shall be represented before the Office in accordance with this Article in all proceedings provided for by this Regulation, other than the filing of an application for a unitary certificate.

2. Natural or legal persons having their domicile or principal place of business or a real and effective industrial or commercial establishment in the Union may be represented before the Office by an employee.

   An employee of a legal person may also represent other legal persons which are economically linked with the legal person being represented by that employee.

   The second subparagraph also applies where those other legal persons have neither their domicile nor their principal place of business nor a real and effective industrial or commercial establishment within the Union.

   Employees who represent natural or legal persons shall, at the request of the Office or, where appropriate, of the party to the proceedings, file with the Office a signed authorisation for insertion in the files.

3. A common representative shall be appointed where there is more than one applicant or more than one third party acting jointly.

4. Only a practitioner established in the Union, entitled to act as a professional representative in patent matters before a national patent office or the European Patent Office, or a lawyer authorised to practise before the courts or tribunals of a Member State, may represent natural or legal persons before the Office.

Article 37

Supplementary Protection Certificates Division

A Supplementary Protection Certificate Division ('SPC Division') shall be set up within the Office and, in addition to the responsibilities under Regulations [COM(2023) 231] and [COM(2023) 223], shall be responsible for implementing the tasks set out in this Regulation and in Regulation [COM(2023) 222], including in particular:

(a) receiving and supervising the examination of applications for unitary certificates, appeals and observations by third parties;

(b) adopting examination opinions on behalf of the Office in relation to applications for unitary certificates;

(c) deciding on oppositions against examination opinions;

(d) deciding on applications for a declaration of invalidity;

(e) processing conversion requests;

(f) maintaining the Register and the database.

Article 38

Decisions and communications of the Office

1. Decisions of the Office under this Regulation shall include examination opinions and shall state the reasons on which they are based. They shall be based only on reasons or evidence on which the parties concerned have had an opportunity to present their comments. Where oral proceedings are held before the Office, the decision may be given orally. Subsequently, the decision or opinion shall be notified in writing to the parties.

2. Any decision, opinion, communication or notice from the Office under this Regulation shall indicate the SPC Division and the relevant panel as well as the name or the names of the examiners responsible. It shall be signed by these examiners, or, instead of a signature, carry a printed or stamped seal of the Office. The Executive Director may determine that other means of identifying the SPC Division and the name of the examiners responsible, or an identification other than a seal, may be used where decisions or other communications are transmitted by any technical means of communication.

3. Decisions of the Office under this Regulation which are open to appeal shall be accompanied by a written communication indicating that any notice of appeal is to be filed in writing at the Office within 2 months of the date of notification of the decision in question. That communication shall also draw the attention of the parties to the provisions laid down in Article 26. The parties may not plead any failure on the part of the Office to communicate the availability of appeal proceedings.

Article 39

Oral proceedings

1. If the Office considers that oral proceedings would be expedient they shall be held either at the instance of the Office or at the request of any party to the proceedings.

2. Oral proceedings before an examination panel, opposition panel or invalidity panel shall not be public.

3. Oral proceedings before the Boards of Appeal, including delivery of the decision and, as the case may be, of a revised opinion, shall be public, unless the Boards of Appeal decide otherwise in cases where admission of the public could have serious and unjustified disadvantages, in particular for a party to the proceedings.

4. The Commission is empowered to adopt delegated acts in accordance with Article 49 to supplement this Regulation by setting out the detailed arrangements for oral proceedings.

Article 40

Taking of evidence

1. In any proceedings before the Office, the means of giving or obtaining evidence shall include the following:

   (a) hearing the parties;

   (b) requests for information;

   (c) the production of documents and items of evidence;

(d) hearing witnesses;

(e) opinions by experts;

(f) statements in writing sworn or affirmed or having a similar effect under the law of the State in which the statement is drawn up.

2. The relevant panel may commission one of its members to examine the evidence adduced.

3. If the Office or the relevant panel considers it necessary for a party, witness or expert to give evidence orally, it shall issue a summons to the person concerned to appear before it. The period of notice provided in such summons shall be at least 1 month, unless they agree to a shorter period.

4. The parties shall be informed of the hearing of a witness or expert before the Office. They shall have the right to be present and to put questions to the witness or expert.

5. The Executive Director shall determine the amounts of expenses to be paid, including advances, as regards the costs of taking of evidence as referred to in this Article.

6. The Commission is empowered to adopt delegated acts in accordance with Article 49 to supplement this Regulation by setting out the detailed arrangements for the taking of evidence.

Article 41

Notification

1. The Office shall, as a matter of course, notify those concerned of decisions, including opinions, summonses and of any notice or other communication from which a time limit is reckoned, or of which those concerned are to be notified under other provisions of this Regulation or of acts adopted pursuant to this Regulation, or of which notification has been ordered by the Executive Director.

2. Notification may be effected by different means, including electronic means. The details regarding electronic means shall be determined by the Executive Director.

3. Where notification is to be effected by public notice, the Executive Director shall determine how the public notice is to be given and shall fix the beginning of the 1-month period on the expiry of which the document shall be deemed to have been notified.

4. The Commission is empowered to adopt delegated acts in accordance with Article 49 to supplement this Regulation by setting out the detailed arrangements for notification.

Article 42

Time limits

1. Time limits shall be laid down in terms of full years, months, weeks or days. Calculation shall start on the day following the day on which the relevant event occurred. The duration of time limits shall be no less than 1 month and no more than 6 months.

2. The Executive Director shall determine, before the commencement of each calendar year, the days on which the Office is not open for receipt of documents or on which ordinary post is not delivered in the locality in which the Office is located.

3. The Executive Director shall determine the duration of the period of interruption in the case of a general interruption in the delivery of post in the Member State where the Office is located or, in the case of an actual interruption of the Office's connection to admitted electronic means of communication.

4. If an exceptional occurrence, such as a natural disaster or strike, interrupts or interferes with proper communication from the parties to the proceedings to the Office or vice-versa, the Executive Director may determine that for parties to the proceedings having their residence or registered office in the Member State concerned or who have appointed a representative with a place of business in the Member State concerned all time limits that otherwise would expire on or after the date of commencement of such occurrence, as determined by the Executive Director, shall extend until a date to be determined by the Executive Director. When determining that date, the Executive Director shall assess when the exceptional occurrence comes to an end. If the occurrence affects the seat of the Office, such determination of the Executive Director shall specify that it applies in respect of all parties to the proceedings.

5. The Commission is empowered to adopt delegated acts in accordance with Article 49 to supplement this Regulation by specifying the details regarding the calculation and duration of time limits.

Article 43

Correction of errors and manifest oversights

1. The Office shall correct any linguistic errors or errors of transcription and manifest oversights in its decisions, including opinions, or technical errors in publishing information in the Register, of its own motion or at the request of a party.

2. Where the Office has made an entry in the Register or taken a decision which contains an obvious error attributable to the Office, it shall ensure that the entry is cancelled or the decision is revoked. The cancellation of the entry in the Register or the revocation of the decision shall be effected within 1 year of the date on which the entry was made in the Register or that decision was taken, after consultation with the parties to the proceedings.

3. The Office shall keep records of any such corrections or cancellations.

4. Corrections and cancellations shall be published by the Office.

Article 44

Restitutio in integrum

1. The applicant for or holder of a unitary certificate, or any other party to proceedings before the Office under this Regulation, who, in spite of all due care required by the circumstances having been taken, was unable to comply with a time limit vis-à-vis the Office shall, upon application, have his rights re-established if the obstacle to compliance has the direct consequence, by virtue of the provisions of this Regulation, of causing the loss of any right or means of redress.

2. The application for re-establishment shall be filed in writing within 2 months of the removal of the obstacle to compliance with the time limit. The omitted act shall be completed within this period. The application shall only be admissible within the year immediately following the expiry of the unobserved time limit.

3. The application for re-establishment shall state the grounds on which it is based and shall set out the facts on which it relies. It shall not be deemed to be filed until the fee for re-establishment of rights has been paid.

4. The SPC Division, or where applicable the Boards of Appeal, shall decide upon the application.

5. This Article shall not be applicable to the time limits referred to in paragraph 2 of this Article, or in Article 15(1) and (3).

Article 45

Interruption of proceedings

1. Proceedings before the Office under this Regulation shall be interrupted:

   (a) in the event of the death or legal incapacity of the applicant or of the person authorised by national law to act on behalf of the applicant. To the extent that that death or incapacity does not affect the authorisation of a representative appointed under Article 36, proceedings shall be interrupted only on application by such representative;

   (b) in the event of the applicant being prevented, for legal reasons resulting from action taken against his property, from continuing the proceedings before the Office;

   (c) in the event of the death or legal incapacity of the representative of the applicant, or of that representative being prevented, for legal reasons resulting from action taken against his property, from continuing the proceedings before the Office.

2. Proceedings before the Office shall be resumed as soon as the identity of the person authorised to continue them has been established.

3. The Commission is empowered to adopt delegated acts in accordance with Article 49 to supplement this Regulation by setting out the detailed arrangements for the resumption of proceedings before the Office.

Article 46

Costs

1. The losing party in opposition proceedings and proceedings for a declaration of invalidity, including in related appeal proceedings, shall bear the fees paid by the other party. The losing party shall also bear all costs incurred by the other party that are essential to the proceedings, including travel and subsistence and the remuneration of a representative, within the maximum rates set for each category of costs in the implementing act to be adopted in accordance with paragraph 7. The fees to be borne by the losing party shall be limited to the fees paid by the other party in those proceedings.

2. Where each party succeeds on some and fails on other heads, or if reasons of equity so dictate, the SPC Division or Board of Appeal shall decide a different apportionment of costs.

3. Where proceedings are terminated the costs shall be at the discretion of the SPC Division or Board of Appeal.

4. Where the parties conclude before the SPC Division or Board of Appeal a settlement of costs differing from that provided for in paragraphs 1 to 3, the body concerned shall take note of that agreement.

5. The SPC Division or Board of Appeal shall fix the amount of the costs to be paid pursuant to paragraphs 1 to 3 of this Article when the costs to be paid are limited to the fees paid to the Office and the representation costs. In all other cases, the registry of the Board of Appeal or SPC Division shall fix, on request, the amount of the costs to be reimbursed. The request shall be admissible only for the period of 2 months following the date on which the decision for which an application was made for the costs to be fixed becomes final and shall be accompanied by a bill and supporting evidence. For the costs of representation an assurance by the representative that the costs that have been incurred shall be sufficient. For other costs, it shall be sufficient if their plausibility is established. Where the amount of the costs is fixed pursuant to the first sentence of this paragraph, representation costs shall be awarded at the level laid down in the implementing act adopted pursuant to paragraph 7 of this Article and irrespective of whether they have been actually incurred.

6. Decisions on the fixing of costs adopted in accordance with paragraph 5 shall state the reasons on which they are based, and may be reviewed by a decision of the SPC Division or Board of Appeal on a request filed within 1 month of the date of notification of the awarding of costs. It shall not be deemed to be filed until the fee for reviewing the amount of the costs has been paid. The SPC Division or the Board of Appeal, as the case may be, shall take a decision on the request for a review of the decision on the fixing of costs without oral proceedings.

7. The Commission shall adopt implementing acts specifying the maximum rates for costs essential to the proceedings and actually incurred by the successful party. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 50.

8. When specifying the maximum rates with respect to travel and subsistence costs, the Commission shall take into account the distance between the place of residence or business of the party, representative or witness or expert and the place where the oral proceedings are held, the procedural stage at which the costs have been incurred, and, as far as costs of representation are concerned, the need to ensure that the obligation to bear the costs may not be misused for tactical reasons by the other party. In addition, subsistence expenses shall be calculated in accordance with the Staff Regulations of Officials of the Union and the Conditions of Employment of Other Servants of the Union, laid down in Council Regulation (EEC, Euratom, ECSC) No 259/68[32]. The losing party shall bear the costs for one party in the proceedings only and, where applicable, one representative only.

[32] Regulation (EEC, Euratom, ECSC) No 259/68 of the Council of 29 February 1968 laying down the Staff Regulations of Officials and the Conditions of Employment of Other Servants of the European

Article 47

Enforcement of decisions fixing the amount of costs

1. Any final decision of the Office fixing the amount of costs shall be enforceable.

2. Enforcement shall be governed by the rules of civil procedure in force in the Member State in the territory of which it is carried out. Each Member State shall designate a single authority responsible for verifying the authenticity of the decision referred to in paragraph 1 and shall communicate its contact details to the Office, the Court of Justice and the Commission. The order for enforcement shall be appended to the decision by that authority, with the verification of the authenticity of the decision as the sole formality

3. When these formalities have been completed on application by the party concerned, the latter may proceed to enforcement in accordance with the national law, by bringing the matter directly before the competent authority.

4. Enforcement may be suspended only by a decision of the Court of Justice. However, the courts of the Member State concerned shall have jurisdiction over complaints that enforcement is being carried out in an irregular manner.

Article 48

Financial provisions

1. The expenses incurred by the Office in carrying out the additional tasks given to it in accordance with this Regulation shall be covered by the procedural fees to be paid to it by applicants and by a fraction of the annual fees paid by the holders of unitary certificates, while the remainder of the annual fees shall be shared with the Member States in accordance with the number of unitary certificates having legal effect in each of them. The fraction of the annual fees to be shared with Member States shall initially be set at a certain value but shall be reviewed every 5 years, in such a manner as to achieve financial sustainability for the activities carried out by the Office under this Regulation as well as under Regulations [COM(2023) 231], [COM(2023) 223] and [COM(2023) 222].

2. For the purposes of paragraph 1, the Office shall keep an account of the annual fees paid to it by holders of unitary certificates in force in the respective Member States.

3. The expenses incurred by a competent national authority participating in proceedings under this Chapter shall be covered by the Office and shall be paid annually, on the basis of the number of proceedings in which that competent national authority was involved during the preceding year.

4. The Commission is empowered to adopt implementing acts laying down rules on the financial transfers between the Office and Member States, the amounts of these transfers, and the remuneration to be paid by the Office regarding the participation of competent national authorities referred to in paragraph 3. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 50.

Commission and instituting special measures temporarily applicable to officials of the Commission (OJ L 56, 4.3.1968, p. 1.)'

5. Article 12 of Regulation (EU) No 1257/2012 shall apply to the annual fees due in respect of unitary certificates.

Article 49

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Articles 15(13), 22(13), 26(8), 28, 32(2), 39(4), 40(6), 41(4), 42(5) and 45(3) shall be conferred on the Commission for an indeterminate period of time from XXX *[OP please insert the date = date of entry into force]*.
3. The delegation of power referred to in Articles 15(13), 22(13), 26(8), 28, 32(2), 39(4), 40(6), 41(4), 42(5) and 45(3) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect on the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Articles 15(13), 22(13), 26(8), 28, 32(2), 39(4), 40(6), 41(4), 42(5) and 45(3) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 50

Committee procedure

1. The Commission shall be assisted by a Committee on Supplementary Protection Certificates established by Regulation [COM(2023) 231]. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Article 51

Evaluation

By xxxxxx *[OP, please insert: five years after the date of application]*, and every five years thereafter, the Commission shall evaluate the implementation of this Regulation.

Article 52

Entry into force and application

This Regulation shall enter into force on XXX [*OP – please insert the date - the 20th day following its publication in the Official Journal of the European Union]*.

It shall apply from xxxxx *[OP please insert first day of the 12th month after the date of entry into force]*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

Council of the European Union

Brussels, 28 April 2023
(OR. en)

8869/23

Interinstitutional File: 2023/0127(COD)

PI 54
PHARM 66
COMPET 381
MI 349
IND 203
IA 87
CODEC 741

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	27 April 2023
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2023) 222 final
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the unitary supplementary certificate for medicinal products, and amending Regulation (EU) 2017/1001, Regulation (EC) No 1901/2006 as well as Regulation (EU) No 608/2013

Delegations will find attached document COM(2023) 222 final.

Encl.: COM(2023) 222 final

EUROPEAN
COMMISSION

Brussels, 27.4.2023
COM(2023) 222 final

2023/0127 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the unitary supplementary certificate for medicinal products, and amending Regulation (EU) 2017/1001, Regulation (EC) No 1901/2006 as well as Regulation (EU) No 608/2013

(Text with EEA relevance)

{SEC(2023) 172 final} - {SWD(2023) 117 final} - {SWD(2023) 118 final} - {SWD(2023) 119 final}

EXPLANATORY MEMORANDUM

CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

Supplementary protection certificates (SPCs) are *sui generis* intellectual property (IP) rights that extend the 20-year term of patents for medicinal or plant protection products (PPPs) by up to 5 years[1]. They aim to offset the loss of effective patent protection due to the compulsory and lengthy testing required in the EU for the regulatory marketing authorisation of these products.

The unitary patent will enter into force on 1 June 2023, allowing for a single patent that covers all participating Member States in a unitary manner[2].

This proposal aims to simplify the EU's SPC system, as well as improve its transparency and efficiency, by creating a unitary certificate for medicinal products. This initiative was announced in the Commission work programme for 2022 as initiative number 16 under Annex II (REFIT initiatives)[3].

Regulation (EC) No 469/2009 provides for SPCs for medicinal products (both human and veterinary medicinal products), at a national level, to be granted by national patent offices on the basis of national applications, on a country-by-country basis. Similarly, Regulation (EC) No 1610/96 provides for SPCs for plant protection products. Together these two measures constitute the EU's SPC regime.

As confirmed by the evaluation carried out in 2020 (SWD(2020)292 final), today's purely national procedures for granting SPCs involve separate examination proceedings (in parallel or subsequent) in Member States. This entails duplication of work, resulting in high costs and more often discrepancies between Member States in decisions to grant or refuse SPCs including in litigation before national courts. Inconsistency between Member States in decisions to grant or refuse SPCs is the single reason most often cited by national courts for preliminary references to the Court of Justice of the European Union on the application of the EU's SPC regime. The current purely national procedures, therefore, lead to significant legal uncertainty.

The Commission's intellectual property action plan of November 2020 (COM(2020) 760 final), which builds on the SPC evaluation, highlighted the need to tackle the remaining fragmentation of the EU's intellectual property system. The plan noted that, for medicinal products and PPPs, SPC protection is only available at national level. At the same time, there is a centralised procedure for granting European patents and a centralised procedure for obtaining marketing authorisations for medicinal products.

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1 An additional 6-month period of protection is available, subject to specific conditions, for medicinal products for use in the paediatric population, as defined by Regulation (EC) 1901/2006.

2 The unitary patent (UP) is a legal title that will provide uniform protection across all participating countries on a one-stop-shop basis. As of April 2023, 17 Member States are expected to participate in the UP system. For updates and more information, see: https://ec.europa.eu/growth/industry/strategy/intellectual-property/patent-protection-eu/unitary-patent_en.

3 European Commission, Annexes to Commission communication – Commission work programme 2022, COM(2021) 645 final, 2021, p. 9 (https://eur-lex.europa.eu/resource.html?uri=cellar%3A9fb5131e-30e9-11ec-bd8e-01aa75ed71a1.0001.02/DOC_2&format=PDF#page=9).

In the same vein, the pharmaceutical strategy for Europe (COM(2020) 761 final) emphasised the importance of investing in R&D to create innovative medicines. The strategy stressed, however, that the differences between Member States in the implementation of intellectual property regimes, especially for SPCs, lead to duplications and inefficiencies that affect the competitiveness of the pharmaceutical industry. Both the Council[4] and the European Parliament[5] have called on the Commission to correct these deficiencies.

Additionally, there is a clear need to complement the unitary patent ('European patent with unitary effect') by a unitary SPC. Indeed, while a unitary patent may be extended by national SPCs, this approach is not optimal in the sense that the unitary protection conferred by a unitary patent would then, after patent expiry, be complemented by a plurality of legally independent national SPCs, without any unitary dimension anymore.

The grant of a unitary SPC could be requested by filing an application that would then be subjected to the same centralised examination procedure also applicable to 'centralised SPC applications' defined in a parallel proposal (COM(2023) 231) with a view to the grant of national SPCs in the Member States designated in the centralised applications. An applicant will have the possibility of filing a 'combined' centralised SPC application in which he/she would request the grant of both a unitary SPC (for those Member States in which the basic patent has unitary effect) and national SPCs (for other Member States).

- **Consistency with existing policy provisions in the policy area**

The core substantive provisions applicable to the unitary certificates to which this proposal relates – i.e. the conditions for obtaining a unitary certificate – are the same as those of the existing SPC regime, while this proposal creates a unitary SPC to be granted following examination by a central authority, which relies on the same substantive rules, with minor modifications, as the centralised procedure for the grant of national certificates established in the parallel proposal COM(2023) 231. This ensures consistency across the whole SPC reform package, especially in the event of a 'combined' application requesting the grant of both a unitary certificate and national certificates, as explained below.

In addition to this proposal, parallel proposals are being made to create a centralised procedure for the grant of national certificates for medicinal products (COM(2023) 231), a centralised procedure for the grant of national certificates for plant protection products (COM(2023) 223), and a unitary certificate for plant protection products (cf. COM(2023) 221). Applications for all of these certificates would undergo the same centralised examination procedure described in this proposal, especially in the event of 'combined' applications that request both a unitary certificate and national certificates, as explained below. This ensures complete consistency across the whole SPC reform package.

[4] Council conclusions on intellectual property policy of 10 November 2020 https://www.consilium.europa.eu/media/46671/st-12750-2020-init.pdf.

[5] European Parliament, Committee on Legal Affairs, Report on an intellectual property action plan to support the EU's recovery and resilience (2021/2007(INI)), https://www.europarl.europa.eu/doceo/document/A-9-2021-0284_EN.html.

This table explains the purposes of the four related proposals:

Medicinal products		**Plant protection products**
PROPOSAL 1 Regulation on the SPC for medicinal products (recast)	← Art. 114 TFEU →	**PROPOSAL 2** Regulation on the SPC for plant protection products (recast)
PROPOSAL 3 Regulation on the unitary SPC for medicinal products	← Art. 118 TFEU →	**PROPOSAL 4** Regulation on the unitary SPC for plant protection products

The proposed creation of a unitary SPC will be fully compatible with the unitary patent system, under Regulation (EU) No 1257/2012 and the Agreement on a Unified Patent Court (UPCA).

In addition, as this was already the case for Regulation (EC) No 469/2009, this proposal is compatible with the pharmaceutical EU legislation, including Regulation 1901/2006 on medicinal products for paediatric use, which provides for a possible 'paediatric extension' of SPCs for medicinal products, under specific conditions.

Finally, this proposal is part of the 'EU patent package' announced in 2023 which, besides the revision, modernisation and introduction of a system for unitary SPCs, includes a new initiative on compulsory licensing and legislation on standard-essential patents. The proposal also complements the unitary patent system, which is a major step towards the completion of the single market for patents.

- **Consistency with other Union policies**

The COVID-19 pandemic has underlined the importance of having a strong and balanced IP system to provide the necessary incentives to develop new treatments and vaccines that patients will have access to. It has also highlighted the need for transparent and easily accessible information on the status of IP rights, including SPCs, to facilitate potential collaborations, licensing and freedom-to-operate analyses[6]. Patents and SPCs are key to supporting the EU in its efforts to build a European Health Union and to other related initiatives such as the new European Health Emergency Preparedness and Response Authority (HERA)[7], EU FAB[8] and the pharmaceutical strategy for Europe.

In addition, this proposal complements the pharmaceutical strategy for Europe and its intention to promote both innovation in medicines and better access to them, including the related legislative changes that are contemplated as regards regulatory protections *([OP, please add a reference to the ongoing reform of the pharmaceutical legislation])*.

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6 Discussions in this regard have been taken to the World Intellectual Property Organisation (WIPO), where national/regional patent offices were invited to share information on their collaborations with publicly accessible databases of patent status information concerning medicines and vaccines, such as MedsPaL. See: WIPO, Standing Committee on the Law of Patents, 32nd session, SCP/32/7, 2020.

7 European Commission, Commission Communication – HERA Incubator: Anticipating together the threat of COVID-19 variants, COM/2021/78, 2021.

8 European Commission, 'Questions and answers : HERA incubator – Anticipating together the threat of COVID-19 variants', 2021 (https://ec.europa.eu/commission/presscorner/detail/en/qanda_21_642).

Finally, SPC reform and the other initiatives listed in the intellectual property action plan contribute to the broader innovation strategy of the EU.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

• Legal basis

The current proposal is based on the first subparagraph of Article 118 of the Treaty on the Functioning of the European Union, which is the only treaty provision suitable for the creation of unitary IP rights as it allows for measures for the creation of European intellectual property rights to provide uniform protection of intellectual property rights throughout the Union and for the setting up of centralised Union-wide authorisation, coordination and supervision arrangements.

Article 118 was introduced by the Treaty on the Functioning of the European Union (TFEU) and provides an express legal base for EU-wide intellectual property rights. It is also the legal basis for Regulation (EU) No 1257/2012 of the European Parliament and of the Council implementing enhanced cooperation in the area of the creation of unitary patent protection.

Together with the parallel proposal relating to a centralised procedure for the grant of national certificates (COM(2023) 231), this proposal addresses the fragmentation of the existing SPC regime, implemented at a purely national level: despite the fact that SPCs are already harmonised – and indeed defined – by EU law, there are still cases where some Member States have granted SPCs while identical applications have been refused in others, or been granted with a different scope. SPC applicants thus face diverging decisions across the EU on the same product, while incurring costs for applying and maintaining SPCs in several Member States. Consequently, further EU action is needed to address these issues and can, unlike national intervention by Member States, ensure a consistent EU-wide framework, and reduce the total costs and burden of fees to be paid in multiple Member States. Further EU-level action would strengthen the integrity of the single market by providing a centralised, balanced and transparent SPC system across the EU, and mitigate the negative consequences of redundant and potentially diverging procedures that applicants face[9]. Hence, by its nature, action at EU level is also justified to ensure the smooth functioning of the single market for innovative medicinal products that are subject to marketing authorisations. EU-level action would also allow innovative and follow-on manufacturers to reap the benefits of an efficient intellectual property framework in the relevant product markets.

• Subsidiarity

EU action is necessary to provide a unitary SPC for the unitary patent. An EU IP right (such as a unitary SPC) can only be created by the EU. National legislation cannot achieve this objective, as it is not able to provide for unitary protection, and the objectives underlying this proposal can thus only be achieved at Union level. The Union-wide approach implemented by the centralised procedure for the grant of national certificates and unitary SPCs will ensure that the applicable rules and procedures are consistent across the Union — at least insofar as the Member States participating in the unitary patent system are concerned —, ensuring legal certainty for all relevant market participants. Moreover, the unitary SPC is an autonomous IP right, applying independently of any national system. Consequently, EU action is needed to create a new unitary SPC complementing the unitary patent.

[9] Case C-58/08 ECLI:EU:C:2010:321.

- **Proportionality**

This initiative does not go beyond what is necessary to achieve the identified objectives. Its scope is limited to those aspects that Member States cannot achieve satisfactorily on their own and where EU action can produce better results, e.g. in terms of consistent decisions on SPC applications to reduce administrative burdens and costs, and improve transparency and legal certainty.

- **Choice of the instrument**

The instrument choice is an EU regulation establishing a unitary SPC. No other instrument can be envisioned for creating a unitary IP right.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Ex-post evaluations and fitness checks of existing legislation**

An evaluation of the SPC regime was carried out in 2020 (SWD(2020) 292). It found that SPCs promote innovation and the availability of new medicines and PPPs because they help companies recoup their R&D investments. Although the SPC Regulations provide a common framework within the EU, they are administered at a national level. This fragmentation leads to high costs and imposes an administrative burden on applicants (especially SMEs) and national administrations. It also leads to legal uncertainty, as the scope of protection can differ across the EU. This has a negative impact on SPC users and makers of generics. These negative effects are amplified by a lack of transparency, especially from a cross-border perspective, making it difficult to trace what SPC protection exists for which products in which Member States. This affects both SPC holders and generics manufacturers.

An evaluation of the SPC manufacturing waiver, which is an exception introduced by Regulation (EU) 2019/933, which amended Regulation (EC) No 469/2009, and is included in this proposal, will be undertaken in the near future (as foreseen in Article 21a of Regulation (EC) No 469/2009).

- **Stakeholder consultations**

The Commission conducted a public consultation during the evaluation (between 12 October 2017 and 4 January 2018). In addition, the Max Planck Institute study mentioned below included a survey of stakeholders in the Member States, conducted in 2017 by the Allensbach Institute ('the Allensbach survey'), which included several questions on the operation of the current (national) SPC regimes. Moreover, from 8 March to 5 April 2022 interested parties could provide feedback to Commission's Call for Evidence. For further information, see Annex 2 of the impact assessment (SWD(2023) 118).

Most of the respondents to the Allensbach survey consultation (conducted by the Allensbach Institute and included in the 2018 study by the Max Planck Institute (MPI))[10] and to the public consultation organised by the Commission endorse the creation of a Unitary SPC. Answers to Question 69 of the Allensbach survey show that there is wide support for a unitary SPC, and that from all categories of respondents. The same can be said of the replies to the questions relating to the unitary SPC included in the public consultation 'on Supplementary Protection

[10] https://ec.europa.eu/docsroom/documents/29524

Certificates and patent research exemption for sectors whose products are subject to regulated market authorisations' that was conducted from 12 October 2017 to 4 January 2018[11].

Moreover, from 8 March to 5 April 2022 interested parties could provide feedback to Commission's Call for Evidence[12]. For further information, see Annex 2 of the Impact Assessment.

- **Collection and use of expertise**

The study[13] carried out in 2018 by the Max Planck Institute on the legal aspects of SPCs in the EU (especially Chapter 22) provides key findings on the operation of the current SPC regime (for medicinal products). In particular that study included a survey among stakeholders in the EU Member States (2017), conducted by the Allensbach Institute[14], which included several questions relating to a possible unitary SPC in addition to the many questions relating to the operation of the current (national) SPC regimes.

- **Impact assessment**

An impact assessment was carried out and submitted to the Regulatory Scrutiny Board in late 2022 and, after resubmission, received a positive opinion on 16 December 2022.

The following options were identified:

– Option 0: No policy change.

– Option 1: Guidelines for the application of the current SPC regimes. This option would provide common guidelines/recommendations to national patent offices (NPOs) on the application of the SPC Regulation, building on their experience and the case law of the Court of Justice of the European Union (CJEU). These guidelines would also recommend common rules for the publication and accessibility of SPC information in national registers.

– Option 2: Mutual recognition of national decisions. This would enable applicants to file an SPC application with a designated NPO, known as the reference office, whose decision would be recognised by all other NPOs.

– Option 3: Centralised filing and examination of SPC applications, resulting in a non-binding opinion. This would create a central authority for filing SPC applications in the EU, which would examine applications and issue an opinion on whether or not to grant an SPC. NPOs could follow this opinion or, alternatively, conduct their own examination. Therefore, the decision on granting SPC protection would be kept at the national level. Only holders of a European patent – and, for medicinal products, of a centralised marketing authorisation – could use this system.

– Option 4: Centralised filing and examination of SPC applications, resulting in a binding opinion. This is identical to option 3, 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 a central authority.

11 https://ec.europa.eu/docsroom/documents/29464

12 https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13353-Medicinal-plant-protection-products-single-procedure-for-the-granting-of-SPCs_en

13 https://ec.europa.eu/docsroom/documents/29524

14 https://ec.europa.eu/docsroom/documents/29524/attachments/4/translations/en/renditions/native

– Option 5: A ‘unitary SPC’ complementing the unitary patent. The central authority, in addition to examining applications, would grant a ‘unitary SPC’ to applicants with a European patent with unitary effect. The unitary SPC would be valid only in the territory of the (initially 17) Member States party to the UPCA.

These options would not replace national SPCs, but would provide alternative routes to obtaining SPC protection across the EU.

A combination of options 4 and 5 constitutes the preferred choice. It would provide for a centralised procedure that could result in the grant of national SPCs in some or all Member States, and/or of a unitary SPC (covering those Member States in which the basic unitary patent has effect). When deciding on who should act as the examination authority, several criteria were considered: accountability (in particular, to the European Parliament), alignment with the EU’s overarching political values and current policy priorities, and experience with substantive SPC assessment. It is therefore proposed that the EU Intellectual Property Office (EUIPO) should become the central examination authority, supported by national offices.

Option 1, on guidelines for examining national SPC applications, would not be sufficient alone to overcome discrepancies between national practices, as the guidance would be non-binding. Nevertheless, in the context of the preferred options 4 and 5, EUIPO should develop guidelines that reflect its practice. These guidelines would be of practical use both to officials in charge of the SPC-related procedures and to their users, including professional advisers who assist applicants (e.g. by offering examples). This guidance would take stock of the practices developed by the examination panels, especially since they will include examiners from several different Member States, to improve consistency between examination practices under the new centralised procedure. Moreover, national offices may also benefit from guidelines developed by the examination authority for their own (national) examination procedures.

Option 2 may not provide enough predictability, as some reference offices could be more lenient than others, thus leading to ‘forum shopping’, while Option 3 alone would allow offices to re-examine the SPC application, and has thus the potential to result in divergences on the decision to grant or refuse an SPC, leading to further fragmentation in the single market.

• **Regulatory fitness and simplification**

Enabling unitary patent holders to obtain through a single procedure a unitary SPC able to be enforced centrally in all relevant Member States represents a considerable simplification compared to the current situation in which national SPCs need to be applied for and enforced separately in each Member State, while noting that SPCs based on European patents (also non-unitary ones) will be able to be enforced before the Unified Patent Court (‘UPC’) once it is operating[15].

• **Fundamental rights**

This proposal will have no impact on fundamental rights, especially since it is not proposed to alter the substantive features of the existing SPC regimes (e.g. conditions for grant, scope, effects). The initiative is consistent with the Charter of Fundamental Rights, as it offers greater legal certainty to applicants for unitary certificates, and where necessary for third

[15] To some extent at least, during the transitional period during which non-unitary European patents will still be able to be litigated before national courts.

parties, by providing for the procedural conditions for the examination, opposition, appeal and invalidity actions before the centralised authority.

In particular, where a centralised examination opinion is negative, the applicant may file an appeal before the Boards of Appeal of the EUIPO.

Moreover, examiners from national offices will play a key role in the centralised examination procedure and participate in the substantive examination of the application, as well as may take part in opposition and invalidity proceedings.

On the other hand, third parties will be able to submit observations during the examination of a centralised application, and to initiate an opposition against an examination opinion. After a unitary SPC is granted by the Office, third parties will also be able to challenge its validity before the Office. Counterclaims for a declaration of invalidity could be raised in the competent court of a Member State.

4. BUDGETARY IMPLICATIONS

This proposal will have no impact on the EU budget, since the system will remain fully self-funded by applicants' fees, as is already the case for the existing SPCs regimes governed by Regulations (EC) No 469/2009 and (EC) No 1610/96, and will be implemented by the examination authority, the EUIPO. The necessary set-up costs of the tasks conferred to the EUIPO, including the costs of new digital systems, will be financed from the EUIPO's accumulated budgetary surplus. A breakdown of the budgetary impact on the examination authority is provided in Annex 5D of the impact assessment.

The financial impacts on Member States (national offices) will also remain low. Indeed, while the number of SPCs applied for each year is likely to increase, it is quite low for the time being, even in large Member States. For instance, in 2017, 70 SPC applications were filed in Germany and 72 in France. The largest number of applications (95) were filed in Ireland. The average cost varies by country. Based on current average coverage (20 Member States) and duration (3.5 years), SPC protection for a given product would cost around EUR 98 500 on average. In order to cover all 27 Member States for 5 years one would pay nearly EUR 192 000 in total (not including any fees charged by patent lawyers). For a breakdown of the costs, see Annex 5B of the impact assessment SWD(2023) 118.

Moreover it may be expected that only some medicinal products will be eligible for a unitary certificate in the first years of operation of the unitary patent system, considering that not all European patents will have unitary effect (which will be a prerequisite for applying for a unitary certificate).

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

It is envisaged that an evaluation will be carried out every 5 years.

- **Detailed explanation of the specific provisions of the proposal**

Overall structure of the proposal

The proposal is structured similarly to the current SPC Regulations and in particular to a parallel proposal relating to the unitary certificate for plant protection products (COM(2023) 221). It first sets out general provisions on SPCs followed by procedural provisions. It also ensures alignment with certain provisions of the corresponding proposal relating to plant protection products (COM(2023) 223), derived from Regulation (EC) No 1610/96.

Furthermore, this proposal would amend:

– Regulation (EU) 2017/1001, that lays down the tasks carried out by the Office (see below under 'Examination/granting authority'), to ensure that the Office will be able to implement the procedures envisaged in the context of the present reform of the SPC regime,

– Regulation (EC) No 1901/2006, to ensure that the paediatric extension it established will also be applicable in respect of unitary SPCs for medicinal products; and

– Regulation (EU) No 608/2013, to ensure that the customs measures it established will also be applicable in respect of unitary SPCs (for medicinal products under this proposal, and for plant protection products under the parallel proposal for plant protection products).

Coherence with the parallel proposal relating to plant protection products

This proposal is extremely similar to the one presented in parallel regarding the unitary SPC for plant protection products (COM(2023) 221), with a limited number of changes directly linked to the intrinsic differences between medicinal products and plant protection products, regarding in particular marketing authorisations (as there are no centralised marketing authorisations for plant protection products). The 'SPC manufacturing waiver' introduced into Regulation (EC) No 469/2009 by Regulation (EU) 2019/933 only applies to SPCs for medicinal products and therefore needs to be reflected in this new Regulation, but not in the above-mentioned parallel proposal regarding unitary SPCs for plant protection products.

Basic patent

It is proposed that a unitary SPC must be based on a European patent with unitary effect only (as the 'basic patent'), which would ensure that its claims are identical for all Member States it covers, and would avoid the risk of the basic patent being revoked, or lapsing, for one or some of these Member States. In this respect it should be noted that paragraph 21 of the explanatory memorandum of the first proposal for a Council Regulation concerning the creation of a supplementary protection certificate for medicinal products (COM(90)101) already envisaged that '*when use is made of the European procedure to obtain a Community patent, it will likewise be necessary that the certificate can apply equally to medicinal products protected by a Community patent*' (now referred to as a 'European patent with unitary effect' or, more informally, a 'unitary patent').

Allowing unitary SPCs to be based on national patents, or even on non-unitary European patents, would be more demanding insofar as the examination of such applications would be concerned, as it would be required to examine separately, for each of the Member States concerned, if the product concerned is indeed protected. This would also raise language issues, and affect legal certainty.

Examination/granting authority

Under this proposal, a central examination authority will carry out a substantive examination of a unitary SPC application, especially as regards the conditions for grant defined in Article 3 of the existing SPC Regulations. The Commission proposes that the EUIPO should be the central examination authority, in particular because it is an EU agency and therefore part of the EU legal order.

After assessing the formal admissibility of the unitary SPC application, the central examination authority would entrust the substantive examination of the application to a panel. This panel would be made up of a member of that central authority and two qualified examiners, experienced in SPC matters, from two different national patent offices in Member

States. Before designating examiners qualified to examine SPC issues, these national patent offices will have agreed, through an ad hoc agreement with the central examination authority, to participate in this centralised examination system. Competencies and skills in SPC matters are scarce and qualified SPC examiners can be found today in national patent offices. Moreover, the relatively low number of products for which SPC applications are made each year (less than 100) justifies making recourse to existing qualified examiners in Member States, as opposed to creating an entirely new body of experts. During the examination, third parties may submit their observations on the validity of a certain unitary SPC application after its publication.

Examination procedure and remedies

After examining the application, the central examination authority will issue an examination opinion stating whether the application fulfils the applicable criteria (and in the first place those defined in Article 3). The applicant can file an appeal against a negative opinion (as further explained below).

In order to account for the need to have a complete system of remedies and avoid the need for third parties challenging a positive examination opinion in national courts which would then in turn have to make reference to the EU Courts, third parties will be able to challenge a positive (or partly positive) opinion by initiating an opposition procedure during 2 months after the publication of the examination opinion. Such an opposition may result in the examination opinion being amended.

Challenges against the examination opinion can be appealed to the Boards of Appeal, and subsequently to the General Court and, possibly, ultimately before the Court of Justice subject to the system of leave to appeal under Articles 170a and following of the Rules of Procedure of the Court of Justice, or under the review procedure in accordance with Article 256, paragraph 2, TFEU, Article 62 of the Statute of the Court and Articles 191 and following of the Rules of Procedure of the CJEU.

On the basis of the examination opinion (as possibly amended following an opposition), the EUIPO will either grant a unitary SPC, or reject the application for it, subject to the outcome of any appeal before the Boards of Appeal of the .

After the grant of a unitary SPCs, third parties will be able to initiate invalidity proceedings (actions for a declaration of invalidity) before the Office. Here as well, related decisions may be appealed to the Boards of Appeal, and may end up before the General Court.

Counterclaims for a declaration of invalidity could be raised in the competent court of a Member State (including the Unified Patent Court where the applicable conditions are met, subject to a suitable amendment of the UPCA).

Marketing authorisations concerned

It is proposed that only a centralised marketing authorisation (as defined in Regulation (EC) No 726/2004) can serve as a basis for an application for a unitary SPC for a medicinal product. Today, most medicinal products are authorised under that centralised marketing authorisation procedure. A unitary SPC application based on national marketing authorisations (such as those granted under the decentralised or mutual recognition procedures) would have significant drawbacks. These would include a bigger examination workload, potential differences between the various national marketing authorisations granted for the product concerned in different Member States, including language issues.

Substantive features of the SPC regime

This reform does not intend to modify, nor further clarify in view of the relevant case law of the Court of Justice, the substantive features currently laid down in Regulation (EC) No 469/2009 for the existing national SPC regimes or the new centralised procedure, including as regards its application to unitary SPCs, since:

– the case law[16] on SPCs is progressively but effectively converging, and steadily reducing uncertainty about the interpretation of the SPC regime[17], while further amendments might trigger new fluctuations and uncertainty as regards the proper interpretation of the amended rules;

– respondents to the Allensbach survey did not call for Article 3 of the SPC Regulations to be amended (question 48) even if they consider that the case law is unclear in some respects (question 46).

That being said, considering that there are national discrepancies in the interpretation of the rule defining the duration of a European patents, which may result in a one-day difference, there is a need to clarify that rule insofar as its application to unitary SPCs is concerned.

New recitals

Certain recitals concern the conditions set out in Article 3 for the grant of SPCs, and incorporate the case law of the Court of Justice. The aim is to ensure consistency. In particular the judgements in cases C- 121/17 and C-673/18 interpret Article 3(a) and 3(d) of Regulation (EC)No 469/2009, respectively, and should be considered settled case law. This is also the case for judgement C471/14, whereby the date of the first marketing authorisation in the Union, within the meaning of Article 13, is the date on which notification of the decision granting the authorisation was given to the addressee of the decision.

The requirement that the product should be protected by the basic patent means that the product should fall within the scope of one or more claims of that patent, as properly interpreted at the basic patent's filing date. This also includes situations where the product corresponds to a general functional definition used by one of the claims of the basic patent, and necessarily comes within the scope of the invention covered by that patent, even if it is not indicated in individualised form as a specific embodiment in the patent, provided that it is specifically identifiable from the patent.

Many general objectives set out in the Explanatory Memorandum of the proposal (COM(90)101) for what became Council Regulation 1768/92/EEC, i.e. the predecessor of Regulation (EC) No 469/2009, remain fully relevant today and should continue to be used as a guide to interpretation, where relevant. This includes the objective that *only one certificate may be granted for any one product, a product being understood to mean an active substance in the strict sense. Minor changes to the medicinal product such as a new dose, the use of a different salt or ester or a different pharmaceutical form will not lead to the issue of a new certificate*.

Furthermore, as regards the rights conferred by a certificate, *the certificate confers the same protection as the basic patent, but only protects the product covered by the authorisation, for all pharmaceutical uses authorised, until the expiry of the basic patent.*

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16 For a full list of cases, see Table 5.5. of the second MPI study.

17 Further clarifications are, however, necessary in certain areas as indicated by two referrals in 2022, cases C-119/22 and C-149/22.

As regards the rights conferred by a certificate, and in line with the earlier statements regarding derivatives, it could be appropriate to consider that the protection conferred by a certificate on a product extends to the therapeutically equivalent derivatives of the product.

For biological products, the application of the rules, both as regards the conditions for grant and the effects of a certificate, should take into account the fact that minor differences may be unavoidable between a subsequent biosimilar and the product initially authorised, given the nature of biological products.

Language regime

This Regulation envisages the possibility of filing a centralised SPC application in any official EU language. In this regard, the amount of text in an SPC application is extremely small, especially compared to patents and this would not present a burden for applicants. Certain matters would not require any translation, such as the identification of the basic patent and the relevant marketing authorisation, the relevant dates, and the identification of the applicant(s) and the product concerned. The translation costs are, therefore, expected to be considerably lower than would be the case for patent applications. See the impact assessment (SWD(2023) 118) for an exact calculation.

Appeals

Decisions of the central examination authority are subject to appeal. This also applies to a negative examination opinion issued by the central examination authority, against which the applicant may file an appeal. This also applies to other decisions of that authority; for instance, the decision relating to an opposition may be appealed by any of its parties. An appeal may result in the examination opinion being amended.

In the event of a 'combined' SPC application as referred to below – namely an SPC application which requests the grant of a unitary SPC and also of national SPCs –, such an appeal would be applicable to the (common) examination opinion relating to the combined SPC application.

The appeal would take place before the Boards of Appeal of the EUIPO. Members from the Boards of Appeal should be appointed in accordance with Article 166 (5) of Regulation 2017/1001. These members may also be national examiners, but they may not be the same examiners already involved in the examination of the centralised applications or applications for unitary certificates.

In terms of workload, SPC applications are made for less than 100 products each year on average, for medicinal products and PPPs together, and introducing third-party observations should help keep the number of appeals at a very low level.

Fees and financial transfers between the central authority and national patent offices (NPOs)

An application fee and possibly other procedural fees, such as the fee for an appeal, and annual (renewal) fees, will have to be paid by applicants to the central examination authority. The level of fees to be paid to the central examination authority will be set in an implementing act.

It would be appropriate that a fraction of the renewal fees paid by unitary SPC holders be transferred to the national patent offices[18] of the Member States in which unitary SPCs have legal effect (as already planned in respect of renewal fees for unitary patents). At the same

[18] Or any other national authority competent for the grant of SPCs.

time, it is necessary to ensure that those national offices that participate in the new procedure as regards the substantive examination of unitary SPC applications are properly remunerated for their participation.

Litigation

It is intended that a unitary SPC will be able to be litigated before the body responsible under national law for the revocation of the corresponding basic patent. It is expected that the definition of SPCs present in the UPCA will be amended to include unitary SPCs as well. Such amendment may be based on Article 87(2) of the UPCA.

Extension of unitary SPCs for paediatric medicinal products

Unitary SPC applicants/holders should be able to apply before the central examination authority for extensions of unitary SPCs for paediatric medicinal products, under the conditions currently provided for by Regulation (EC) No 1901/2006 – which, therefore, needs to be amended so as to ensure that it also applies to unitary SPCs in addition to national SPCs.

Centralised procedure for the grant of national SPCs

A parallel proposal (COM(2023) 231) is intended to create a centralised procedure for the filing and examination of 'centralised SPC applications', able to result in the grant (at a national level) of national SPCs in the Member States designated in that application. This procedure would be available potentially for all Member States, and only on the basis of a European patent as basic patent.

It is proposed that the procedure for the filing and examination of unitary SPC applications would be the same (mutatis mutandis) as the centralised procedure defined in the above-mentioned parallel proposal. In this manner, a 'combined' SPC application could possibly include both a request for the grant of a unitary SPC (for the Member States covered by the basic patent) and a request for the grant of national SPCs in other Member States. That 'combined' application would undergo a single examination procedure, ruling out any discrepancies, and considerably reducing costs and administrative burden for applicants.

2023/0127 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the unitary supplementary certificate for medicinal products, and amending Regulation (EU) 2017/1001, Regulation (EC) No 1901/2006 as well as Regulation (EU) No 608/2013

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 118, first paragraph, thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[19],

Having regard to the opinion of the Committee of the Regions[20],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Pharmaceutical research plays a decisive role in the continuing improvement in public health. Medicinal products, in particular those that are the result of long, costly research will not continue to be developed in the Union unless they are covered by favourable rules that provide for sufficient protection to encourage such research.

(2) The period that elapses between the filing of an application for a patent for a new medicinal product and the authorisation to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research.

(3) Uniform patent and supplementary certificate protection within the internal market, or at least a significant part thereof, should feature amongst the legal instruments which pharmaceutical undertakings have at their disposal.

(4) In its Communication of 25 November 2020 entitled 'Making the most of the EU's innovative potential – An intellectual property action plan to support the EU's recovery and resilience'[21], the Commission highlighted the need to tackle the remaining fragmentation of the Union's intellectual property system. In that Communication, the Commission noted that, for medicinal products and plant protection products, supplementary protection is only available at national level. At the same time, there is a centralised procedure for granting European patents, as well

[19] OJ C […], […], p. […].
[20] OJ C […], […], p. […].
[21] COM(2020)760 final.

as a centralised procedure for obtaining marketing authorisations for medicinal products. In addition, the 'unitary patent' as laid down in Regulation (EU) No 1257/2012 of the European Parliament and of the Council[22] enters into force in June 2023 in respect of the Member States having ratified the Agreement on a Unified Patent Court ('UPC').

(5) Regulation (EU) No 1257/2012 has created the possibility to provide unitary patents. However, Regulation (EU) No 1257/2012 does not provide for a unitary supplementary protection certificate ('unitary certificate').

(6) In the absence of a unitary certificate, a unitary patent could only be extended by applying for several national certificates in each Member State where protection is sought, preventing the holder of a unitary patent from obtaining unitary protection during the whole combined protection period conferred by that unitary patent and subsequently by these certificates. Therefore, a unitary certificate for medicinal products should be created, that would allow a unitary patent to be extended in a unitary manner. Such a unitary certificate should be applied for on the basis of a unitary basic patent and a centralised authorisation; it would have the same legal effects as national certificates in all Member States in which that basic patent has unitary effect. The main feature of such a unitary certificate should be its unitary character.

(7) A unitary certificate should provide uniform protection and have equal effect in all Member States where the basic patent it relies upon has unitary effect. Consequently, a unitary certificate should only be transferred or revoked, or expire, in respect of all those Member States.

(8) Regulation [COM(2023) 231] replaces Regulation (EC) No 469/2009 of the European Parliament and of the Council[23], and includes new provisions establishing a centralised procedure for the examination of supplementary protection certificates for medicinal products.

(9) Considering that products authorised under procedures other than the centralised one should still be able to enjoy supplementary protection, and that certain Member States have not yet joined the unitary patent system, certificates granted by national patent offices should remain available.

(10) To avoid discrimination between applicants for certificates under Regulation [COM(2023) 231] and for unitary certificates under this Regulation, and distortions of the internal market, the same substantive rules should apply, with appropriate adaptations, to certificates under Regulation [COM(2023) 231] and to unitary certificates, in particular as regards the conditions for grant of a certificate, as well as the duration and effects of a certificate.

(11) In particular, the duration of the protection granted by a unitary certificate should be identical to the duration provided for as regards national certificates under Regulation [COM(2023) 231]*;* namely, the holder of both a unitary patent and a unitary certificate should be able to enjoy an overall maximum of 15 years of exclusivity from the time

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22 Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection (OJ L 361, 31.12.2012, p. 1).

23 Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ L 152, 16.6.2009, p. 1).

the medicinal product in question first obtains an authorisation to be placed on the market in the Union. Since the unitary certificate would take effect at the expiry of the basic patent, and in order to take into account discrepancies in national practices regarding the date of expiry of a patent which may result in 1-day differences, this Regulation should clarify when exactly the protection conferred by a unitary certificate should take effect.

(12) Regulation (EU) No 2017/1001 of the European Parliament and of the Council[24] has established, under its Article 2, a European Union Intellectual Property Office ('the Office'). In the interest of the internal market, and due to the autonomous nature of the unitary certificate, its examination and grant procedure should be carried out by a single examining authority. This can be achieved by the Office being given the task of examining both applications for unitary certificates in accordance with this Regulation and Regulation [COM(2023) 221] and centralised applications for certificates under Regulations [COM(2023) 231] and [COM(2023) 223]. To ensure consistency with this Regulation, Regulation (EU) No 2017/1001 should be amended.

(13) A unitary certificate for a medicinal product should be based only on a centralised marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council[25] or Regulation (EU) 2019/6 of the European Parliament and of the Council[26] only. These authorisations refer to human medicinal and veterinary medicinal products respectively. Such an authorisation, unlike national authorisations, relates to the same medicinal product throughout the Union, and this would thus facilitate the examination of applications for unitary certificates.

(14) An applicant should also be allowed to lodge a 'combined application' that would also include the designation of Member States, other than those in which the basic patent has unitary effect, in which the grant of national certificates would be requested as set out in Regulation [COM(2023) 231]. Such a combined application should undergo a single examination procedure.

(15) In such an event, double protection by both a unitary certificate and a national certificate – whether obtained on the basis of a national application or of a centralised application – should be excluded in any Member State.

(16) One of the conditions for the grant of a certificate should be that the product is protected by the basic patent, in the sense that the product should fall within the scope of one or more claims of that patent, as interpreted by the person skilled in the art by the description of the patent on its filing date. This should not necessarily require that the active ingredient of the product be explicitly identified in the claims. Or, in the event of a combination product, this should not necessarily require that each of its active ingredients be explicitly identified in the claims provided that each of them is specifically identifiable in the light of all the information disclosed by that patent.

(17) To avoid overprotection, it should be provided that no more than one certificate, whether national or unitary, may protect the same product in a Member State.

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24 Regulation (EU) 2017/1001 of the European Parliament and of the Council of 14 June 2017 on the European Union trade mark (OJ L 154, 16.6.2017, p. 1).

25 Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

26 Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).

Therefore it should be required that the product, or any therapeutically equivalent derivative such as salts, esters, ethers, isomers, mixtures of isomers, complexes or biosimilars, should not have already been the subject of a prior certificate, either alone or in combination with one or more additional active ingredients, whether for the same therapeutic indication or for a different one.

(18) Within the limits of the protection conferred by the basic patent, the protection conferred by a unitary certificate should extend only to the product, namely the active ingredient or combinations thereof, covered by the authorisation to place it on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the unitary certificate.

(19) To ensure balanced protection, however, a unitary certificate should entitle its holder to prevent a third party from manufacturing not only the product identified in the unitary certificate but also therapeutically equivalent derivatives of that product, such as salts, esters, ethers, isomers, mixtures of isomers or complexes, as well as biosimilars, even where such derivatives are not explicitly mentioned in the product description on the unitary certificate. There is therefore a need to consider that the protection conferred by the unitary certificate extends to such equivalent derivatives, within the limits of the protection conferred by the basic patent.

(20) As a further measure to ensure that no more than one certificate may protect the same product in any Member State, the holder of more than one patent for the same product should not be granted more than one certificate for that product. However, where two patents protecting the product are held by two holders, one certificate for that product should be allowed to be granted to each of those holders, where they can demonstrate that they are not economically linked. Furthermore, no certificate should be granted to the proprietor of a basic patent in respect of a product which is the subject of an authorisation held by a third party, without that party's consent.

(21) Where the marketing authorisation submitted in support of the application for a certificate for a biological medicinal product identifies that product by means of its International Nonproprietary Name (INN), the protection conferred by the certificate should extend to all therapeutically equivalent products having the same International Nonproprietary Name as the product referred to in the marketing authorisation, irrespective of possible minor differences between a subsequent biosimilar and the product authorised, which are usually unavoidable given the nature of biological products.

(22) Regulation [COM(2023) 231] provides for an exception according to which, under narrowly defined circumstances and subject to various safeguards, the protection conferred by a national supplementary protection certificate for medicinal products does not extend to a product that would be manufactured in the Union by a person other than the holder of that certificate, where it is manufactured for the purpose of being exported to a third country, or of being stored in the Union in view of its entry into the Union market upon expiry of the certificate. To avoid discrimination between applicants for certificates under Regulation [COM(2023) 231] and for unitary certificates under this Regulation, similar rights and limitations should be conferred by certificates under Regulation [COM(2023) 231] and by unitary certificates, and therefore that exception should also be available in respect of unitary certificates. The reasons for the introduction for the waiver and the conditions for its application should be applicable for unitary certificates.

(23) To ensure alignment with the rules applicable to unitary patents, a unitary certificate as an object of property should be dealt with, in its entirety and in all Member States in which it has effect, as a national certificate of the Member State determined in accordance with the law that applies to the basic patent.

(24) To avoid discrimination between applicants for national certificates under Regulation [COM(2023) 231] and applicants for unitary certificates under this Regulation, an extension of the duration of a certificate as defined by Article 36 of Regulation (EC) No 1901/2006 of the European Parliament and of the Council[27] should also be available for unitary certificates. For this purpose that Regulation should be amended.

(25) To guarantee a fair and transparent process, ensure legal certainty and reduce the risk of subsequent validity challenges, third parties should have the possibility, after the publication of the unitary certificate application, to submit within 3 months observations to the Office while the centralised examination is being performed. These third parties allowed to submit observations should also include Member States. This, however, should not affect the rights of third parties to initiate subsequent invalidity proceedings before the Office. These provisions are necessary to ensure involvement of third parties both before and after the grant of certificates.

(26) The examination of an application for a unitary certificate should be conducted, under supervision of the Office, by an examination panel including one member of the Office as well as two examiners employed by the national patent offices. This would ensure that optimal use be made of expertise in supplementary protection certificates matters, located today at national offices only. To ensure an optimal quality of the examination, suitable criteria should be laid down in respect of the participation of specific examiners in the procedure, in particular as regards qualification and conflicts of interest.

(27) The Office should examine the application for a unitary certificate and issue an examination opinion. That opinion should state the reasons for which it is positive or negative.

(28) To safeguard third parties' procedural rights and ensure a complete system of remedies, third parties should be able to challenge an examination opinion, by initiating opposition proceedings within a short duration following the publication of that opinion, and that opposition may result in that opinion being amended.

(29) After the completion of the examination of a unitary certificate application, and after the time limits for appeal and opposition have expired, or, the case being, after a final decision on the merits has been issued, the Office should implement the examination opinion by granting a unitary certificate or rejecting the application, as applicable.

(30) Where the applicant or another party is adversely affected by a decision of the Office, the applicant or that party should have the right, subject to a fee, to file within 2 months an appeal against the decision, before a Board of Appeal of the Office. This also applies to the examination opinion, that may be appealed by the applicant. Decisions of that Board of Appeal should, in turn, be amenable to actions before the General Court, which has jurisdiction to annul or to alter the contested decision. In

[27] Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1).

case of a combined application including the designation of additional Member States with a view to the grant of national certificates, a common appeal may be filed.

(31) When appointing members of the Boards of Appeal in matters regarding applications for unitary certificates, their prior experience in supplementary protection certificate or patent matters should be taken into account.

(32) Any person may challenge the validity of a unitary certificate by lodging with the Office an application for a declaration of invalidity.

(33) The Office should have the possibility to charge a fee for the application for a unitary certificate and for an application for the extension of duration of a unitary certificate in the case of paediatric medicinal products, as well as other procedural fees such as those for oppositions, appeals and invalidity. The fees charged by the Office should be laid down by an implementing act.

(34) Annual fees in respect of unitary certificates (also known as renewal fees) should be paid to the Office, which should retain a part of them to cover the expenses generated by carrying out tasks in relation to the grant of unitary certificates while the remaining part would be shared with those Member States in which unitary certificates have effect.

(35) To ensure transparency, a register should be set up that can serve as a single access point providing information on applications for unitary certificates as well as granted unitary certificates and their status. The register should be available in all official languages of the Union.

(36) For the tasks conferred on the Office under this Regulation, the languages of the Office should be all official languages of the Union, to enable actors across the Union to easily apply for unitary certificates or submit third party observations and result in optimal transparency for all stakeholders across the Union. The Office should accept verified translations, into one of the official languages of the Union, of documents and information. The Office may, if appropriate, use verified machine translations.

(37) Financial provision should be made to ensure competent national authorities that participate in the centralised procedure are adequately remunerated for their participation.

(38) The necessary set-up costs related to the tasks conferred to the Office, including the costs of new digital systems, should be financed from the Office's accumulated budgetary surplus.

(39) To ensure that Regulation (EU) No 608/2013 of the European Parliament and of the Council[28] also covers unitary certificates, that Regulation should be amended.

(40) In order to supplement certain non-essential elements of this Regulation, the power to adopt acts, in accordance with Article 290 of the Treaty on the Functioning of the European Union, should be delegated to the Commission in respect of: (i) specifying the content and form of the notice of appeal and the content and the form of the Boards of Appeal's decision, (ii) specifying the details concerning the organisation of the Boards of Appeal in proceedings relating to certificates, (iii) specifying the rules on the means of communication, including the electronic means of communication, to be

[28] Regulation (EU) No 608/2013 of the European Parliament and of the Council of 12 June 2013 concerning customs enforcement of intellectual property rights and repealing Council Regulation (EC) No 1383/2003.

used by the parties to proceedings before the Office and the forms to be made available by the Office, (iv) setting out the detailed arrangements for oral proceedings, (v) setting out the detailed arrangements for the taking of evidence, (vi) setting out the detailed arrangements for notification, (vii) specifying the details regarding the calculation and duration of time limits and (viii) setting out the detailed arrangements for the resumption of proceedings. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016.[29] In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

(41) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards: (i) the application forms to be used; (ii) rules on procedures relating to the filing, and procedures regarding the way in which examination panels examine centralised applications and prepare examination opinions, as well as the issuance of examination opinions by the Office, (iii) the criteria in the ways the examination panels are to be set up, and the criteria for the selection of examiners, (iv) the amounts of the applicable fees to be paid to the Office, (v) specifying the maximum rates for costs essential to the proceedings and actually incurred by the successful party, and (vi) rules on the financial transfers between the Office and Member States, the amounts of these transfers, and the remuneration to be paid by the Office regarding the participation of competent national authorities. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[30].

(42) The Commission should regularly report on the operation of this Regulation, in coordination with that required in Regulation [COM(2023) 231]. The Commission should regularly evaluate the impact of unitary supplementary protection on access to medicines.

(43) This Regulation respects fundamental rights and observes the principles recognised by the Charter of Fundamental Rights of the European Union ('the Charter'). The rules in this Regulation should be interpreted and applied in accordance with those rights and principles. In particular, this Regulation seeks to ensure full respect for the right to property and the right to health care and the right to an effective remedy in Articles 17 and 35 and 47 of the Charter. This also applies to the above-mentioned exception, which maintains the core rights of the certificate, by being limited to the making of a product, or a medicinal product containing that product, only for the purpose of export outside the Union or for the purpose of storing for a limited period of time with a view to entry into the Union market upon expiry of the protection, and to the acts strictly necessary for such making or for the actual export or the actual storing. In the light of those fundamental rights and principles, the exception does not go beyond what is necessary and appropriate in the light of its overall objective, which is to promote the

[29] Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making (OJ L 123, 12.5.2016, p. 1).

[30] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

competitiveness of the Union by avoiding relocation and allowing makers of generics and biosimilars established in the Union to compete, on the one hand, on fast-growing global markets where protection does not exist or has already expired, and on the other, on the Union market upon expiry of the certificate.

(44) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States but can rather, by reason of the autonomous nature of the unitary certificate being independent from national systems, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

(45) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725[31] and delivered an opinion on XXX *[OP, please add reference once available]*.

(46) Provision should be made for appropriate arrangements to facilitate a smooth implementation of the rules provided for in this Regulation. To allow for sufficient time for the Office to prepare the operational set-up and launch of the procedure to be used for the grant of unitary certificates, as set out in this Regulation, the application of this Regulation should be deferred,

HAVE ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation lays down rules on the unitary supplementary protection certificate ('unitary certificate') for medicinal products protected by a European patent with unitary effect and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure as laid down in Regulation (EC) No 726/2004, or Regulation (EU) 2019/6.

Article 2

Definitions

For the purposes of this Regulation the following definitions shall apply:

(1) 'medicinal product' means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals;

(2) 'product' means the active ingredient or combination of active ingredients of a medicinal product;

[31] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

(3) 'European patent' means a patent granted by the European Patent Office ('EPO') under the rules and procedures laid down in the European Patent Convention[32] ('EPC');

(4) 'unitary patent' means a European patent which benefits from unitary effect in those Member States participating in the enhanced cooperation laid down in Regulation (EU) No 1257/2012;

(5) 'basic patent' means a unitary patent which protects a product as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a unitary certificate;

(6) 'application for an extension of the duration' means an application for an extension of the duration of a unitary certificate pursuant to Article 20(3) of this Regulation and Article 36 of Regulation (EC) No 1901/2006;

(7) 'maker' means the person, established in the Union, on whose behalf the making of a product, or a medicinal product containing that product, for the purpose of export to third countries or for the purpose of storing, is carried out;

(8) 'centralised application' means an application made before the European Union Intellectual Property Office ('the Office') pursuant to Chapter III of Regulation [COM(2023) 231] with a view to the grant of certificates, for the product identified in the application, in the designated Member States;

(9) 'competent national authority' means the national authority that is competent, in a given Member State, for the grant of certificates and for the rejection of applications for certificates.

Article 3

Conditions for obtaining a unitary certificate

1. A unitary certificate shall be granted by the Office on the basis of a basic patent if, in each of the Member States in which that basic patent has unitary effect, at the date of the application, all of the following conditions are fulfilled:

   (a) the product is protected by that basic patent in force;

   (b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Regulation (EU) 2019/6, or with the centralised procedure under Regulation (EC) No 726/2004;

   (c) the product has not already been the subject of a certificate, nor of a unitary certificate;

   (d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.

2. The holder of more than one patent for the same product shall not be granted more than one certificate or unitary certificate for that product for any given Member State.

[32] Convention on the Grant of European Patents of 5 October 1973, as revised on 17 December 1991 and on 29 November 2000.

Where two or more applications, whether national or centralised applications for certificates, or applications for unitary certificates, concerning the same product and submitted by two or more holders of different patents are pending in a given Member State, one certificate or unitary certificate for that product may be granted to each of those holders, where they are not economically linked, by a competent national authority or by the Office, as applicable.

Article 4

Scope of the protection

Within the limits of the protection conferred by the basic patent, the protection conferred by a unitary certificate shall extend only to the product covered by the authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the unitary certificate.

Article 5

Effects of the unitary certificate

1. The unitary certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations, in all Member States in which the basic patent has unitary effect.

2. A unitary certificate shall have a unitary character. It shall provide uniform protection and shall have equal effect in all Member States in which the basic patent has unitary effect. The unitary certificate may only be limited, transferred or revoked, or lapse, in respect of all those Member States.

3. By way of derogation from paragraph 1, the unitary certificate shall not confer protection against certain acts which would otherwise require the consent of the unitary certificate holder, if all of the following conditions are met:

   (a) the acts comprise any of the following:

      (i) the making of a product, or a medicinal product containing that product, for the purpose of export to third countries;

      (ii) any related act that is strictly necessary for the making, in the Union, referred to in point (i), or for the actual export;

      (iii) the making, no earlier than 6 months before the expiry of the unitary certificate, of a product, or a medicinal product containing that product, for the purpose of storing it in the Member State of making, in order to place that product, or a medicinal product containing that product, on the market of Member States after the expiry of the corresponding certificate;

      (iv) any related act that is strictly necessary for the making, in the Union, referred to in point (iii), or for the actual storing, provided that such related act is carried out no earlier than 6 months before the expiry of the unitary certificate.

   (b) the maker, through appropriate and documented means, notifies the Office, and the competent industrial property office of the respective Member State, and informs the unitary certificate holder, of the information referred to in paragraph 6 no later than 3 months before the start date of the making in that

Member State, or no later than 3 months before the first related act, prior to that making, that would otherwise be prohibited by the protection conferred by a unitary certificate, whichever is the earlier;

(c) if the information referred to in paragraph 6 of this Article changes, the maker notifies the Office and the competent industrial property office of the respective Member State, and informs the certificate holder, before those changes take effect;

(d) in the case of products, or medicinal products containing those products, made for the purpose of export to third countries, the maker ensures that a logo, in the form set out in Annex I, is affixed to the outer packaging of the product, or the medicinal product containing that product, referred to in point (a)(i) of this paragraph, and, where feasible, to its immediate packaging;

(e) the maker complies with paragraph 10 of this Article and, if applicable, with Article 31(4).

4. Paragraph 3 shall not apply to any act or activity carried out for the import of products, or medicinal products containing those products, into the Union merely for the purpose of repackaging, re-exporting or storing.

5. The information provided to the unitary certificate holder for the purposes of paragraph 3, points (b) and (c), shall be used exclusively for the purposes of verifying whether the requirements of this Regulation have been met and, where applicable, initiating legal proceedings for non-compliance.

6. For the purposes of paragraph 3, point (b), the maker shall provide all of the following information:

(a) the name and address of the maker;

(b) an indication of whether the making is for the purpose of export, for the purpose of storing, or for the purpose of both export and storing;

(c) the Member State in which the making and, if applicable, also the storing is to take place, and the Member State in which the first related act, if any, prior to that making is to take place;

(d) the number of the unitary certificate having effect in the Member State of making, and the number of the certificate or unitary certificate granted in the Member State of the first related act, if any, prior to that making;

(e) for medicinal products to be exported to third countries, the reference number of the marketing authorisation, or the equivalent of such authorisation, in each third country of export, as soon as it is publicly available.

7. For the purposes of the notifications to the Office and to the competent industrial property office referred to in paragraph 3, points (b) and (c), the maker shall use the standard form for notification set out in Annex II.

8. Failure to provide the information referred to in paragraph 6, point (e), with regard to a third country shall only affect exports to that third country, and those exports shall not benefit from the exception laid down in paragraph 3.

9. The maker shall ensure that medicinal products made pursuant to paragraph 3, point (a)(i), do not bear an active unique identifier within the meaning of Delegated Regulation (EU) 2016/161[33].

10. The maker shall ensure, through appropriate and documented means, that any person in a contractual relationship with the maker that performs acts falling under paragraph 3, point (a), is fully informed and aware of all of the following:

(a) that those acts are subject to paragraph 3;

(b) that the placing on the market, import or re-import of the product, or the medicinal product containing that product, referred to in paragraph 3, point (a)(i), or the placing on the market of the product, or the medicinal product containing that product, referred to in paragraph 3, point (a)(iii), could infringe the unitary certificate referred to in that paragraph where, and for as long as, that certificate applies.

Article 6

Entitlement to the unitary certificate

1. The unitary certificate shall be granted to the holder of the basic patent or to the successor in title of that holder.

2. Notwithstanding paragraph 1, where a basic patent has been granted in respect of a product that is the subject of an authorisation held by a third party, a unitary certificate for that product shall not be granted to the holder of the basic patent without the consent of that third party.

Article 7

The unitary certificate as an object of property

A unitary certificate or an application for a unitary certificate as an object of property shall be treated in its entirety, in each Member State in which the basic patent has unitary effect, in accordance with the national law applicable to the basic patent as an object of property.

Article 8

Application for a unitary certificate

1. The application for a unitary certificate shall be lodged within 6 months of the date on which the authorisation referred to in Article 3(1), point (b), to place the product on the market as a medicinal product was granted.

2. Notwithstanding paragraph 1, where the authorisation to place the product on the market is granted before unitary effect is attributed to the basic patent, the application for a unitary certificate shall be lodged within 6 months of the date on which unitary effect is attributed to the basic patent.

3. The application for an extension of the duration may be lodged at the same time when lodging the application for a unitary certificate or when the application for the

[33] Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use (OJ L 32, 9.2.2016, p. 1).

unitary certificate is pending and the appropriate requirements of Article 9(1), point (d), or Article 9(2), respectively, are fulfilled.

4. The application for an extension of the duration of a unitary certificate already granted shall be lodged not later than 2 years before the expiry of the unitary certificate.

Article 9

Content of the application for a unitary certificate

1. The application for a unitary certificate shall contain the following:

(a) a request for the grant of a unitary certificate, stating the following information:

(i) the name and address of the applicant;

(ii) if the applicant has appointed a representative, the name and address of that representative;

(iii) the number of the basic patent and the title of the invention;

(iv) the number and date of the first authorisation to place the product on the market, as referred to in Article 3(1), point (b) and, if this authorisation is not the first authorisation for placing the product on the market in the Union, the number and date of that authorisation;

(b) a copy of the authorisation to place the product on the market, as referred to in Article 3(1), point (b), in which the product is identified, containing in particular the number and date of the authorisation and the summary of the product characteristics listed in Article 11 of Directive 2001/83/EC of the European Parliament and of the Council[34] or Article 35 of Regulation (EU) 2019/6;

(c) where the authorisation referred to in point (b) is not the first authorisation for placing the product on the market as a medicinal product in the Union, information regarding the identity of the product thus authorised and the legal provision under which the authorisation procedure took place, together with a copy of the notice publishing the authorisation in the appropriate official publication or, in the absence of such a notice, any other document proving that the authorisation has been issued, the date on which it was issued and the identity of the product authorised.

(d) where the application for a unitary certificate for a medicinal product includes a request for an extension of the duration:

(i) a copy of the statement indicating compliance with an agreed completed paediatric investigation plan as referred to in Article 36(1) of Regulation (EC) No 1901/2006;

(ii) where necessary, in addition to the copy of the authorisation to place the product on the market as referred to in point (b), proof of possession of

[34] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

authorisations to place the product on the market of all other Member States, as referred to in Article 36(3) of Regulation (EC) No 1901/2006.

2. Where an application for a unitary certificate is pending, an application for an extension of the duration in accordance with Article 8(3) shall include the documents referred to in paragraph 1, point (d) of this Article and a reference to the application for a certificate already lodged.

3. The application for an extension of the duration of a unitary certificate already granted shall contain the documents referred to in paragraph 1, point (d), and a copy of the certificate already granted.

4. The applications referred to in this Article shall be filed by using specific application forms.

The Commission is empowered to adopt implementing acts laying down rules on the application form to be used. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55.

Article 10

Lodging of an application for a unitary certificate

The application for a unitary certificate and, where applicable, the application for an extension of the duration of a unitary certificate, shall be lodged with the Office.

Article 11

Examination of the admissibility of an application for a unitary certificate

1. The Office shall examine the following:

(a) whether the application for a unitary certificate complies with Article 9;

(b) whether the application complies with Article 8;

(c) whether the application fee referred to in Article 31(1) has been paid within the prescribed period.

2. Where the centralised application does not satisfy the requirements referred to in paragraph 1, the Office shall request the applicant to take the measures necessary to satisfy those requirements, and shall set a deadline for such compliance.

3. Where the fee referred to in paragraph 1, point (c), has not been paid or has not been paid in full, the Office shall inform the applicant accordingly.

4. If the applicant does not satisfy the requirements referred to in paragraph 1 within the deadline referred to in paragraph 2, the Office shall reject the application for a unitary certificate.

Article 12

Publication of the application

If the application for a unitary certificate complies with Article 11(1), or if an application for an extension of the duration of a unitary certificate complies with Article 9(3), the Office shall publish the application in the Register.

Article 13

Examination of the application for a unitary certificate

1. The Office shall assess the application on the basis of all the conditions in Article 3(1), for all Member States in which the basic patent has unitary effect.

2. Where the application for a unitary certificate and the product to which it relates comply with Article 3(1) for each of the Member States referred to in paragraph 1, the Office shall issue a reasoned positive examination opinion in respect of the grant of a unitary certificate. The Office shall notify that opinion to the applicant.

3. Where the application for a unitary certificate and the product to which it relates does not comply with Article 3(1) in respect of one or more of those Member States, the Office shall issue a reasoned negative examination opinion on the grant of a unitary certificate. The Office shall notify that opinion to the applicant.

4. The Office shall translate the examination opinion in the official languages of all designated Member States. The Office may use verified machine translation to that effect.

5. The Commission is empowered to adopt implementing acts laying down rules on procedures relating to the filing, and procedures regarding the way in which examination panels examine applications for unitary certificates and prepare examination opinions, as well as the issuance of examination opinions by the Office. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55.

Article 14

Observations by third parties

1. Any natural or legal person may submit written observations to the Office concerning the eligibility for supplementary protection of the product to which the application relates, in one or more of the Member States in which the basic patent has unitary effect.

2. A natural or legal person that has submitted the written observations in accordance with paragraph 1 shall not be a party to the proceedings.

3. Third party observations shall be submitted within 3 months after publication of the application in the Register.

4. Any observations by a third party shall be submitted in writing in one of the official languages of the Union and state the grounds on which they are based.

5. Any observations by a third party shall be notified to the applicant. The applicant may comment on the observations within a time limit set by the Office.

Article 15

Opposition

1. Within a period of 2 months following the publication of the examination opinion in respect of an application for a unitary certificate, any person (‘opponent’) may file with the Office a notice of opposition to that opinion.

2. Opposition may only be filed on the grounds that one or more of the conditions set out in Article 3 are not fulfilled for one or more of the Member States in which the basic patent has unitary effect.

3. Opposition shall be filed in writing, and shall specify the grounds on which it is made. It shall not be considered as duly filed until the opposition fee has been paid.

4. The notice of opposition shall contain:

   (a) the references of the unitary certificate application against which opposition is filed, the name of its holder, and the identification of the product;

   (b) the particulars of the opponent and, where applicable, of its representative;

   (c) a statement of the extent to which the examination opinion is opposed, and of the grounds on which the opposition is based.

5. The opposition shall be examined by an opposition panel set up by the Office in accordance with the rules applicable to examination panels as referred to in Article 17. However, the opposition panel shall not include any examiner previously involved in the examination panel that examined the unitary certificate application.

6. If the opposition panel notes that the notice of opposition does not comply with paragraphs 2, 3 or 4, it shall reject the opposition as inadmissible, and communicate this to opponent, unless these deficiencies have been remedied before expiry of the opposition filing period referred to in paragraph 1.

7. The decision to reject an opposition as inadmissible shall be communicated to the holder of the unitary certificate application, together with a copy of the notice of opposition.

8. A notice of opposition shall be inadmissible where a previous appeal relating to the same subject matter and cause of action has been adjudicated on its merits by the Office, and the decision of the Office on that appeal has acquired the authority of a final decision.

9. Where the opposition is not rejected as inadmissible, the Office shall promptly transmit the notice of opposition to the applicant, and shall publish it in the Register. If several notices of opposition have been filed, the Office shall promptly communicate them to the other opponents.

10. The Office shall issue a decision on the opposition within 6 months, unless the complexity of the case requires a longer period.

11. If the opposition panel considers that no ground for opposition prejudices the maintenance of the examination opinion, it shall reject the opposition, and the Office shall mention this in the Register.

12. If the opposition panel considers that at least one ground for opposition prejudices the maintenance of the examination opinion, it shall adopt an amended opinion, and the Office shall mention this in the Register.

13. The Commission is empowered to adopt delegated acts in accordance with Article 54 to supplement this Regulation by specifying the details of the procedure for filing and examining an opposition.

Article 16

Role of competent national authorities

1. On a request made to the Office, any competent national authority may be appointed by the Office as a participating office in the examination procedure. Once a competent national authority is appointed in accordance with this Article, that authority shall designate one or more examiners to be involved in the examination of one or more applications for unitary certificates.

2. The Office and the competent national authority shall conclude an administrative agreement before that competent national authority is appointed as participating office as referred to in paragraph 1.

   The agreement shall specify the rights and obligations of the parties, in particular the formal undertaking by the competent national authority concerned to comply with this Regulation as regards the examination of applications for unitary certificates.

3. The Office may appoint a competent national authority as a participating office as referred to in paragraph 1 for 5 years. That appointment may be extended for further periods of 5 years.

4. The Office shall, before appointing a competent national authority, or extending its appointment, or before any such appointment expires, hear the competent national authority concerned.

5. Each competent national authority appointed under this Article shall provide the Office with a list identifying the individual examiners who are available for participation in examination, opposition and invalidity proceedings. Each such competent national authority shall update that list in the event of a change.

Article 17

Examination panels

1. The assessments under Articles 13, 15, 19 and 23 shall be conducted by an examination panel including one member of the Office as well as two examiners as referred to in Article 16(1) from two different participating competent national authorities, under supervision of the Office.

2. Examiners shall be impartial in the exercise of their duties and shall declare to the Office any real or perceived conflict of interest upon their designation.

3. When setting up an examination panel, the Office shall ensure the following:

   (a) geographical balance amongst the participating offices;

   (b) the respective workload of the examiners is taken into account;

   (c) no more than one examiner employed by a competent national authority making use of the exemption set out in Article 10(5) of Regulation [COM(2023) 231].

4. The Office shall publish a yearly an overview of the number of procedures, including those for examination, opposition, appeal and invalidity, each competent national authority participated in.

5. The Commission is empowered to adopt implementing acts to determine the criteria in the ways the panels are to be set up and the criteria for the selection of examiners.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55.

Article 18

Grant of a unitary certificate or rejection of the application for a unitary certificate

After the period during which an appeal or an opposition may be filed has expired without any appeal nor opposition being filed, or after a final decision on the merits has been issued, the Office shall take one of the following decisions:

(a) where the examination opinion is positive, the Office shall grant a unitary certificate;

(b) where the examination opinion is negative, the Office shall reject the application for a unitary certificate.

Article 19

Grant of an extension of the duration of a unitary certificate

1. After ensuring that the application for an extension of the duration of a unitary certificate complies with Article 9(3), the Office shall assess that application on the basis of the conditions laid down in Article 36 of Regulation (EC) No 1901/2006.

2. Third parties may also submit observations in respect of an application for an extension of the duration of a unitary certificate.

3. Where the application for an extension of the duration complies with the conditions referred to in paragraph 1, the Office shall grant an extension of the duration of the unitary certificate.

4. Where the application for an extension of the duration does not comply with the conditions referred to in paragraph 1, the Office shall reject that application.

Article 20

Duration of the unitary certificate

1. The unitary certificate shall take effect at the end of the lawful term of the basic patent, namely on the twentieth anniversary of the filing date of the application for that patent, for a period equal to the period which elapsed between the date on which the application for the basic patent was lodged and the date of the first authorisation to place the product on the market in the Union, reduced by a period of 5 years.

2. The duration of the unitary certificate may not exceed 5 years from the date on which it takes effect.

3. The periods laid down in paragraphs 1 and 2 shall be extended by 6 months in the case where Article 36 of Regulation (EC) No 1901/2006 applies. In that case, the duration of the period laid down in paragraph 1 of this Article may be extended only once.

Article 21

Expiry of the unitary certificate

The unitary certificate shall lapse in any of the following events:

(a) at the end of the period provided for in Article 20;

(b) if the unitary certificate holder surrenders it;

(c) if the annual fee laid down in accordance with Article 31(3) is not paid in time;

(d) if and as long as the product covered by the unitary certificate may no longer be placed on the market following the withdrawal of the appropriate authorisation to place on the market in accordance with Regulation (EC) No 726/2004 or Regulation (EU) 2019/6.

For the purposes of the first subparagraph, point (d), the Office may decide on the lapse of the certificate either of its own motion or at the request of a third party.

Article 22

Invalidity of the unitary certificate

The unitary certificate shall be invalid in any of the following events:

(a) the certificate was granted contrary to Article 3;

(b) the basic patent has lapsed before its lawful term expires;

(c) the basic patent is revoked or limited to the extent that the product for which the unitary certificate was granted would no longer be protected by the claims of the basic patent or, after the basic patent has expired, grounds for revocation exist which would have justified such revocation or limitation.

Article 23

Application for a declaration of invalidity

1. Any person may file with the Office an application for a declaration of invalidity of a unitary certificate.

2. An application for a declaration of invalidity may only be filed on the grounds that one or more of the conditions set out in Article 22 are not fulfilled for one or more of the Member States in which the basic patent has unitary effect.

3. An application for a declaration of invalidity shall be filed in writing, and shall specify the grounds on which it is made. It shall not be considered as duly filed until the related fee has been paid.

4. The application for a declaration of invalidity shall contain:

(a) the references of the unitary certificate against which that application is filed, the name of its holder, and the identification of the product;

(b) the particulars of the person referred to in paragraph 1 (‘applicant’) and, where applicable, of its representative;

(c) a statement of the grounds on which the application for a declaration of invalidity is based.

5. The application for a declaration of invalidity shall be examined by an invalidation panel set up by the Office in accordance with the rules applicable to examination panels. However, the invalidation panel shall not include any examiner previously involved in the examination panel that examined the unitary certificate application, nor, the case being, any examiner involved in possible related opposition proceedings, nor in related appeal proceedings.

1. An application for a declaration of invalidity shall be inadmissible where an application relating to the same subject matter and cause of action, and involving the same parties, has been adjudicated on its merits, either by the Office or by a competent court as referred to in Article 24, and the decision of the Office or that court on that application has acquired the authority of a final decision.

7. If the invalidation panel notes that the application for a declaration of invalidity does not comply with paragraphs 2, 3 or 4, it shall reject that application as inadmissible, and communicate this to applicant.

8. The decision to reject an application for a declaration of invalidity as inadmissible shall be communicated to the holder of the unitary certificate, together with a copy of that application.

9. Where the application for a declaration of invalidity is not rejected as inadmissible, the Office shall promptly transmit that application to the holder of the unitary certificate, and shall publish it in the Register. If several applications for a declaration of invalidity have been filed, the Office shall promptly communicate them to the other applicants.

10. The Office shall issue a decision on the application for a declaration of invalidity within 6 months, unless the complexity of the case requires a longer period.

11. If the examination of the application for a declaration of invalidity reveals that the one or more of the conditions set out in Article 22 are met, the unitary certificate shall be declared invalid. Otherwise the application for a declaration of invalidity shall be rejected. The outcome shall be mentioned in the Register.

12. The unitary certificate shall be deemed not to have had, as from the outset, the effects specified in this Regulation, to the extent that it has been declared invalid.

13. The Commission is empowered to adopt delegated acts in accordance with Article 54 to supplement this Regulation by specifying the details of the procedure governing the declaration of invalidity.

Article 24

Counterclaim for the invalidity of a certificate

1. A counterclaim for a declaration of invalidity may only be based on the grounds for invalidity set out in Article 22.

2. The competent court of a Member State shall reject a counterclaim for a declaration of invalidity if a decision taken by the Office relating to the same subject matter and cause of action and involving the same parties has already become final.

3. If the counterclaim is brought in a legal action to which the holder of the unitary certificate is not already a party, that holder shall be informed thereof and may be joined as a party to the action in accordance with the conditions applicable before the competent court.

4. The competent court of a Member State with which a counterclaim for a declaration of invalidity of the unitary certificate has been filed shall not proceed with the examination of the counterclaim, until either the interested party or the court has informed the Office of the date on which the counterclaim was filed. The Office shall record that information in the Register. If an application for a declaration of invalidity of the unitary certificate had already been filed before the Office before the counterclaim was filed, the court shall be informed thereof by the Office and stay the proceedings until the decision on the application is final or the application is withdrawn.

5. Where the competent court of a Member State has given a judgment which has become final on a counterclaim for a declaration of invalidity of a unitary certificate, a copy of the judgment shall be sent to the Office without delay, either by the court or by any of the parties to the national proceedings. The Office or any other interested party may request information about such transmission. The Office shall mention the judgment in the Register and shall take the necessary measures to comply with its operative part.

6. The competent court hearing a counterclaim for a declaration of invalidity may stay the proceedings on application by the holder of a unitary certificate and after hearing the other parties and may request the defendant to submit an application for a declaration of invalidity to the Office within a time limit which it shall determine. If the application is not made within the time limit, the proceedings shall continue; the counterclaim shall be deemed withdrawn. Where the competent court of a Member State stays the proceedings it may order provisional and protective measures for the duration of the stay.

Article 25

Revocation of an extension of the duration of a unitary certificate for a medicinal product

1. The Office may revoke an extension of the duration if it was granted contrary to Article 36 of Regulation (EC) No 1901/2006.

2. Any person may submit an application for revocation of the extension of the duration to the Office.

Article 26

Notification of lapse or invalidity

1. Where the unitary certificate lapses in accordance with Article 21, point (b), (c) or (d), or is invalid in accordance with Article 22 and 23, the Office shall promptly publish a notification thereof.

2. Where the extension of the duration is revoked in accordance with Article 25, the Office shall promptly publish a notification thereof.

Article 27

Conversion

1. Where the unitary effect of the basic patent is revoked while the application for a unitary certificate is still pending, the holder of that application may, subject to a fee,

request the conversion of that application into a centralised application for certificates.

2. Where the unitary effect of the basic patent is revoked after the unitary certificate has been granted, the holder of that certificate may, subject to a fee, request the conversion of that unitary certificate into national certificates.

3. A request for conversion may be filed with the Office within 3 months after notification of the revocation of the unitary effect of the basic patent.

4. A request for conversion, as well as its outcome, shall be published in the Register.

5. The Office shall check whether the conversion requested fulfils the conditions set out in this Article, together with the formal conditions specified in the implementing act adopted pursuant to paragraph 8. If the conditions governing the request are not fulfilled, the Office shall notify the applicant of the deficiencies. If the deficiencies are not remedied within a period to be specified by the Office, the Office shall reject the request for conversion. Where the conversion fee has not been paid within the relevant period of 3 months, the Office shall inform the applicant that the request for conversion is deemed not to have been filed.

6. Where a request under paragraph 1 complies with paragraph 5, the Office shall convert the application for a unitary certificate into a centralised application for certificates designating the Member States in which the basic patent had unitary effect. In the event of a combined application, the designation of the Member States in which the basic patent had unitary effect shall be added to the designation of other Member States already included in the combined application.

7. Where a request under paragraph 2 complies with paragraph 5, the Office shall transmit the request for conversion to the competent national authorities of each Member State in which the basic patent had unitary effect and for which the request has been found admissible. The competent national authorities shall take decisions accordingly.

8. The Commission shall adopt implementing acts specifying the details to be contained in a request for conversion of the for a unitary certificate or unitary certificate into a centralised application for certificates or national certificates. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55.

Article 28

Appeals

1. Any party to proceedings under this Regulation, adversely affected by a decision of the Office, including the adoption of an examination opinion, may appeal the decision to the Boards of Appeal.

2. The filing of the appeal shall have suspensive effect. A decision of the Office that has not been contested shall take effect on the day following the date of expiry of the appeal period referred to in paragraph 3.

3. Notice of appeal shall be filed in writing at the Office within 2 months of the date of notification of the decision. The notice shall be deemed to have been filed only when the fee for appeal has been paid. In case of an appeal, a written statement setting out

the grounds of appeal shall be filed within 4 months of the date of notification of the decision.

4. Following an examination of admissibility of the appeal, the Boards of Appeal shall decide on the merits of the appeal.

5. Where an appeal results in a decision which is not in line with the examination opinion, the decision of the Boards may annul or alter the opinion.

6. An action may be brought before the General Court of the European Union against a decision of the Boards of Appeal in relation to appeals, within 2 months of the date of notification of that decision, on grounds of infringement of an essential procedural requirement, infringement of the Treaty on the Functioning of the European Union, infringement of this Regulation or of any rule of law relating to their application or misuse of power. The action shall be open to any party to proceedings before the Board of Appeal adversely affected by its decision. The General Court shall have jurisdiction to annul or to alter the contested decision.

7. The decisions of the Boards of Appeal shall take effect on the day following the date of expiry of the period referred to in paragraph 6 or, if an action has been brought before the General Court within that period, as from the date following the day of dismissal of such action or of dismissal of any appeal filed with the Court of Justice of the European Union against the decision of the General Court. The Office shall take the necessary measures to comply with the judgement of the General Court or, in the event of an appeal against that judgement, the Court of Justice.

8. The Commission is empowered to adopt delegated acts in accordance with Article 54 to supplement this Regulation by specifying the content and form of the notice of appeal referred to in paragraph 3, the procedure for the filing and examination of an appeal and the content and the form of the Boards of Appeal's decision referred to in paragraph 4.

Article 29

Boards of Appeal

1. In addition to the powers conferred upon it by Article 165 of Regulation (EU) 2017/1001, the Boards of Appeal instituted by that Regulation shall be responsible for deciding on appeals against decisions of the Office taken on the basis of Article 25(1).

2. A Board of Appeal in matters regarding unitary certificates shall consist of three members, at least two of whom are legally qualified. Where the Board of Appeal considers that the nature of the appeal so requires, it may call up to two further members for that case.

3. There shall be no Grand Board as referred to in Article 165(2), (3) and (4), and Article 167(2) of Regulation (EU) 2017/1001 in matters regarding unitary certificates. Decisions taken by a single member as under Article 165(2) of Regulation (EU) 2017/1001 shall not be possible.

4. Members of the Boards of Appeal in matters regarding unitary certificates shall be appointed in accordance with Article 166(5) of Regulation (EU) 2017/1001.

Article 30

Delegation of power regarding the Boards of Appeal

The Commission is empowered to adopt delegated acts in accordance with Article 54 to supplement this Regulation by specifying the details concerning the organisation of the Boards of Appeal in proceedings relating to unitary certificates under this Regulation.

Article 31

Fees

1. The Office shall charge a fee for an application for a unitary certificate, and for an application for the extension of the duration of a unitary certificate.
2. The Office shall charge a fee for appeals, for oppositions, for applications for a declaration of invalidity and for conversions.
3. The unitary certificate shall be subject to the payment of annual maintenance fees to the Office.
4. The notifications referred to in Article 5(3), points (b) and (c), shall be subject to the payment of a fee to the Office.
5. The Commission is empowered to adopt implementing acts determining the amounts of the fees charged by the Office, the time limits within which they have to be paid, and the ways in which they are to be paid. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55.

Article 32

Combined applications

An application for a unitary certificate may be included in a combined centralised application in which the applicant also requests the grant of national certificates, in the designated Member States, in accordance with the centralised procedure under Regulation [COM(2023) 231]. In that case, Article 39 of that Regulation shall apply.

Article 33

Languages

1. All documents and information sent to the Office in respect of the procedures under this Regulation shall be in one of the official languages of the Union.
2. For the tasks conferred on the Office under this Regulation, the languages of the Office shall be all the official languages of the Union in accordance with Council Regulation No 1[35].

[35] Council Regulation No 1 determining the languages to be used by the European Economic Community (OJ 17, 6.10.1958, p. 385).

Article 34

Communications to the Office

1. Communications addressed to the Office may be effected by electronic means. The Executive Director shall determine to what extent and under which technical conditions those communications may be submitted electronically.

2. The Commission is empowered to adopt delegated acts in accordance with Article 54 to supplement this Regulation by specifying the rules on the means of communication, including the electronic means of communication, to be used by the parties to proceedings before the Office and the forms to be made available by the Office.

Article 35

Register

1. As regards applications for unitary certificates for medicinal products, the Register set up under Article 35 of Regulation [COM(2023) 231][36] shall include, for each unitary certificate, or application for a unitary certificate, or application for an extension of the duration of a unitary certificate, the following information, as applicable:

   (a) the name and address of the applicant or certificate holder;

   (b) the name and business address of the representative, other than a representative as referred to in Article 38(3);

   (c) the application as well as its date of lodging and date of publication;

   (d) whether the application relates to a medicinal product or to a plant protection product;

   (e) where applicable, an indication that the application includes an application for an extension of the duration;

   (f) the number of the basic patent;

   (g) an identification of the product for which a unitary certificate is requested;

   (h) the number and date of the authorisation to place the product on the market referred to in Article 3(1), point (b), and an identification of the product identified therein;

   (i) the number and date of the first authorisation to place the product on the market in the Union;

   (j) the date and a summary of the examination opinion of the Office in respect of each of the Member States in which the basic patent has unitary effect;

   (k) where applicable, the number and the duration of the unitary certificate;

   (l) where applicable, the date and a summary of the examination opinion relating to an application for an extension of the duration of a unitary certificate;

[36] Regulation of the European Parliament and of the Council on the supplementary protection certificate for medicinal products [COM(2023) 231].

(m) where applicable, the filing of an opposition, and the outcome of the opposition proceedings, including where applicable a summary of the revised examination opinion;

(n) where applicable, the filing of an appeal, and the outcome of the appeal proceedings, including where applicable a summary of the revised examination opinion;

(o) where applicable, a mention that a certificate has lapsed or was declared invalid;

(p) where applicable, the filing of an application for a declaration of invalidity and, once available, the outcome of the related proceedings;

(q) where applicable, information relating to a request for conversion, and its outcomes;

(r) information on the payment of annual fees.

2. The Register shall contain changes to the information in paragraph 1, including transfers, each accompanied by the date of recording of such entry.

3. The Register and information referred to in paragraphs 1 and 2 shall be available in all official languages of the Union. The Office may use verified machine translation for the information to be published in the Register.

4. The Executive Director of the Office may determine that information other than those referred to in paragraphs 1 and 2 shall be entered in the Register.

5. The Office shall collect, organise, make public and store the information referred to in paragraphs 1 and 2, including any personal data, for the purposes laid down in paragraph 7. The Office shall keep the Register easily accessible for public inspection.

6. The Office shall provide certified or uncertified extracts from the Register on request and on payment of a fee.

7. The processing of the data concerning the entries set out in paragraphs 1 and 2, including any personal data, shall take place for the purposes of the following:

(a) administering the applications and unitary certificates in accordance with this Regulation and the acts adopted pursuant to it;

(b) maintaining the Register and making it available for inspection by public authorities and economic operators;

(c) producing reports and statistics enabling the Office to optimise its operations and improve the functioning of the system.

8. All the data, including personal data, concerning the entries in paragraphs 1 and 2 shall be considered to be of public interest and may be accessed by any third party. For reasons of legal certainty, the entries in the Register shall be kept for an indefinite period of time.

Article 36

Database

1. In addition to the obligation to keep a Register, the Office shall collect and store in an electronic database all the particulars provided by applicants or any other third party observations pursuant to this Regulation or acts adopted pursuant to it.

2. The electronic database may include personal data, beyond those included in the Register, to the extent that such particulars are required by this Regulation or by acts adopted pursuant to it. The collection, storage and processing of such data shall serve the purposes of:

   (a) administering the applications and/or certificate registrations as described in this Regulation and in acts adopted pursuant to it;

   (b) accessing the information necessary for conducting the relevant proceedings more easily and efficiently;

   (c) communicating with the applicants and other third parties;

   (d) producing reports and statistics enabling the Office to optimise its operations and improve the functioning of the system.

3. The Executive Director shall determine the conditions of access to the electronic database and the manner in which its contents, other than the personal data referred to in paragraph 2 of this Article but including those listed in Article 35, may be made available in machine-readable form, including the charge for such access.

4. Access to the personal data referred to in paragraph 2 shall be restricted and such data shall not be made publicly available unless the party concerned has given his express consent.

5. All data shall be kept indefinitely. However, the party concerned may request the removal of any personal data from the database after 18 months from the expiry of the unitary certificate or, the case being, the closure of the relevant *inter partes* procedure. The party concerned shall have the right to obtain the correction of inaccurate or erroneous data at any time.

Article 37

Transparency

1. Regulation (EC) No 1049/2001 of the European Parliament and of the Council[37] shall apply to documents held by the Office.

2. The Management Board of the Office shall adopt detailed rules for applying Regulation (EC) No 1049/2001 in the context of this Regulation.

3. Decisions taken by the Office under Article 8 of Regulation (EC) No 1049/2001 may be challenged through the European Ombudsman or form the subject of an action before the Court of Justice of the European Union, under the conditions laid down in Articles 228 and 263 TFEU respectively.

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[37] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

4. The processing of personal data by the Office shall be subject to Regulation (EC) No 45/2001 of the European Parliament and of the Council[38].

Article 38

Representation

1. Natural or legal persons having neither their domicile nor their principal place of business or a real and effective industrial or commercial establishment in the European Economic Area shall be represented before the Office in accordance with this Article in all proceedings provided for by this Regulation, other than the filing of an application for a unitary certificate.

2. Natural or legal persons having their domicile or principal place of business or a real and effective industrial or commercial establishment in the Union may be represented before the Office by an employee.

   An employee of a legal person may also represent other legal persons which are economically linked with the legal person being represented by that employee.

   The second subparagraph also applies where those other legal persons have neither their domicile nor their principal place of business nor a real and effective industrial or commercial establishment within the Union.

   Employees who represent natural or legal persons shall, at the request of the Office or, where appropriate, of the party to the proceedings, file with the Office a signed authorisation for insertion in the files.

3. A common representative shall be appointed where there is more than one applicant or more than one third party acting jointly.

4. Only a practitioner established in the Union, entitled to act as a professional representative in patent matters before a national patent office or the European Patent Office, or a lawyer authorised to practise before the courts or tribunals of a Member State, may represent natural or legal persons before the Office.

Article 39

Supplementary Protection Certificates Division

A Supplementary Protection Certificate Division ('SPC Division') shall be set up within the Office and, in addition to the responsibilities under Regulations [COM(2023) 231] and [COM(2023) 223], shall be responsible for implementing the tasks set out in this Regulation and in Regulation [COM(2023) 221], including in particular:

(a) receiving and supervising the examination of applications for unitary certificates, applications for an extension of the duration of unitary certificates, appeals and observations by third parties;

(b) adopting examination opinions on behalf of the Office in relation to applications for unitary certificates, as well as in relation to applications for an extension of the duration of unitary certificates;

[38] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

(c) deciding on oppositions against examination opinions;

(d) deciding on applications for a declaration of invalidity;

(e) processing conversion requests;

(f) maintaining the register and the database.

Article 40

Decisions and communications of the Office

1. Decisions of the Office under this Regulation shall include examination opinions and shall state the reasons on which they are based. They shall be based only on reasons or evidence on which the parties concerned have had an opportunity to present their comments. Where oral proceedings are held before the Office, the decision may be given orally. Subsequently, the decision or opinion shall be notified in writing to the parties.

2. Any decision, opinion, communication or notice from the Office under this Regulation shall indicate the SPC Division and the relevant panel as well as the name or the names of the examiners responsible. It shall be signed by these examiners, or, instead of a signature, carry a printed or stamped seal of the Office. The Executive Director may determine that other means of identifying the SPC Division and the name of the examiners responsible, or an identification other than a seal, may be used where decisions or other communications are transmitted by any technical means of communication.

3. Decisions of the Office under this Regulation which are open to appeal shall be accompanied by a written communication indicating that any notice of appeal is to be filed in writing at the Office within 2 months of the date of notification of the decision in question. That communication shall also draw the attention of the parties to the provisions laid down in Article 28. The parties may not plead any failure on the part of the Office to communicate the availability of appeal proceedings.

Article 41

Oral proceedings

1. If the Office considers that oral proceedings would be expedient they shall be held either at the instance of the Office or at the request of any party to the proceedings.

2. Oral proceedings before an examination panel, opposition panel or invalidity panel shall not be public.

3. Oral proceedings before the Boards of Appeal, including delivery of the decision and, as the case may be, of a revised opinion, shall be public, unless the Boards of Appeal decide otherwise in cases where admission of the public could have serious and unjustified disadvantages, in particular for a party to the proceedings.

4. The Commission is empowered to adopt delegated acts in accordance with Article 54 to supplement this Regulation by setting out the detailed arrangements for oral proceedings.

Article 42

Taking of evidence

1. In any proceedings before the Office, the means of giving or obtaining evidence shall include the following:
   (a) hearing the parties;
   (b) requests for information;
   (c) the production of documents and items of evidence;
   (d) hearing witnesses;
   (e) opinions by experts;
   (f) statements in writing sworn or affirmed or having a similar effect under the law of the State in which the statement is drawn up.
2. The relevant panel may commission one of its members to examine the evidence adduced.
3. If the Office or the relevant panel considers it necessary for a party, witness or expert to give evidence orally, it shall issue a summons to the person concerned to appear before it. The period of notice provided in such summons shall be at least 1 month, unless they agree to a shorter period.
4. The parties shall be informed of the hearing of a witness or expert before the Office. They shall have the right to be present and to put questions to the witness or expert.
5. The Executive Director shall determine the amounts of expenses to be paid, including advances, as regards the costs of taking of evidence as referred to in this Article.
6. The Commission is empowered to adopt delegated acts in accordance with Article 54 to supplement this Regulation by setting out the detailed arrangements for the taking of evidence.

Article 43

Notification

1. The Office shall, as a matter of course, notify those concerned of decisions, including opinions, summonses and of any notice or other communication from which a time limit is reckoned, or of which those concerned are to be notified under other provisions of this Regulation or of acts adopted pursuant to this Regulation, or of which notification has been ordered by the Executive Director.
2. Notification may be effected by different means, including electronic means. The details regarding electronic means shall be determined by the Executive Director.
3. Where notification is to be effected by public notice, the Executive Director shall determine how the public notice is to be given and shall fix the beginning of the 1-month period on the expiry of which the document shall be deemed to have been notified.
4. The Commission is empowered to adopt delegated acts in accordance with Article 54 to supplement this Regulation by setting out the detailed arrangements for notification.

Article 44

Time limits

1. Time limits shall be laid down in terms of full years, months, weeks or days. Calculation shall start on the day following the day on which the relevant event occurred. The duration of time limits shall be no less than 1 month and no more than 6 months.

2. The Executive Director shall determine, before the commencement of each calendar year, the days on which the Office is not open for receipt of documents or on which ordinary post is not delivered in the locality in which the Office is located.

3. The Executive Director shall determine the duration of the period of interruption in the case of a general interruption in the delivery of post in the Member State where the Office is located or, in the case of an actual interruption of the Office's connection to admitted electronic means of communication.

4. If an exceptional occurrence, such as a natural disaster or strike, interrupts or interferes with proper communication from the parties to the proceedings to the Office or vice-versa, the Executive Director may determine that for parties to the proceedings having their residence or registered office in the Member State concerned or who have appointed a representative with a place of business in the Member State concerned all time limits that otherwise would expire on or after the date of commencement of such occurrence, as determined by the Executive Director, shall extend until a date to be determined by the Executive Director. When determining that date, the Executive Director shall assess when the exceptional occurrence comes to an end. If the occurrence affects the seat of the Office, such determination of the Executive Director shall specify that it applies in respect of all parties to the proceedings.

5. The Commission is empowered to adopt delegated acts in accordance with Article 54 to supplement this Regulation by specifying the details regarding the calculation and duration of time limits.

Article 45

Correction of errors and manifest oversights

1. The Office shall correct any linguistic errors or errors of transcription and manifest oversights in its decisions, including opinions, or technical errors in publishing information in the Register, of its own motion or at the request of a party.

2. Where the Office has made an entry in the Register or taken a decision which contains an obvious error attributable to the Office, it shall ensure that the entry is cancelled or the decision is revoked. The cancellation of the entry in the Register or the revocation of the decision shall be effected within 1 year of the date on which the entry was made in the Register or that decision was taken, after consultation with the parties to the proceedings.

3. The Office shall keep records of any such corrections or cancellations.

4. Corrections and cancellations shall be published by the Office.

Article 46

Restitutio in integrum

1. The applicant for or holder of a unitary certificate, or any other party to proceedings before the Office under this Regulation, who, in spite of all due care required by the circumstances having been taken, was unable to comply with a time limit vis-à-vis the Office shall, upon application, have his rights re-established if the obstacle to compliance has the direct consequence, by virtue of the provisions of this Regulation, of causing the loss of any right or means of redress.

2. The application for re-establishment shall be filed in writing within 2 months of the removal of the obstacle to compliance with the time limit. The omitted act shall be completed within this period. The application shall only be admissible within the year immediately following the expiry of the unobserved time limit.

3. The application for re-establishment shall state the grounds on which it is based and shall set out the facts on which it relies. It shall not be deemed to be filed until the fee for re-establishment of rights has been paid.

4. The SPC Division, or where applicable the Boards of Appeal, shall decide upon the application.

5. This Article shall not be applicable to the time limits referred to in paragraph 2 of this Article, or in Article 15(1) and (3).

Article 47

Interruption of proceedings

1. Proceedings before the Office under this Regulation shall be interrupted:

   (a) in the event of the death or legal incapacity of the applicant or of the person authorised by national law to act on behalf of the applicant. To the extent that that death or incapacity does not affect the authorisation of a representative appointed under Article 39, proceedings shall be interrupted only on application by such representative;

   (b) in the event of the applicant being prevented, for legal reasons resulting from action taken against his property, from continuing the proceedings before the Office;

   (c) in the event of the death or legal incapacity of the representative of the applicant, or of that representative being prevented, for legal reasons resulting from action taken against his property, from continuing the proceedings before the Office.

2. Proceedings before the Office shall be resumed as soon as the identity of the person authorised to continue them has been established.

3. The Commission is empowered to adopt delegated acts in accordance with Article 54 to supplement this Regulation by setting out the detailed arrangements for the resumption of proceedings before the Office.

Article 48

Costs

1. The losing party in opposition proceedings and proceedings for a declaration of invalidity, including in related appeal proceedings, shall bear the fees paid by the other party. The losing party shall also bear all costs incurred by the other party that are essential to the proceedings, including travel and subsistence and the remuneration of a representative, within the maximum rates set for each category of costs in the implementing act to be adopted in accordance with paragraph 7. The fees to be borne by the losing party shall be limited to the fees paid by the other party in those proceedings.

2. Where each party succeeds on some and fails on other heads, or if reasons of equity so dictate, the SPC Division or Board of Appeal shall decide a different apportionment of costs.

3. Where proceedings are terminated the costs shall be at the discretion of the SPC Division or Board of Appeal.

4. Where the parties conclude before the SPC Division or Board of Appeal a settlement of costs differing from that provided for in paragraphs 1 to 3, the body concerned shall take note of that agreement.

5. The SPC Division or Board of Appeal shall fix the amount of the costs to be paid pursuant to paragraphs 1 to 3 of this Article when the costs to be paid are limited to the fees paid to the Office and the representation costs. In all other cases, the registry of the Board of Appeal or SPC Division shall fix, on request, the amount of the costs to be reimbursed. The request shall be admissible only for the period of 2 months following the date on which the decision for which an application was made for the costs to be fixed becomes final and shall be accompanied by a bill and supporting evidence. For the costs of representation an assurance by the representative that the costs that have been incurred shall be sufficient. For other costs, it shall be sufficient if their plausibility is established. Where the amount of the costs is fixed pursuant to the first sentence of this paragraph, representation costs shall be awarded at the level laid down in the implementing act adopted pursuant to paragraph 7 of this Article and irrespective of whether they have been actually incurred.

6. Decisions on the fixing of costs adopted in accordance with paragraph 5 shall state the reasons on which they are based, and may be reviewed by a decision of the SPC Division or Board of Appeal on a request filed within 1 month of the date of notification of the awarding of costs. It shall not be deemed to be filed until the fee for reviewing the amount of the costs has been paid. The SPC Division or the Board of Appeal, as the case may be, shall take a decision on the request for a review of the decision on the fixing of costs without oral proceedings.

7. The Commission shall adopt implementing acts specifying the maximum rates for costs essential to the proceedings and actually incurred by the successful party. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55.

8. When specifying the maximum rates with respect to travel and subsistence costs, the Commission shall take into account the distance between the place of residence or business of the party, representative or witness or expert and the place where the oral proceedings are held, the procedural stage at which the costs have been incurred, and, as far as costs of representation are concerned, the need to ensure that the

obligation to bear the costs may not be misused for tactical reasons by the other party. In addition, subsistence expenses shall be calculated in accordance with the Staff Regulations of Officials of the Union and the Conditions of Employment of Other Servants of the Union, laid down in Council Regulation (EEC, Euratom, ECSC) No 259/68[39]. The losing party shall bear the costs for one party in the proceedings only and, where applicable, one representative only.

Article 49

Enforcement of decisions fixing the amount of costs

1. Any final decision of the Office fixing the amount of costs shall be enforceable.
2. Enforcement shall be governed by the rules of civil procedure in force in the Member State in the territory of which it is carried out. Each Member State shall designate a single authority responsible for verifying the authenticity of the decision referred to in paragraph 1 and shall communicate its contact details to the Office, the Court of Justice and the Commission. The order for enforcement shall be appended to the decision by that authority, with the verification of the authenticity of the decision as the sole formality
3. When these formalities have been completed on application by the party concerned, the latter may proceed to enforcement in accordance with the national law, by bringing the matter directly before the competent authority.
4. Enforcement may be suspended only by a decision of the Court of Justice. However, the courts of the Member State concerned shall have jurisdiction over complaints that enforcement is being carried out in an irregular manner.

Article 50

Amendment to Regulation (EU) 2017/1001

Regulation (EU) 2017/1001 is amended as follows:

(1) Article 151(1) is amended as follows:

(a) point (c) is replaced by the following:

‘(c) promoting convergence of practices and tools in the fields of trade marks and designs as well as supplementary protection certificates, in cooperation with the central industrial property offices in the Member States, including the Benelux Office for Intellectual Property’;

(b) the following points (f) and (g) are added:

'(f) the tasks referred to in Chapter III of Regulation [COM(2023) 231] and in Chapter III of Regulation [COM(2023) 223] as well as in Regulations [COM(2023) 222] and [COM(2023) 221];

(g) on the basis of requests for participation in the centralised examination procedure, and after giving the Commission an opportunity to comment on

[39] Regulation (EEC, Euratom, ECSC) No 259/68 of the Council of 29 February 1968 laying down the Staff Regulations of Officials and the Conditions of Employment of Other Servants of the European Commission and instituting special measures temporarily applicable to officials of the Commission (OJ L 56, 4.3.1968, p. 1.)’

them, appointing, by concluding an agreement, those competent national authorities whose examiners will be able to participate in the centralised examination of centralised applications for certificates under Regulations [COM(2023) 231] and [COM(2023) 223], including opposition proceedings, and of applications for unitary certificates under Regulation [COM(2023) 222] and Regulation [COM(2023) 221], including opposition and invalidity proceedings';

(2) in Article 152(1), the first subparagraph is replaced by the following:

'The Office and the central industrial property offices of the Member States and the Benelux Office for Intellectual Property shall cooperate with each other to promote convergence of practices and tools in the field of trade marks, designs, and supplementary protection certificates.'.

Article 51

Amendment to Regulation (EU) No 608/2013

Article 2(1) of Regulation (EU) No 608/2013 is amended as follows:

(1) points (f) and (g) are replaced by the following:

'(f) a supplementary protection certificate for medicinal products as provided for in Regulation [COM(2023) 231] of the European Parliament and of the Council of ddddd concerning the supplementary protection certificate for medicinal products[40] *[OP, please insert the No and date of COM(2023) 231 once adopted, as well as its O.J. reference in the footnote]*;

(g) a supplementary protection certificate for plant protection products as provided for in Regulation [COM(2023) 223] of the European Parliament and of the Council of ddddd concerning the creation of a supplementary protection certificate for plant protection products[41] *[OP, please insert the No and date of COM(2023) 223 once adopted, as well as its O.J. reference in the footnote]*;';

(2) the following points (m) and (n) are inserted:

'(m) a unitary supplementary protection certificate for medicinal products as provided for in Regulation [COM(2023) 222] of the European Parliament and of the Council of ddddd on the unitary supplementary protection certificate for medicinal products and amending Regulation (EU) 2017/1001, Regulation (EC) No 1901/2006 as well as Regulation (EU) No 608/2013[42] *[OP, please insert the No and date of COM(2023) 222 once adopted, as well as its O.J. reference in the footnote];*

(n) a unitary supplementary protection certificate for plant protection products as provided for in Regulation [COM(2023) 221] of the European Parliament and of the Council of dddddd on the unitary supplementary protection certificate for plant protection products[43] *[OP, please insert the No and date of COM(2023) 221 once adopted, as well as its O.J. reference in the footnote]*.'.

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40 O.J. reference to be inserted
41 O.J. reference to be inserted
42 O.J. reference to be inserted
43 O.J. reference to be inserted

Article 52

Amendment to Regulation (EC) No 1901/2006

Regulation (EC) No 1901/2006 is amended as follows:

(1) in Article 2, point (4) is replaced by the following:

> '(4) 'paediatric use marketing authorisation' means a marketing authorisation granted in respect of a medicinal product for human use which is not protected by a supplementary protection certificate or unitary supplementary protection certificate under Regulation [COM(2023) 231] or Regulation [COM(2023) 222], or by a patent which qualifies for the grant of the supplementary protection certificate, covering exclusively therapeutic indications which are relevant for use in the paediatric population, or subsets thereof, including the appropriate strength, pharmaceutical form or route of administration for that product;';

(2) in Article 8, the first paragraph is replaced by the following:

> 'In the case of authorised medicinal products which are protected either by a supplementary protection certificate or unitary supplementary protection certificate under Regulation [COM(2023) 231] or Regulation [COM(2023) 222], or by a patent which qualifies for the grant of the supplementary protection certificate, Article 7 of this Regulation shall apply to applications for authorisation of new indications, including paediatric indications, new pharmaceutical forms and new routes of administration.';

(3) Article 36 is amended as follows:

(a) in paragraph 1, the first subparagraph is replaced by the following:

> 'Where an application under Article 7 or 8 includes the results of all studies conducted in compliance with an agreed paediatric investigation plan, the holder of the patent or supplementary protection certificate or unitary supplementary protection certificate shall be entitled to a six-month extension of the periods referred to in Articles 13(1) and 13(2) of Regulation [COM(2023) 231] or Article 20(1) and 20(2) of Regulation [COM(2023) 222].';

(b) in paragraph 4, the first sentence is replaced by the following:

> 'Paragraphs 1, 2 and 3 shall apply to products that are protected by a supplementary protection certificate or unitary supplementary protection certificate under Regulation [COM(2023) 231] or Regulation [COM(2023) 222], or under a patent which qualifies for the grant of the supplementary protection certificate.'.

Article 53

Financial provisions

1. The expenses incurred by the Office in carrying out the additional tasks given to it in accordance with this Regulation shall be covered by the procedural fees to be paid to it by applicants and by a fraction of the annual fees paid by the holders of unitary certificates, while the remainder of the annual fees shall be shared with the Member States in accordance with the number of unitary certificates having legal effect in each of them. The fraction of the annual fees to be shared with Member States shall

initially be set at a certain value but shall be reviewed every 5 years, in such a manner as to achieve financial sustainability for the activities carried out by the Office under this Regulation as well as under Regulations [COM(2023) 231], [COM(2023) 223] and [COM(2023) 221].

2. For the purposes of paragraph 1, the Office shall keep an account of the annual fees paid to it by holders of unitary certificates in force in the respective Member States.

3. The expenses incurred by a competent national authority participating in proceedings under this Chapter shall be covered by the Office and shall be paid annually, on the basis of the number of proceedings in which that competent national authority was involved during the preceding year.

4. The Commission is empowered to adopt implementing acts laying down rules on the financial transfers between the Office and Member States, the amounts of those transfers, and the remuneration to be paid by the Office regarding the participation of competent national authorities referred to in paragraph 3. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55.

5. Article 12 of Regulation (EU) No 1257/2012 shall apply to the annual fees due in respect of unitary certificates.

Article 54

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Articles 15(13), 23(13), 28(8), 30, 34(2), 41(4), 42(6), 43(4), 44(5) and 47(3) shall be conferred on the Commission for an indeterminate period of time from XXX *[OP please insert the date = date of entry into force]*.

3. The delegation of power referred to in Articles 15(13), 23(13), 28(8), 30, 34(2), 41(4), 42(6), 43(4), 44(5) and 47(3) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect on the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 15(13), 23(13), 28(8), 30, 34(2), 41(4), 42(6), 43(4), 44(5) or 47(3) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both

informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 55

Committee procedure

1. The Commission shall be assisted by a Committee on Supplementary Protection Certificates established by Regulation [COM(2023) 231]. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Article 56

Evaluation

By xxxxxx *[OP, please insert: five years after the date of application]*, and every five years thereafter, the Commission shall evaluate the implementation of this Regulation.

Article 57

Entry into force and application

This Regulation shall enter into force on XXX [*OP – please insert the date - the 20th day following its publication in the Official Journal of the European Union]*.

It shall apply from xxxxx *[OP please insert first day of the 12th month after the date of entry into force]*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

Council of the European Union

Brussels, 28 April 2023
(OR. en)

8887/23

Interinstitutional File: 2023/0128(COD)

PI 55
PHARM 67
COMPET 383
MI 351
IND 204
IA 88
CODEC 746

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	27 April 2023
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2023) 223 final
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the supplementary protection certificate for plant protection products (recast)

Delegations will find attached document COM(2023) 223 final.

Encl.: COM(2023) 223 final

EUROPEAN
COMMISSION

Brussels, 27.4.2023
COM(2023) 223 final

2023/0128 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the supplementary protection certificate for plant protection products (recast)

(Text with EEA relevance)

{SWD(2023) 117-119} - {SEC(2023) 172}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

Supplementary protection certificates (SPCs) are *sui generis* intellectual property (IP) rights that extend the 20-year term of patents for medicinal or plant protection products (PPPs) by up to 5 years[1]. They aim to offset the loss of effective patent protection due to the compulsory and lengthy testing required in the EU for the regulatory marketing authorisation of these products.

The unitary patent will enter into force on 1 June 2023, allowing for a single patent that covers all participating Member States in a unitary manner[2].

This proposal aims to simplify the EU's SPC system as regards national SPCs for plant protection products, as well as improve its transparency and efficiency. This initiative was announced in the Commission work programme for 2022 as initiative number 16 under Annex II (REFIT initiatives)[3].

Regulation (EC) No 1610/96 provides for SPCs for plant protection products, to be granted at a national level on the basis of national applications, on a country-by-country basis. Similarly, Regulation (EC) No 469/2009 provides for SPCs for medicinal products. Together these two measures constitute the EUs SPC regime. As amendments are to be made to Regulation (EC) No 1610/96, that Regulation should be recast, which is the **first objective of this proposal,** and of a similar parallel proposal regarding medicinal products (COM(2023) 231).

As confirmed by the evaluation carried out in 2020 (SWD(2020)292 final), today's purely national procedures for granting SPCs involve separate examination proceedings (in parallel or subsequent) in Member States. This entails duplication of work, resulting in high costs and more often discrepancies between Member States in decisions to grant or refuse SPCs including in litigation before national courts. Inconsistency between Member States in decisions to grant or refuse SPCs is the single reason most often cited by national courts for preliminary references to the Court of Justice of the European Union on the application of the EU's SPC regime. The current purely national procedures, therefore, lead to significant legal uncertainty.

The Commission's intellectual property action plan of November 2020 (COM(2020) 760 final), which builds on the SPC evaluation, highlighted the need to tackle the remaining fragmentation of the EU's intellectual property system. The plan noted that, for medicinal products and PPPs, SPC protection is only available at national level. At the same time, there is a centralised procedure for granting European patents, as well as a single set of rules for obtaining marketing authorisations for plant protection products.

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1 An additional 6-month period of protection is available, subject to specific conditions, for medicinal products for use in the paediatric population, as defined by Regulation (EC) No 1901/2006.

2 The unitary patent (UP) is a legal title that will provide uniform protection across all participating countries on a one-stop-shop basis. As of April 2023, 17 Member States are expected to participate in the UP system. For updates and more information, see: https://ec.europa.eu/growth/industry/strategy/intellectual-property/patent-protection-eu/unitary-patent_en.

3 European Commission, Annexes to Commission communication – Commission work programme 2022, COM(2021) 645 final, 2021, p. 9 (https://eur-lex.europa.eu/resource.html?uri=cellar%3A9fb5131e-30e9-11ec-bd8e-01aa75ed71a1.0001.02/DOC_2&format=PDF#page=9).

In addition, many of the arguments made in the pharmaceutical strategy for Europe (COM(2020) 761 final) as regards SPCs for medicinal products are also applicable to SPCs for PPPs. That Strategy emphasised the importance of investing in R&D to create innovative medicines. The strategy stressed, however, that the differences between Member States in the implementation of intellectual property regimes, especially for SPCs, lead to duplications and inefficiencies that affect the competitiveness of the pharmaceutical industry. Both the Council[4] and the European Parliament[5] have called on the Commission to correct these deficiencies.

Therefore, a **second objective of this proposal** is to introduce a centralised procedure for granting SPCs for PPPs. This would allow applicants to obtain SPCs in the respective designated Member States (subject to marketing authorisations having been granted in/for each of them), by filing a single 'centralised SPC application' that would undergo a single centralised examination procedure.

While that examination would be conducted by a centralised authority, the actual granting of SPCs would be done by the respective national offices of the designated Member States, based on a positive opinion from the central examination authority. The opinion of the central examination authority would be binding upon the national offices of the designated Member States.

- **Consistency with existing policy provisions in the policy area**

The core substantive features of the proposed centralised procedure – i.e. the conditions for obtaining certificates, as well as their legal effect – are the same as those of the existing SPC regime. This proposal introduces new procedural provisions as regards the centralised examination and is not intended to modify the scope nor the effect of the rights conferred by national SPCs currently granted according to Regulation (EC) No 1610/96. The same new procedural provisions are also inserted in the above-mentioned parallel proposal on SPCs for medicinal products (COM(2023) 231).

At the same time, parallel proposals are being made to create unitary certificates for medicinal products (cf. (COM(2023) 222) and for PPPs (COM(2023) 221). Applications for these unitary certificates would undergo the same centralised examination procedure described in this proposal, especially in the event of 'combined' applications that request both a unitary certificate and national certificates, as explained below. This ensures complete consistency across the whole SPC reform package.

[4] Council conclusions on intellectual property policy of 10 November 2020: https://www.consilium.europa.eu/media/46671/st-12750-2020-init.pdf.

[5] European Parliament, Committee on Legal Affairs, Report on an intellectual property action plan to support the EU's recovery and resilience (2021/2007(INI)): https://www.europarl.europa.eu/doceo/document/A-9-2021-0284_EN.html.

This table explains the purposes of the four related proposals:

Medicinal products		**Plant protection products**
PROPOSAL 1 Regulation on the SPC for medicinal products (recast)	← Art. 114 TFEU →	**PROPOSAL 2** Regulation on the SPC for plant protection products (recast)
PROPOSAL 3 Regulation on the unitary SPC for medicinal products	← Art. 118 TFEU →	**PROPOSAL 4** Regulation on the unitary SPC for plant protection products

Moreover it should be noted that nothing will prevent national SPCs – as defined in Regulation (EC) No 1610/96 and in Chapter II of this proposal – from being granted on the basis of a unitary patent as the basic patent.

Finally, this proposal is part of the 'EU patent package' announced in 2023 which, besides the revision, modernisation and introduction of a system for unitary supplementary protection certificates, includes a new initiative on compulsory licensing and legislation on standard-essential patents. The proposal also complements the unitary patent system, which is a major step towards the completion of the single market for patents.

- **Consistency with other Union policies**

The proposed centralised procedure is fully consistent with the existing legislation relating to agrochemical products and with other relevant legislation. This includes the *European patent with unitary effect* ('unitary patent') as set out in Regulation (EU) No 1257/2012, and the related Agreement on a Unified Patent Court (UPCA). The unitary patent system will enter into force on 1 June 2023.

Finally, the SPC reform and the other initiatives listed in the intellectual property action plan contribute to the broader innovation strategy of the EU.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- **Legal basis**

This proposal is based on Article 114(1) of the Treaty on the Functioning of the European Union on the single (or 'internal') market. This is the same legal basis used for Regulations (EC) No 469/2009 and (EC) No 1610/96 (Articles 100a, and then 95, respectively, of the Treaty establishing the European Community, as it then was), and it is once again necessary to have recourse to Article 114 in order to adapt the EU SPC regime in the light of how the existing system has been applied. Despite the fact that SPCs are already harmonised – and indeed defined – by EU law, there are still cases where some Member States have granted SPCs while identical applications have been refused in others, or been granted with a different scope. SPC applicants thus face diverging decisions across the EU on the same product, while incurring costs for applying and maintaining SPCs in several Member States. Consequently, further EU action is needed to address these issues and can, unlike national intervention by Member States, ensure a consistent EU-wide framework, and reduce the total costs and burden of fees to be paid in multiple Member States. Further EU-level action would strengthen the integrity of the single market by providing a centralised, balanced and

transparent SPC system across the EU, and mitigate the negative consequences of redundant and potentially diverging procedures that applicants face[6]. Hence, by its nature, action at EU level is also justified to ensure the smooth functioning of the single market for innovative plant protection products that are subject to marketing authorisations. EU-level action would also allow innovative and follow-on manufacturers to reap the benefits of an efficient intellectual property framework in the relevant product markets.

- **Subsidiarity**

The objectives underlying the proposal can only be achieved at Union level. The Union-wide approach implemented by the centralised procedure envisaged in this proposal will ensure that the applicable rules and procedures are consistent across the Union, ensuring legal certainty for all relevant market participants.

- **Proportionality**

This initiative does not go beyond what is necessary to achieve the identified objectives. Its scope is limited to those aspects that Member States cannot achieve satisfactorily on their own and where EU action can produce better results, e.g. in terms of consistent decisions on SPC applications to reduce administrative burdens and costs, and improve transparency and legal certainty.

- **Choice of the instrument**

As the current SPC legislation is only governed by Regulations, no other instrument can be envisioned for recasting the existing EU SPC legislation (Regulation (EC) No 1610/96) and introducing a centralised procedure.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Ex-post evaluations and fitness checks of existing legislation**

An evaluation of the SPC regime was carried out in 2020 (SWD(2020) 292). It found that SPCs promote innovation and the availability of new medicines and PPPs because they help companies recoup their R&D investments. Although the SPC Regulations provide a common framework within the EU, they are administered at national level. This fragmentation leads to high costs and imposes an administrative burden on applicants (especially SMEs) and national administrations. It also leads to legal uncertainty, as the scope of protection can differ across the EU. This has a negative impact on SPC users and makers of follow-on products. These negative effects are amplified by a lack of transparency, especially from a cross-border perspective, making it difficult to trace what SPC protection exists for which products in which Member States. This affects both SPC holders and manufacturers of follow-on products.

- **Stakeholder consultations**

The Commission conducted a public consultation during the evaluation of the SPC regime (between 12 October 2017 and 4 January 2018)[7]. In addition, the Max Planck Institute study mentioned below included a survey of stakeholders in the Member States, conducted in 2017 by the Allensbach Institute ('the Allensbach survey'), which included several questions on the operation of the current (national) SPC regimes. Moreover, from 8 March to 5 April 2022

6 Case C-58/08 ECLI:EU:C:2010:321.

7 https://ec.europa.eu/docsroom/documents/29464

interested parties could provide feedback to Commission's Call for Evidence. For further information, see Annex 2 of the impact assessment (SWD(2023) 118).

- **Collection and use of expertise**

The study carried out in 2018 by the Max Planck Institute on the legal aspects of SPCs in the EU[8] (especially Chapter 22) provides key findings on the operation of the current SPC regime (for medicinal products). The additional Max Planck Institute study completed in 2022[9] provides a deeper analysis of the design of a centralised procedure.

- **Impact assessment**

An impact assessment was carried out and submitted to the Regulatory Scrutiny Board in late 2022 and, after resubmission, received a positive opinion on 16 December 2022 (SWD(2023) 118).

The following options were identified:

– Option 0: No policy change.

– Option 1: Guidelines for the application of the current SPC regimes. This option would provide common guidelines/recommendations to national patent offices (NPOs) on the application of the SPC Regulation, building on their experience and the case law of the Court of Justice of the European Union (CJEU). These guidelines would also recommend common rules for the publication and accessibility of SPC information in national registers.

– Option 2: Mutual recognition of national decisions. This would enable applicants to file an SPC application with a designated NPO, known as the reference office, whose decision would be recognised by all other NPOs.

– Option 3: Centralised filing and examination of SPC applications, resulting in a non-binding opinion. This would create a central authority for filing SPC applications in the EU, which would examine applications and issue an opinion on whether or not to grant an SPC. NPOs could follow this opinion or, alternatively, conduct their own examination. Therefore, the decision on granting SPC protection would be kept at the national level. Only holders of a European patent – and, for medicinal products, of a centralised marketing authorisation – could use this system.

– Option 4: Centralised filing and examination of SPC applications, resulting in a binding opinion. This is identical to option 3, 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 a central authority.

– Option 5: A 'unitary SPC' complementing the unitary patent. The central authority, in addition to examining applications, would grant a 'unitary SPC' to applicants with a European patent with unitary effect. The unitary SPC would be valid only in the territory of the (initially 17) Member States party to the UPCA.

These options would not replace national SPCs, but would provide alternative routes to obtaining SPC protection across the EU.

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8 https://ec.europa.eu/docsroom/documents/29524

9 https://op.europa.eu/en/publication-detail/-/publication/94cb20ea-2ff0-11ed-975d-01aa75ed71a1/language-en

A combination of options 4 and 5 constitutes the preferred choice. It would provide for a centralised procedure that could result in the grant of national SPCs in some or all Member States, and/or of a unitary SPC (covering those Member States in which the basic unitary patent has effect). When deciding on who should act as the examination authority, several criteria were considered: accountability (in particular, to the European Parliament), alignment with the EU's overarching political values and current policy priorities, and experience with substantive SPC assessment. It is therefore proposed that the EU Intellectual Property Office (EUIPO) should become the central examination authority, supported by national offices.

Option 1, on guidelines for examining national SPC applications, would not be sufficient alone to overcome discrepancies between national practices, as the guidance would be non-binding. Nevertheless, in the context of the preferred options 4 and 5, EUIPO should develop guidelines that reflect its practice. These guidelines would be of practical use both to officials in charge of the SPC-related procedures and to their users, including professional advisers who assist applicants (e.g. by offering examples). This guidance would take stock of the practices developed by the examination panels, especially since they will include examiners from several different Member States, to improve consistency between examination practices under the new centralised procedure. Moreover, national offices may also benefit from guidelines developed by the examination authority for their own (national) examination procedures.

Option 2 may not provide enough predictability, as some reference offices could be more lenient than others, thus leading to 'forum shopping', while Option 3 alone would allow offices to re-examine the SPC application, and has thus the potential to result in divergences on the decision to grant or refuse an SPC, leading to further fragmentation in the single market.

- **Regulatory fitness and simplification**

Enabling holders of European patents to obtain several (national) SPCs across the EU through a centralised procedure would represent a considerable simplification compared to the current situation in which national SPCs need to be applied for and granted separately in each Member State. The proposed new centralised procedure is expected to result in significant reductions in costs and administrative burden for applicants, and in improved legal certainty and transparency, including for third parties (e.g. makers of follow-on products).

Moreover, since this proposal will recast and repeal Regulations (EC) No 1610/96, it will achieve a 'one in, one out' outcome.

- **Fundamental rights**

This proposal will have no impact on fundamental rights, especially since it is not proposed to alter the substantive features of the existing SPC regimes (e.g. conditions for grant, scope, effects). The initiative is consistent with the Charter of Fundamental Rights as it offers greater legal certainty to applicants for an intellectual property right, and where necessary for third parties, by providing for the procedural conditions for the examination, opposition and appeal before the centralised authority.

In particular, where a centralised examination opinion is negative, the applicant may file an appeal before the Boards of Appeal of the EUIPO.

In addition, a national office may decide to not grant an SPC, despite a positive examination opinion, in certain narrowly defined situations, namely where material circumstances, in that Member State have changed since the filing of the centralised application (such as the basic patent being no longer in force). Moreover, examiners from national offices will play a key

role in the centralised examination procedure and participate in the substantive examination of the application, as well as may take part in opposition proceedings.

On the other hand, third parties will be able to submit observations during the examination of a centralised application, and to initiate an opposition against an examination opinion. Where national SPCs are granted by national offices on the basis of a positive opinion, third parties will also be able to challenge their validity before the respective national courts or other competent bodies, as already possible today pursuant to Regulation (EU) No 1610/96.

As further explained below under 'Unitary SPC', this proposal does not exclude centralised SPC applications designating one or more Member States participating in the unitary patent system, potentially resulting in national SPCs being granted in these Member States, as long as double protection is excluded, even where the conditions are met for the grant of a unitary SPC.

4. BUDGETARY IMPLICATIONS

This proposal will have no impact on the EU budget, since the system will remain fully self-funded by applicants' fees, as is already the case for the existing SPCs regimes governed by Regulations (EC) No 469/2009 and (EC) No 1610/96, and will be implemented by the examination authority, the EUIPO. The necessary set-up costs of the tasks conferred to the EUIPO, including the costs of new digital systems, will be financed from the EUIPO's accumulated budgetary surplus. A breakdown of the budgetary impact on the examination authority is provided in Annex 5D of the impact assessment.

The financial impacts on Member States (national offices) will also remain low. Indeed, while the number of SPCs applied for each year is likely to increase, it is quite low for the time being, even in large Member States. For instance, in 2017, 70 SPC applications were filed in Germany and 72 in France. The largest number of applications (95) were filed in Ireland. The average cost varies by country. Based on current average coverage (20 Member States) and duration (3.5 years), SPC protection for a given product would cost around EUR 98 500 on average. In order to cover all 27 Member States for 5 years one would pay nearly EUR 192 000 in total (not including any fees charged by patent lawyers). For a breakdown of the costs, see Annex 5B of the impact assessment (SWD(2023) 118).

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

It is envisaged that an evaluation will be carried out every 5 years.

- **Detailed explanation of the specific provisions of the proposal**

Overall structure of the proposal

Chapter I of the proposal includes definitions and other general provisions.

Chapter II of the proposal includes most of the existing provisions of Regulation (EC) No 1610/96 regarding national applications for certificates, filed at national offices[10], without changing their substance, except for minor technical adaptations that bring the recast regulation up to current drafting standards.

[10] More precisely, filed with the competent industrial property office of the Member State concerned, unless another authority was designated for that purpose.

Chapter III includes new provisions defining the new centralised procedure. That Section is further described below.

Chapter IV contains final provisions, including the repeal of Regulation (EC) No 1610/96.

Coherence with the parallel proposal relating to medicinal products

This proposal is extremely similar to the one presented in parallel regarding SPCs for medicinal products (COM(2023) 231), with a limited number of changes directly linked to the intrinsic differences between medicinal products and plant protection products, regarding in particular marketing authorisations (as there are no centralised marketing authorisations for plant protection products). Moreover the 'SPC manufacturing waiver' introduced into Regulation (EC) No 469/2009 by Regulation (EU) 2019/933 only applies to SPCs for medicinal products and therefore does not need to be reflected in this new (recast) version of Regulation (EC) No 1610/96.

Basic patent

The existing SPC Regulations do not impose any limitation on the types of ('basic') patents on which a national SPC application must rely, which may thus be: (1) a national patent resulting from either a national patent application or from a European patent application; or (2) a unitary patent (a 'European patent with unitary effect'). To remove any residual legal uncertainty, the option to rely on this second type of patent will be clarified through minor amendments, in the recitals of this proposal, that explicitly refer to unitary patents. In this respect it should be noted that paragraph 28 of the explanatory memorandum of the proposal for a European Parliament and Council Regulation (EC) concerning the creation of a supplementary protection certificate for plant protection products (COM(94)579) envisaged that '*when use is made of the European procedure to obtain a Community patent, it will be all the more necessary for the certificate to apply equally to plant protection products protected by a Community patent'* (now referred to as a 'European patent with unitary effect' (or, more informally, a 'unitary patent').

It is proposed that applications for SPCs filed under the new centralised procedure (Chapter III of this proposal) must be based on European patents only as 'basic patents', including a European patent with unitary effect. This will facilitate the examination of centralised SPC applications because the filing and examination of a European patent application, if positive, results in the grant of a European patent having, with a few exceptions, identical claims for all designated countries, which is required for unitary patents.

Moreover, today most inventions patented in the EU are protected by European patents, which are granted only as the result of a thorough examination procedure, and not by national patents, which in several Member States are not subject to an in-depth substantive examination.

Therefore, under the proposed centralised procedure, allowing centralised SPC applications to be based on national patents would be more demanding as regards the examination of such applications, as it would be necessary to examine separately, for each of the designated Member States, whether the product concerned is indeed protected by each of the respective national patents in force, which will not necessarily have the same claims. This may also affect legal certainty.

A requirement that the claims of the basic (European) patent must be identical for all Member States designated in a centralised SPC application would make it easier to examine the application. However, the cases where a European patent includes two or more sets of claims for different Member States are quite rare, and it is very exceptional that there are more than two sets of claims. For this reason, this proposal does not include a requirement that the

claims of the basic patent must be identical for all Member States designated in a centralised SPC application.

Examination/granting authority

Under the proposed centralised procedure, a central examination authority will carry out a substantive examination of a centralised SPC application, especially as regards the conditions for grant defined in Article 3 of the existing SPC Regulations. The Commission proposes that the EUIPO should be the central examination authority, in particular because it is an EU agency and therefore part of the EU legal order.

After assessing the formal admissibility of the centralised SPC application, the central examination authority would entrust the substantive examination of the application to a panel. This panel would be made up of a member of that central authority and two qualified examiners, experienced in SPC matters, from two different national patent offices in Member States. Before designating examiners qualified to examine SPC issues, these national patent offices will have agreed, through an ad hoc agreement with the central examination authority, to participate in this centralised examination system. Competencies and skills in SPC matters are scarce and qualified SPC examiners can be found today in national patent offices. Moreover, the relatively low number of products for which SPC applications are made each year (less than 100) justifies making recourse to existing qualified examiners in Member States, as opposed to creating an entirely new body of experts. During the examination, third parties may submit their observations on the validity of a certain centralised SPC application after its publication.

Examination procedure and remedies

After examining the centralised SPC application, the central examination authority will issue an examination opinion stating, for each of the designated Member States, whether a national SPC fulfilling the applicable criteria (and in the first place those defined in Article 3) should be granted or refused. The applicant can file an appeal against a negative or partly negative opinion (as further explained below).

In order to account for the need to have a complete system of remedies and avoid the need for third parties challenging a positive examination opinion in national courts which would then in turn have to make reference to the EU Courts, third parties will be able to challenge a positive (or partly positive) opinion by initiating an opposition procedure during 2 months after the publication of the examination opinion. Such an opposition may result in the examination opinion being amended.

Challenges against the examination opinion can be appealed to the Boards of Appeal, and subsequently to the General Court and, possibly, ultimately before the Court of Justice subject to the system of leave to appeal under Articles 170a and following of the Rules of Procedure of the Court of Justice, or under the review procedure in accordance with Article 256, paragraph 2, TFEU, Article 62 of the Statute of the Court and Articles 191 and following of the Rules of Procedure of the CJEU.

The opinion (including where amended following an opposition) will then be transmitted to the national offices of each of the designated Member States. Where the opinion is positive the designated Member States will grant a national SPC in accordance with their national rules, e.g. as regards publication, registration in relevant databases and the payment of annual (renewal) fees, unless circumstances have changed, such as the basic patent no longer being in force in a certain Member State. Subject to the outcome of any appeal before the Boards of Appeal or the EU courts, if the examination opinion is negative, the national office concerned must reject the application.

After the grant of SPCs at a national level, third parties will still be able to initiate invalidity proceedings before the body responsible under national law for the revocation of the corresponding basic patents, or the competent courts of the Member States, including the Unified Patent Court ('UPC'), as applicable. The same applies to a possible counterclaim for a declaration of invalidity of an SPC.

Marketing authorisations concerned

Given that there is a zonal system of marketing authorisation for PPPs in the EU and that only national marketing authorisations exist for PPPs, the requirement for a centralised authorisation, included in the parallel proposal (COM(2023) 231) which creates a centralised procedure for the grant of certificates for medicinal products, cannot be applied in this Regulation, applicable to PPPs. Therefore, national marketing authorisations will be allowed to serve as basis for the grant of certificates for PPPs under the centralised procedure laid down in this Regulation.

Moreover, since marketing authorisations for a given plant protection product are often granted at different dates in different Member States, it may happen that, at the date of filing a centralised application for certificates, authorisations have been granted in some of the designated Member States but not in all of them. Since this situation is expected to be frequent, the traditional requirement for the availability of valid authorisations at the date of filing of the application would often severely restrict the number of Member States that could be validly designated in a centralised application for certificates for a certain PPP.

To address this situation, it is proposed to allow the grant of certificates for a PPP, through the centralised procedure, when two conditions are fulfilled in respect of marketing authorisations, as a derogation from the above-mentioned traditional requirement:

– at the date of filing of the application, it is only required that marketing authorisations have been *applied for* in each of the designated Member States, but

– before the end of the examination process, authorisations must have been *granted* in each of the designated Member States. At the same time, it would be required that the examination process does not end earlier than 18 months from the filing of the application, to increase the likelihood that the 'missing' authorisations may have been granted by then. Where this condition is not met in one of the designated Member States, however, the examination proceedings would be suspended until the 'missing' authorisation is possibly granted, provided that – for legal certainty reasons – this takes place before the expiry of the basic patent.

Substantive features of the SPC regime

This reform does not intend to modify, nor further clarify in view of the relevant case law of the Court of Justice, the substantive features currently laid down in Regulation (EC) No 1610/96 for the existing national SPC regimes or the new centralised procedure, since:

– the case law[11] on SPCs is progressively converging, and steadily reducing uncertainty about the interpretation of the SPC regime[12], while further amendments might trigger new fluctuations and uncertainty as regards the proper interpretation of the amended rules;

[11] For a full list of cases, see Table 5.5. of the second MPI study.

[12] Further clarifications are, however, necessary in certain areas as indicated by two referrals in 2022, cases C-119/22 and C-149/22.

– respondents to the Allensbach survey did not call for Article 3 of the SPC Regulations to be amended (question 48) even if they consider that the CJEU case law is unclear in some respects (question 46).

New recitals

It was noted that there were no relevant recitals in Regulation (EC) No 1610/96 that could assist in interpretation of Article 3. Accordingly, certain recitals concern the conditions (as set out in Article 3) for the grant of SPCs and incorporate the case law of the Court of Justice. The aim is to ensure consistency. In particular the judgements in cases C- 121/17 and C-673/18 interpret Article 3(1)(a) and 3(1)(d) of the current SPC Regulation, respectively, and should be considered settled case law. This is also the case for judgement C-471/14, whereby the date of the first marketing authorisation in the Union, within the meaning of Article 13, is the date on which notification of the decision granting the authorisation was given to the addressee of the decision.

The requirement that the product should be protected by the basic patent means that the product should fall within the scope of one or more claims of that patent, as properly interpreted at the basic patent's filing date. This also includes situations where the product corresponds to a general functional definition used by one of the claims of the basic patent, and necessarily comes within the scope of the invention covered by that patent, even if it is not indicated in individualised form as a specific embodiment in the patent, provided that it is specifically identifiable from the patent.

Many general objectives set out in the Explanatory Memorandum of the proposal (COM(94)579) for what became Council Regulation (EC) No 1610/96, remain fully relevant today, and should continue to be used as a guide to interpretation, where relevant. This includes the objective that *if a certificate has already been granted for the active substance itself, a new certificate may not be granted for that active substance, whatever changes may have been made regarding other features of the plant protection product (use of a different salt, different excipients, different presentation, etc.)*.

Furthermore, as regards the rights conferred by a certificate, *the certificate confers the same protection as the basic patent, but only protects the product covered by the authorisation, for all pharmaceutical uses authorised, until the expiry of the basic patent*.

As regards the rights conferred by a certificate, and in line with the earlier statements regarding derivatives, it is appropriate to consider that the protection conferred by a certificate on a product extends to the derivatives of that product that are equivalent to the product from a phytosanitary perspective.

Language regime

This Regulation envisages the possibility of filing a centralised SPC application in any official EU language. In this regard, the amount of text in an SPC application is extremely small, especially compared to patents, and this would not present a burden for applicants. Certain matters would not require any translation, such as the identification of the basic patent and the relevant marketing authorisations, the relevant dates, and the identification of the applicant(s) and the product concerned. The translation costs are, therefore, expected to be considerably lower than would be the case for patent applications. See the impact assessment (SWD(2023) 118) for an exact calculation.

Appeals

Decisions of the central examination authority are subject to appeal. This also applies to a negative (or partly negative) examination opinion issued by the central examination authority,

an appeal could be filed by an applicant before the central examination authority, during a limited period after the issuance of the examination opinion. This also applies to other decisions of that authority; for instance, the decision relating to an opposition may be appealed by any of its parties. An appeal may result in the examination opinion being amended.

In the event of a 'combined' SPC application as referred to below – namely an SPC application which requests the grant of a unitary SPC and also of national SPCs –, such an appeal would be applicable to the (common) examination opinion relating to the combined SPC application.

The appeal would take place before the Boards of Appeal of the EUIPO. Members from the Boards of Appeal should be appointed in accordance with Article 166 (5) of Regulation 2017/1001. These members may also be national examiners, but they may not be the same examiners already involved in the examination of the centralised applications or applications for unitary certificates.

In terms of workload, SPC applications are made for less than 100 products each year on average, for medicinal products and PPPs together, and introducing third-party observations should help keep the number of appeals at a very low level.

Fees

An application fee and possibly other procedural fees, such as the fee for oppositions and appeals, will have to be paid to the central examination authority. For national SPCs granted under the centralised procedure, renewal fees would have to be paid to the national patent offices of all the Member States where such certificates have been granted. This would differ, however, for unitary certificates granted under the parallel proposals COM(2023) 222 and COM(2023) 221, whereby the examination authority shall charge application and annual (renewal) fees. The level of fees to be paid to the central examination authority will be set in an implementing act.

Financial transfers between the central authority and national patent offices (NPOs)

As the procedural fees paid by applicants to the central examination authority may not be sufficient to cover the costs incurred by that authority under the new centralised procedure, it is necessary to ensure that a fraction of the renewal fees collected by national offices for SPCs granted on the basis of the centralised procedure will be transferred to the central examination authority. This already happens between national patent offices and the European Patent Office (EPO) in respect of renewal fees for European patents. At the same time, it is necessary to ensure that those national offices that participate in the new centralised procedure as regards the substantive examination of centralised SPC applications are properly remunerated for their participation.

Litigation

Whether it was obtained under today's current national procedures or under the newly proposed centralised procedure, an SPC based on an European patent, including a unitary patent, will be able to be litigated before the body responsible under national law for the revocation of the corresponding basic patent, which is typically a national court, and may also, for those Member States participating in the unitary patent system (i.e. that have ratified

the UPCA), be the Unified Patent Court where the applicable conditions are fulfilled (cf. Article 3(b) of the UPCA, together with Article 2(g) and Article 32)[13].

National aspects

As the proposed centralised procedure results in the grant of national certificates (SPCs), many existing national requirements and procedures, currently applicable to the SPCs applied for nationally, will be equally applicable to the certificates granted under the proposed centralised procedure. This relates in particular to publication requirements, national registers and the payment of renewal fees.

No changes are proposed to the judicial procedures applicable to nationally granted SPCs, whether granted on the basis of a national application or of a centralised application, e.g. as regards revocation and enforcement, subject to the provisions of the UPCA, for its parties, where applicable. In other words, invalidity actions and infringement actions may be brought before the UPC also in respect of a nationally granted SPC based on a European patent, subject to the applicable conditions, in particular the requirement that neither the patent nor the SPC has been opted-out from the jurisdiction of the UPC.

Unitary SPCs

A parallel proposal (COM(2023) 221) is intended to create a unitary SPC for plant protection products. This unitary certificate would be available only on the basis of a European patent with unitary effect ('unitary patent'), as a basic patent, and would exert its effects uniformly in all the Member States in which the basic patent has unitary effect (17 initially).

The procedure for the centralised filing and examination of applications for such unitary certificates would be the same *mutatis mutandis* as the centralised procedure set out in this proposal. In this manner, a 'combined' SPC application could possibly include both a request for the grant of a unitary SPC (for the Member States covered by the basic patent) and a request for the grant of national SPCs in other Member States. This 'combined' application would undergo a single examination procedure, ruling out any discrepancies, and considerably reducing costs and the administrative burden for applicants. For the sake of clarity, this proposal does not exclude centralised SPC applications designating one or more Member States participating in the unitary patent system, as long as no unitary SPC is simultaneously requested in such a case.

[13] Where the related basic patent or the SPC itself has not been opted-out from the competence of the UPC and where no action has already been brought before a national court (as far as those Member States in which the patent has unitary effect are concerned).

↓ 1610/96 (adapted)

2023/0128 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the supplementary protection certificate for plant protection products (recast)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty ⊠on the Functioning of the European Union⊠, and in particular Article ~~100a~~ ⊠ 114(1) ⊠ thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[14],

Having regard to the opinion of the Committee of the Regions[15],

Acting in accordance with the ordinary legislative procedure,

Whereas:

⇩ new

(1) Regulation (EC) No 1610/96 of the European Parliament and of the Council[16] has been substantially amended several times[17]. Since further amendments are to be made, that Regulation should be recast in the interests of clarity.

↓ 1610/96 recital 1

(2) Research into plant protection products contributes to the continuing improvement in the production and procurement of plentiful food of good quality at affordable prices.

[14] OJ C […], […], p. […].

[15] OJ C […], […], p. […].

[16] 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 (*OJ L 198, 8.8.1996, p. 30*).

[17] See Annex I.

↓ 1610/96 recital 2

(3) Plant protection research contributes to the continuing improvement in crop production.

↓ 1610/96 recital 3 (adapted)

(4) Plant protection products, especially those that are the result of long, costly research, will continue to be developed in the ~~Community~~ ⌦ Union ⌫ ~~and in Europe~~ if they are covered by favourable rules that provide for sufficient protection to encourage such research.

↓ 1610/96 recital 4

(5) The competitiveness of the plant protection sector, by the very nature of the industry, requires a level of protection for innovation which is equivalent to that granted to medicinal products by Regulation (EC) No 469/2009 of the European Parliament and of the Council[18] *[OP, please insert new Regulation reference to COM(2023) 231]* ~~Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products~~[(3)].

↓ 1610/96 recital 5 (adapted)

(6) ~~at the moment,~~ T~~t~~he period that elapses between the filing of an application for a patent for a new plant protection product and ⌦ the ⌫ authorisation to place the said plant protection product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research and to generate the resources needed to maintain a high level of research.

↓ 1610/96 recital 6

(7) This situation leads to a lack of protection which penalises plant protection research and the competitiveness of the sector.

↓ 1610/96 recital 7 (adapted)
⇨ new

(8) One of the main objectives of the supplementary protection certificate ⌦ ('certificate') ⌫ is to place European industry on the same competitive footing as ~~its North American and Japanese counterparts~~ ⇨ third countries ⇦.

[18] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ L 152, 16.6.2009, p. 1).

↓ 1610/96 recital 8 (adapted)

~~In its Resolution of 1 February 1993[19] on a Community programme of policy and action in relation to the environment and sustainable development, the Council adopted the general approach and strategy of the programme presented by the Commission, which stressed the interdependence of economic growth and environmental quality. Improving protection of the environment means maintaining the economic competitiveness of industry. Accordingly, the issue of a supplementary protection certificate can be regarded as a positive measure in favour of environmental protection.~~

↓ 1610/96 recital 9 (adapted)

(9) A uniform solution at ~~Community~~ ⌦ Union ⌫ level should be provided for, thereby preventing the heterogeneous development of national laws leading to further disparities which would be likely to hinder the free movement of plant protection products within the ~~Community~~ ⌦ Union ⌫ and thus directly affect the functioning of the internal market~~; whereas this is in accordance with the principle of subsidiarity as defined by Article 3b of the Treaty~~.

↓ 1610/96 recital 10 (adapted)
⇨ new

(10) Therefore, there is a need to ~~create~~ ⌦ provide for ⌫ a ~~supplementary protection~~ certificate granted, under the same conditions, by each of the Member States at the request of the holder of a national ⌦ patent ⌫ or European patent ⇨ , with or without unitary effect, ⇦ relating to a plant protection product for which marketing authorisation has been granted. ~~is necessary; whereas a Regulation is therefore the most appropriate legal instrument.~~ ⇨ The certificate should provide its holder with an adequate additional period of effective protection subsequent to the expiry of the basic patent. An application for such a certificate should be filed with competent industrial property office ('competent national authority') of the Member State concerned. ⇦

⇩ new

(11) One of the conditions for the grant of a certificate should be that the product is protected by the basic patent, in the sense that the product should fall within the scope of one or more claims of that patent, as interpreted by the person skilled in the art by the description of the patent on its filing date. This should not necessarily require that the active substance of the product be explicitly identified in the claims. Or, in the event of a preparation, this should not necessarily require that each of its active substances be explicitly identified in the claims, provided that each of them is specifically identifiable in the light of all the information disclosed by that patent.

[19] ~~Opinion of the European Parliament of 15 June 1995 (OJ C 166, 3. 7. 1995, p. 89), common position of the Council of 27 November 1995 (OJ C 353, 30. 12. 1995, p. 36) and decision of the European Parliament of 12 March 1996 (OJ C 96, 1. 4. 1996, p. 30).~~

(12) To avoid overprotection, it should be provided that no more than one certificate, whether national or unitary, may protect the same product in a Member State. Therefore it should be required that the product, or any derivative such as salts, esters, ethers, isomers, mixtures of isomers, or complexes, equivalent to the product from a phytosanitary perspective, should not have already been the subject of a prior certificate, either alone or in combination with one or more additional active ingredients, whether for the same application or for a different one.

(13) Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate should extend only to the product, namely the active substance or combinations thereof, covered by the authorisation to place it on the market and for any use of the product as a plant protection product that has been authorised before the expiry of the certificate.

(14) To ensure balanced protection, however, a certificate should entitle its holder to prevent a third party from manufacturing not only the product identified in the certificate but also derivatives of that product, such as salts, esters, ethers, isomers, mixtures of isomers, or complexes, equivalent to the product from a phytosanitary perspective, even where such derivatives are not explicitly mentioned in the product description on the certificate. There is therefore a need to consider that the protection conferred by the certificate extends to such equivalent derivatives, within the limits of the protection conferred by the basic patent.

(15) As a further measure to ensure that no more than one certificate may protect the same product in any Member State, the holder of more than one patent for the same product should not be granted more than one certificate for that product. However, where two patents protecting the product are held by two holders, one certificate for that product should be allowed to be granted to each of those holders, where they can demonstrate that they are not economically linked. Furthermore, no certificate should be granted to the proprietor of a basic patent in respect of a product which is the subject of an authorisation held by a third party, without that party's consent.

(16) In order to ensure maximum flexibility and not unduly discriminate between holders of different types of patents, there should be no limitation on the type of patent on which a national certificate can be applied for before a competent national authority. Therefore, this should continue to be possible on the basis of a national patent or of a European patent, and, in particular, this should also be possible in respect of a European patent with unitary effect ('unitary patent').

↓ 1610/96 recital 11 (adapted)

(17) The duration of the protection granted by the certificate should be such as to provide adequate~~,~~ effective protection. For this purpose, the holder of both a patent and a certificate should be able to enjoy an overall maximum of ~~fifteen~~ ⌦ 15 ⌫ years of exclusivity from the time the plant protection product in question first obtains authorisation to be placed on the market in the ~~Community~~ ⌦ Union ⌫.

↓ 1610/96 recital 12 (adapted)
⇨ new

(18) All the interests at stake in a sector as complex and sensitive as plant protection ~~must nevertheless~~ ⌦ should ⌫ be taken into account. For this purpose, the certificate cannot be granted for a period exceeding ~~five~~ ⌦ 5 ⌫ years. ⇨ The protection granted should furthermore be strictly confined to the product which obtained authorisation to be placed on the market of a Member State as a plant protection product.⇦

↓ 1610/96 recital 13 (adapted)

~~The certificate confers the same rights as those conferred by the basic patent; consequently, where the basic patent covers an active substance and its various derivatives (salts and esters), the certificate confers the same protection.~~

↓ 1610/96 recital 14 (adapted)

~~The issue of a certificate for a product consisting of an active substance does not prejudice the issue of other certificates for derivatives (salts and esters) of the substance, provided that the derivatives are the subject of patents specifically covering them.~~

↓ 1610/96 recital 15 (adapted)

~~A fair balance should also be struck with regard to the determination of the transitional arrangements. Such arrangements should enable the Community plant protection industry to catch up to some extent with its main competitors, while making sure that the arrangements do not compromise the achievement of other legitimate objectives concerning the agricultural policy and environment protection policy pursued at both national and Community level.~~

↓ 1610/96 recital 16 (adapted)

(19) Only action at ~~Community~~ ⌦ Union ⌫ level will ⌦ allow ⌫~~enable the objective, which consists in~~ ensuring adequate protection for innovation in the field of plant protection, while guaranteeing the proper functioning of the internal market for plant protection products, to be attained effectively.

↓ 1610/96, recital 17 (adapted)

(20) The detailed rules ⌦ referred to ⌫ in recitals 13, 14 and 15~~12, 13 and 14~~ and ⌦ laid down in ⌫ in Article 4, Article 8 (1), point (c), and Article 17 (2) of this Regulation are also valid, *mutatis mutandis*, for the interpretation in particular of recital 9 and Articles 3~~,~~ and 4, Article 8 (1), point (c), and Article 17 of ~~Council~~ Regulation (EC) No 469/2009 [*OP please insert new reference to COM(2023) 231*].

⇩ new

(21) Since the creation of supplementary protection, certificates were only applied for and granted nationally, thus requiring several similar applications to be filed and examined in parallel in a number of Member States. This has resulted in duplication of work for both applicants and competent industrial property offices ('competent national authorities') conducting separate examination proceedings in respect of a given product, as well as in occasional discrepancies in the decisions taken by the competent national authorities in different Member States. Such differences usually pertain to the conditions for the grant or refusal of a certificate and include the grant of a certificate in one Member State but the refusal in another Member State regarding the same product or differences in the application of the conditions that apply to prior marketing authorisation or whether the product has already been the subject of a supplementary protection certificate. This leads to legal uncertainty and is inconsistent with the aims of the internal market.

(22) There is a centralised procedure for granting European patents. In addition, the 'unitary patent' as laid down in Regulation (EU) No 1257/2012 of the European Parliament and of the Council[20] is to enter into force on 1 June 2023 in respect for all Member States having ratified the Agreement on a Unified Patent Court ('UPC').

(23) Therefore, it is necessary to complement the existing national procedures for the grant of certificates for plant protection products with a centralised procedure. That procedure should make it possible, where the basic patent is a European patent, including a unitary patent, to request the grant of national certificates for two or more designated Member States through the filing and examination of a single 'centralised' application. Following the grant of certificates under the centralised procedure, these certificates should be equivalent to the certificates granted under national procedures and be subject to the same rules.

(24) Regulation (EU) No 2017/1001 of the European Parliament and of the Council[21] has established, under its Article 2, a European Union Intellectual Property Office ('the Office'). In the interest of the internal market, the centralised procedure should be carried out by a single examining authority. This can be achieved by the Office being given the task of examining applications for certificates under the centralised procedure in accordance with this Regulation.

(25) In order to provide for a simplified examination of a centralised application, its filing should be available only on the basis of a European patent, including a unitary patent. The centralised application should not be available on the basis of a set of independent national patents, as their claims are likely to be different, resulting in greater complexity in examination compared to the situations where the basic patent is a European patent.

(26) Since marketing authorisations for a given plant protection product may be granted at different dates in different Member States, the Member States that could be validly

[20] Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection (OJ L 361, 31.12.2012, p. 1).

[21] Regulation (EU) 2017/1001 of the European Parliament and of the Council of 14 June 2017 on the European Union trade mark (OJ L 154, 16.6.2017, p. 1).

designated in a centralised application for certificates for a certain plant protection product would be severely restricted, if it were to be required that authorisations should have been granted in all Member States designated in the application. The grant of certificates on the basis of such a centralised application should therefore be allowed where marketing authorisations have at least been applied for in all designated Member States, provided that such authorisations are granted before the end of the examination process. For this reason, the examination opinion should not be adopted earlier than 18 months from the filing of the centralised application. Where no authorisation has been granted in a designated Member State before that period has elapsed, however, the Office should, in respect of that Member State, suspend the examination proceedings, and resume them, on request, provided that such an authorisation is eventually granted before the expiry of the basic patent.

(27) The Office should have the possibility to charge a fee for the centralised application for a certificate, as well as other procedural fees such as a fee for opposition or appeal. The fees charged by the Office should be laid down by an implementing act.

(28) An applicant should also be allowed to lodge a 'combined application' that would include an application for a unitary certificate as set out in Regulation [COM(2023) 221]. Such a combined application should undergo a single examination procedure.

(29) In order to avoid double protection, it should not be possible to grant certificates – whether national certificates or unitary certificates – for the same product in the same Member State based on both a national application and a centralised application.

(30) To guarantee a fair and transparent process, ensure legal certainty and reduce the risk of subsequent validity challenges, third parties should have the possibility, after the publication of the centralised application, to submit within 3 months observations to the Office while the centralised examination is being performed. These third parties allowed to submit observations should also include Member States. This, however, should not affect the rights of third parties to initiate invalidity proceedings before the body responsible under national law for the revocation of the corresponding basic patent. These provisions are necessary to ensure involvement of third parties both before and after the grant of certificates.

(31) The Office should examine the centralised application for certificates and issue an examination opinion. That opinion should state the reasons for which it is positive or negative in respect of each of the designated Member States.

(32) The examination of a centralised application for a certificate should be conducted, under supervision of the Office, by an examination panel including one member of the Office as well as two examiners employed by the national patent offices. This would ensure that optimal use be made of expertise in supplementary protection certificates matters, located today at national offices only. To ensure an optimal quality of the examination, suitable criteria should be laid down in respect of the participation of specific examiners in the centralised procedure, in particular as regards qualification and conflicts of interest.

(33) Where the Office finds that the conditions for grant of a certificate are fulfilled in one or more of the Member States designated in a centralised application, but are not fulfilled in one or more of the other ones, including where in one of the designated Member States the basic European patent has different claims which do not cover the product, the Office should issue a positive opinion for those designated Members

States in which the conditions for obtaining a certificate are fulfilled, and a negative opinion for those in which the conditions are not fulfilled.

(34) To safeguard third parties' procedural rights and ensure a complete system of remedies, third parties should be able to challenge an examination opinion, by initiating opposition proceedings within a short duration following the publication of that opinion, and that opposition may result in that opinion being amended.

(35) After the completion of the examination of a centralised application, and after the time limits for appeal and opposition have expired, or, the case being, after a final decision on the merits has been issued, the opinion should be transmitted to the respective national patent offices of the designated Member States.

(36) Where the examination opinion is positive for one or several Member States, the respective competent national authorities should grant a certificate in accordance with the applicable domestic rules, in particular as regards publication, registration in relevant databases and the payment of annual fees.

(37) Where the examination opinion is negative for one or several Member States, the respective competent national authorities should reject the application in accordance with the applicable domestic rules.

(38) For the sake of coherence and legal certainty, the same substantive provisions should apply to national applications and to centralised applications regarding in particular the scope, the conditions for obtaining certificates, the subject-matter of protection and effect of certificates, and their publication. The centralised procedure would result in the grant of national certificates fully identical to those granted on the basis of national applications.

(39) Since certain competent national authorities may have limited administrative capacity to conduct a full substantive examination of applications for certificates, competent national authorities should remain able to not verify all the conditions for granting a certificate on the basis of a national application. However, to ensure the quality and uniformity of the certificates granted under the centralised procedure, the Office should examine all of the conditions for grant of a certificate under the centralised procedure.

(40) Where the applicant or another party is adversely affected by a decision of the Office, the applicant or that party should have the right, subject to a fee, to file within 2 months an appeal against the decision, before a Board of Appeal of the Office. This also applies to the examination opinion, that may be appealed by the applicant. Decisions of that Board of Appeal should, in turn, be amenable to actions before the General Court, which has jurisdiction to annul or to alter the contested decision. In case of a combined application including a request for a unitary certificate, a common appeal may be filed.

(41) When appointing members of the Boards of Appeal in matters regarding centralised applications for certificates, their prior experience in supplementary protection certificate or patent matters should be taken into account.

(42) Any person may challenge the validity of a certificate granted following the centralised procedure before a competent court of a Member State, which includes the Unified Patent Court where the conditions are met.

(43) To ensure transparency, a register should be set up that can serve as a single access point providing information on applications for certificates under the centralised

procedure and their status, including on certificates granted on that basis by national offices, which should share with the Office any related information. The register should be available in all official languages of the Union.

(44) Regulation [COM(2023) 221][22] creates a unitary supplementary protection certificate for plant protection products, which may be requested for those Member States in which the basic patent has unitary effect. The request for such a unitary certificate may be made in a combined application for a certificate under the centralised procedure covered by this Regulation. In such a case, the combined application including both requests should be subject to a single centralised examination procedure. Double protection by both a unitary certificate and a certificate granted pursuant to this Regulation should be excluded.

(45) For the tasks conferred on the Office under this Regulation, the languages of the Office should be all official languages of the Union. The Office should accept verified translations, into one of the official languages of the Union, of documents and information. The Office may, if appropriate, use verified machine translations.

(46) Financial provision should be made to ensure that competent national authorities that participate in the centralised procedure are adequately remunerated for their participation.

(47) The necessary set-up costs related to the tasks conferred to the Office, including the costs of new digital systems, should be financed from the Office's accumulated budgetary surplus.

(48) In order to supplement certain non-essential elements of this Regulation, the power to adopt acts, in accordance with Article 290 of the Treaty on the Functioning of the European Union, should be delegated to the Commission in respect of: (i) specifying the content and form of the notice of appeal and the content and the form of the Boards of Appeal's decision, (ii) specifying the details concerning the organisation of the Boards of Appeal in proceedings relating to certificates, (iii) specifying the rules on the means of communication, including the electronic means of communication, to be used by the parties to proceedings before the Office and the forms to be made available by the Office, (iv) setting out the detailed arrangements for oral proceedings, (v) setting out the detailed arrangements for the taking of evidence, (vi) setting out the detailed arrangements for notification, (vii) specifying the details regarding the calculation and duration of time limits and (viii) setting out the detailed arrangements for the resumption of proceedings. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016.[23] In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

(49) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards: (i) the

[22] Regulation of the European Parliament and of the Council on the unitary supplementary protection certificate for plant protection products [COM(2023) 221].

[23] Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making (OJ L 123, 12.5.2016, p. 1).

application forms to be used; (ii) rules on procedures relating to the filing, and procedures regarding the way in which examination panels examine centralised applications and prepare examination opinions, as well as the issuance of examination opinions by the Office, (iii) the criteria in the ways the examination panels are to be set up, and the criteria for the selection of examiners, (iv) the amounts of the applicable fees to be paid to the Office, (v) specifying the maximum rates for costs essential to the proceedings and actually incurred by the successful party, and (vi) rules on the financial transfers between the Office and Member States, the amounts of these transfers, and the remuneration to be paid by the Office regarding the participation of competent national authorities. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[24].

(50) The Commission should regularly report on the operation of the centralised procedure, in coordination with that required in Regulation [COM(2023) 231].

(51) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union ('the Charter'). The rules in this Regulation should be interpreted and applied in accordance with those rights and principles. In particular, this Regulation seeks to ensure full respect for the right to property and the right to health care and the right to an effective remedy in Articles 17 and 47 of the Charter.

(52) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States but can rather, with a view to ensuring that the applicable rules and procedures are consistent across the Union, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

(53) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 of the European Parliament and of the Council[25] and delivered an opinion on XXX *[OP, please add reference once available]*.

(54) Appropriate arrangements should be made to facilitate a smooth transition from the rules provided for in Regulation (EC) No 1610/96 to the rules laid down in this Regulation. To allow for sufficient time for the Office to implement and launch the centralised procedure, the provisions on centralised applications laid down in this Regulation should apply from [OP: please insert - one year after the entry into force of this Regulation],

[24] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

[25] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

↓ 1610/96 (adapted)

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article ~~2~~ 1

~~Scope~~ ⊠ Subject matter ⊠

~~Any product~~ ⊠This Regulation lays down rules on the supplementary protection certificate ('certificate') for plant protection products ⊠ protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a plant protection product, to an administrative authorisation procedure as laid down in ~~Article 4 of Directive 91/414/EEC~~ Regulation (EC) No 1107/2009 of the European Parliament and of the Council[26]~~, or pursuant to an equivalent provision of national law if it is a plant protection product in respect of which the application for authorisation was lodged before Directive 91/414/EEC was implemented by the Member State concerned, may, under the terms and conditions provided for in this Regulation, be the subject of a certificate~~.

↓ 1610/96 (adapted)

Article ~~1~~ 2

Definitions

For the purposes of this Regulation, the following definitions shall apply:

(1) 'plant protection products'~~:~~ ⊠means⊠ active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to:

(a) protect plants or plant products against all harmful organisms or prevent the action of such organisms, in so far as such substances or preparations are not otherwise defined below;

(b) influence the life processes of plants, other than as a nutrient (e.g. plant growth regulators);

(c) preserve plant products, in so far as such substances or products are not subject to special Council or Commission provisions on preservatives;

(d) destroy undesirable plants; or

(e) destroy parts of plants, check or prevent undesirable growth of plants;

[26] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309 24.11.2009, p. 1).

(2) ‘substances’≒ ⌦means⌫ chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing process;

(3) ‘active substances’≒ ⌦means⌫ substances or micro-organisms including viruses, having general or specific action:

(a) against harmful organisms; or

(b) on plants, parts of plants or plant products;

(4) ‘preparations’≒ ⌦means⌫ mixtures or solutions composed of two or more substances, of which at least one is an active substance, intended for use as plant protection products;

(5) ‘plants’≒ ⌦means⌫ live plants and live parts of plants, including fresh fruit and seeds;

(6) ‘plant products’≒ ⌦means⌫ products in the unprocessed state or having undergone only simple preparation such as milling, drying or pressing, derived from plants, but excluding plants themselves ~~as defined in point 5~~;

(7) ‘harmful organisms’≒ ⌦means⌫ pests of plants or plant products belonging to the animal or plant kingdom, and also viruses, bacteria and mycoplasmas and other pathogens;

(8) ‘product’≒ ⌦means⌫ the active substance ~~as defined in point 3~~ or combination of active substances of a plant protection product;

(9) 'basic patent'≒ ⌦means⌫ a patent which protects a product ~~as defined in point 8~~ as such, a preparation ~~as defined in point 4~~, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for ~~grant~~ ⌦the grant⌫ of a certificate;

~~'certificate': the supplementary protection certificate;.~~

⇩ new

(10) ‘national application’ means an application for a certificate made before a competent national authority pursuant to Article 9;

(11) ‘centralised application’ means an application made before the Office pursuant to Article 19 with a view to the grant of certificates, for the product identified in the application, in the designated Member States;

(12) 'designated Member State’ means a Member State for which a certificate is sought under the centralised examination procedure laid down in Chapter III, as identified in a centralised application for a certificate;

(13) 'European patent' means a patent granted by the European Patent Office (EPO) under the rules and procedures laid down in the European Patent Convention (‘EPC’)[27];

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[27] Convention on the Grant of European Patents of 5 October 1973, as revised on 17 December 1991 and on 29 November 2000

(14) ‘unitary patent’ means a European patent which benefits from unitary effect in those Member States participating in the enhanced cooperation laid down in Regulation (EU) No 1257/2012;

(15) 'competent national authority' means the national authority that is competent, in a given Member State, for the grant of certificates and for the rejection of applications for certificates, as referred to in Article 9(1).

CHAPTER II
NATIONAL APPLICATIONS FOR A CERTIFICATE

↓ 1610/96 (adapted) ⇨ new

Article 3

Conditions for obtaining a certificate

1. A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application ⇨ , all of the following conditions are fulfilled ⇦:

   (a) the product is protected by a basic patent in force;

   (b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with ~~Article 4 of Directive 91/414/EEC~~ Regulation (EC) No 1107/2009 ~~or an equivalent provision of national law~~;

   (c) the product has not already been the subject of a certificate;

   (d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a plant protection product.

2. The holder of more than one patent for the same product shall not be granted more than one certificate for that product. However, where two or more applications concerning the same product and emanating from two or more holders of different patents are pending, one certificate for ~~this~~ ⌦ that ⌫ product may be issued to each of ~~these~~ ⌦ those ⌫ holders ⇨, where they are not economically linked ⇦.

Article 4

⌦ Scope ⌫ ~~Subject matter of~~ ⌦ the ⌫ protection

Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorisations to place the corresponding plant protection product on the market and for any use of the product as a plant protection product that has been authorised before the expiry of the certificate.

Article 5

Effects of the certificates

~~Subject to Article 4,~~ T~~t~~he certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations.

Article 6

Entitlement to the certificate

1. The certificate shall be granted to the holder of the basic patent or ~~his~~ ⌦ to the ⌫ successor in title ⌦ of that holder ⌫.

⇩ new

2. Notwithstanding paragraph 1, where a basic patent has been granted in respect of a product that is the subject of an authorisation held by a third party, a certificate for that product shall not be granted to the holder of the basic patent without the consent of that third party.

🡻 1610/96 (adapted)
⇨ new

Article 7

Application for a certificate

1. The application for a certificate shall be lodged within ⌦ 6 ⌫ ~~six~~ months of the date on which the authorisation referred to in Article 3(1), point (b), to place the product on the market as a plant protection product was granted.

2. Notwithstanding paragraph 1, where the authorisation to place the product on the market is granted before the basic patent is granted, the application for a certificate shall be lodged within ⌦ 6 ⌫ ~~six~~ months of the date on which the patent is granted.

Article 8

Content of the application for a certificate

1. The application for a certificate shall contain ⌦ the following ⌫:

   (a) a request for the grant of a certificate, stating in particular:

      (i) the name and address of the applicant;

      (ii) ⌦ if the applicant has appointed a representative, ⌫the name and address of ⌦ that ⌫ ~~the~~ representative~~, if any~~;

      (iii) the number of the basic patent and the title of the invention;

      (iv) the number and date of the first authorisation to place the product on the market, as referred to in Article 3(1), point (b), and, if this authorisation is not the first authorisation for placing the product on the market in the ~~Community~~ ⌦ Union⌫, the number and date of that authorisation;

   (b) a copy of the authorisation to place the product on the market, as referred to in Article 3(1), point (b), in which the product is identified, containing in particular the number and date of the authorisation and the summary of the product characteristics listed in ~~Part A.I (points 1-7) or B.I (points 1-7) of~~

~~Annex II to Directive 91/414/EEC~~ , Part A, section 1, points 1.1 to 1.7 of the Annex to Commission Regulation 283/2013[28] or Part B, Section 1, points 1.1 to 1.4.3 thereof ~~or in equivalent national laws of the Member State in which the application was lodged~~;

(c) ⌦ where ⌫ ~~if~~ the authorisation referred to in point (b) is not the first authorisation for placing the product on the market as a medicinal product in the ~~Community~~ ⌦ Union ⌫, information regarding the identity of the product thus authorised and the legal provision under which the authorisation procedure took place, together with a copy of the notice publishing the authorisation in the appropriate official publication or, ~~failing~~ ⌦ in the absence of ⌫ such a notice, any other document proving that the authorisation has been issued, the date on which it was issued and the identity of the product authorised;

2. Member States may provide that a fee is to be payable upon application for a certificate.

Article 9

Lodging of an application for a certificate

1. The application for a certificate shall be lodged with the competent industrial property office of the Member State which granted the basic patent or on whose behalf it was granted and in which the authorisation referred to in Article 3(1), point (b), to place the product on the market was obtained, unless the Member State designates another authority for ⌦ that ⌫ ~~the~~ purpose.

2. Notification of the application for a certificate shall be published by the authority referred to in paragraph 1. The notification shall contain ~~at least~~ ⇨ all of ⇦ the following information:

(a) the name and address of the applicant;

(b) the number of the basic patent;

(c) the title of the invention;

(d) the number and date of the authorisation to place the product on the market, referred to in Article 3(1), point (b), and the product identified in that authorisation;

(e) where relevant, the number and date of the first authorisation to place the product on the market in the ~~Community~~ ⌦ Union ⌫.

Article 10

Grant of the certificate or rejection of the application

1. Where the application for a certificate and the product to which it relates meet the conditions laid down in this Chapter~~Regulation~~, the authority referred to in Article 9(1) shall grant the certificate.

[28] Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 93, 3.4.2013, p. 1).

2. The authority referred to in Article 9(1) shall, subject to paragraph 3 ⌦ of this Article ⌫, reject the application for a certificate if the application or the product to which it relates does not meet the conditions laid down in this ChapterRegulation.

3. Where the application for a certificate does not meet the conditions laid down in Article 8, the authority referred to in Article 9(1) shall ask the applicant to rectify the irregularity, or to settle the fee, within a stated time.

4. If the irregularity is not rectified or the fee is not settled under paragraph 3 within the stated time, the application shall be rejected ⌦ the authority shall reject the application ⌫.

5. Member States may provide that the authority referred to in Article 9(1) is to grant certificates without verifying that the conditions laid down in Article 3(1), points (c) and (d), are met.

Article 11

Publication

1. ⌦ The authority referred to in Article 9(1) shall publish, as soon as possible, ⌫ nNotification of the fact that a certificate has been granted shall be published by the authority referred to in Article 9(1). The notification shall contain at least ⇨ all of ⇦ the following information:

   (a) the name and address of the holder of the certificate;

   (b) the number of the basic patent;

   (c) the title of the invention;

   (d) the number and date of the authorisation to place the product on the market referred to in Article 3(1), point (b), and the product identified in that authorisation;

   (e) where relevant, the number and date of the first authorisation to place the product on the market in the Community ⌦ Union ⌫;

   (f) the duration of the certificate.

2. ⌦ The authority referred to in Article 9(1) shall publish, as soon as possible, ⌫ a nNotification of the fact that the application for a certificate has been rejected shall be published by the authority referred to in Article 9(1). The notification shall contain at least the information listed in Article 9(2).

Article 12

Annual fees

Member States may require that the certificate be subject to the payment of annual fees.

Article 13

Duration of the certificate

1. The certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorisation to place the

product on the market in the ~~Community~~ ⌦ Union ⌫, reduced by a period of ⌦ 5 ⌫ ~~five~~ years.

2. Notwithstanding paragraph 1, the duration of the certificate may not exceed ⌦ 5 ⌫ ~~five~~ years from the date on which it takes effect.

3. For the purposes of calculating the duration of the certificate, account shall be taken of a provisional first marketing authorisation only if it is directly followed by a definitive authorisation concerning the same product.

Article 14

Expiry of the certificate

The certificate shall lapse ⌦ in any of the following events ⌫:

(a) at the end of the period provided for in Article 13;

(b) if the certificate holder surrenders it;

(c) if the annual fee laid down in accordance with Article 12 is not paid in time;

(d) if and as long as the product covered by the certificate may no longer be placed on the market following the withdrawal of the appropriate authorisation or authorisations to place on the market in accordance with ~~Article 4 of Directive 91/414/EEC~~ Regulation (EC) No 1107/2009 or equivalent provisions of national law ⌦ , as applicable ⌫.

⇨ For the purposes of point (d), ⇦ t~~T~~he authority referred to in Article 9(1) ~~of this Regulation~~ may decide on the lapse of the certificate either of its own motion or at the request of a third party.

Article 15

Invalidity of the certificate

1. The certificate shall be invalid ⌦ in any of the following events ⌫ ~~if~~:

(a) ⌦ the certificate ⌫ ~~it~~ was granted contrary to ~~the provisions of~~ Article 3;

(b) the basic patent has lapsed before its lawful term expires;

(c) the basic patent is revoked or limited to the extent that the product for which the certificate was granted would no longer be protected by the claims of the basic patent or, after the basic patent has expired, grounds for revocation exist which would have justified such revocation or limitation.

2. Any person may submit an application or bring an action for a declaration of invalidity of the certificate before the body responsible under national law for the revocation of the corresponding basic patent ⇨ , or before a competent court of a Member State ⇦.

Article 16

Notification of lapse or invalidity

If the certificate lapses in accordance with Article 14, points (b), (c) or (d), or is invalid in accordance with Article 15, ⌦ the authority referred to in Article 9(1) shall publish ⌫ notification thereof ~~shall be published by the authority referred to in Article 9(1)~~.

Article 17

Appeals

1. The decisions of the authority referred to in Article 9(1) or of the body referred to in Article 15(2) taken under this ~~Regulation~~ Chapter shall be open to the same appeals as those provided for in national law against similar decisions taken in respect of national patents.

2. The decision to grant the certificate shall be open to an appeal aimed at rectifying the duration of the certificate where the date of the first authorisation to place the product on the market in the ~~Community~~ ⌦ Union ⌫, contained in the application for a certificate as provided for in Article 8, is incorrect.

Article 18

Procedure

1. In the absence of procedural provisions in this Regulation, the procedural provisions applicable under national law to the corresponding basic patent and, where appropriate, the procedural provisions applicable to the certificates referred to in Regulation (EC) No 469/2009 ~~(EEC) No 1768/92~~ *[OP, please insert reference to COM(2023) 231]*, shall apply to the certificate, unless national law lays down special procedural provisions for certificates.

2. Notwithstanding paragraph 1, the procedure for opposition to the grant~~ing~~ of a certificate shall be excluded.

⇩ new

CHAPTER III
CENTRALISED PROCEDURE FOR CERTIFICATES

Article 19

Scope of the centralised application

1. Where the basic patent is a European patent, including a unitary patent, and authorisations to place the product on the market have been granted in at least one Member State in accordance with Regulation (EC) No 1107/2009, the procedure in this Chapter may be used.

2. A centralised application shall be lodged with the European Union Intellectual Property Office established by Article 2 of Regulation (EU) 2017/1001 ('the Office').

3. Articles 1 to 7 and 13 to 17 shall apply to centralised applications.

4. The centralised application shall be lodged by using a specific application form.

The Commission is empowered to adopt implementing acts laying down rules on the application form to be used to lodge a centralised application. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55.

Article 20

Content of the centralised application

The centralised application shall contain the following:

(a) designation of the Member States in which certificates are sought under the centralised procedure;

(b) the information referred to in Article 8(1).

Article 21

Examination of the admissibility of a centralised application

1. The Office shall examine the following:

(a) whether the centralised application complies with Article 20;

(b) whether the centralised application complies with Article 7;

(c) whether the application fee referred to in Article 33(1) has been paid within the prescribed period.

2. Where the centralised application does not satisfy the requirements referred to in paragraph 1, the Office shall request the applicant to take the measures necessary to satisfy those requirements and shall set a deadline for such compliance.

3. Where the fee referred to in paragraph 1, point (c), has not been paid or has not been paid in full, the Office shall inform the applicant accordingly.

4. If the applicant does not satisfy the requirements referred to in paragraph 1 within the deadline referred to in paragraph 2, the Office shall reject the application.

Article 22

Publication of the centralised application

If the centralised application complies with Article 21, the Office shall publish the application, without undue delay, in the Register.

Article 23

Examination of the centralised application

1. The Office shall assess the application on the basis of all the conditions in Article 3(1) for each of the designated Member States.

2. Where the centralised application for a certificate and the product to which it relates comply with Article 3(1) in respect of all or some of the designated Member States, the Office shall adopt a reasoned positive examination opinion in respect of such Member States. The Office shall notify that opinion to the applicant.

3. Where the centralised application for a certificate and the product to which it relates does not comply with Article 3(1) in respect of all or some of the designated Member States, the Office shall adopt a reasoned negative examination opinion in respect of such Member States. The Office shall notify that opinion to the applicant.

4. The Office shall translate the examination opinion in the official languages of all designated Member States. The Office may use verified machine translation to that effect.

5. The Commission is empowered to adopt implementing acts laying down rules on procedures relating to the filing, and procedures regarding the way in which examination panels examine centralised applications and prepare examination opinions, as well as the issuance of examination opinions by the Office. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55.

Article 24

Extended conditions for obtaining a certificate

1. By way of derogation from Article 3(1), point (b), the Office shall adopt a positive opinion for a given plant protection product, on the basis of a centralised application, for each designated Member State where both of the following conditions are fulfilled:

   (a) at the date of that application, an authorisation to place the product on the market as a plant protection product has been applied for in accordance with Regulation (EC) No 1107/2009;

   (b) a valid authorisation was granted before the examination opinion is adopted.

2. The examination opinion shall not be adopted earlier than 18 months after the centralised application was filed, unless 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 in each of the designated Member States, at the filing date of the centralised application.

3. In respect of a designated Member State in which no authorisation was granted earlier than 18 months after the centralised application was filed, the Office shall suspend the examination proceedings, and shall resume those proceedings if and when such an authorisation is granted by the competent national authority, and is submitted to the Office by the applicant before the expiry of the basic patent.

Article 25

Observations by third parties

1. Any natural or legal person may submit written observations to the Office concerning the eligibility for supplementary protection of the product to which the application relates in one or more of the Member States designated therein.

2. A natural or legal person that has submitted the written observations in accordance with paragraph 1 shall not be a party to the proceedings.

3. Third party observations shall be submitted within 3 months after publication of the centralised application in the Register.

4. Any observations by a third party shall be submitted in writing in one of the official languages of the Union and state the grounds on which they are based.

5. Any observations by a third party shall be notified to the applicant. The applicant may comment on the observations within a time limit set by the Office.

Article 26

Opposition

1. Within a period of 2 months following the publication of the examination opinion in respect of a centralised application, any person ('opponent') may file with the Office a notice of opposition to that opinion.

2. Opposition may only be filed on the grounds that one or more of the conditions set out in Article 3 are not fulfilled for one or more of the designated Member States.

3. Opposition shall be filed in writing, and shall specify the grounds on which it is made. It shall not be considered as duly filed until the opposition fee has been paid.

4. The notice of opposition shall contain:

   (a) the references of the centralised application against which opposition is filed, the name of its holder, and the identification of the product;

   (b) the particulars of the opponent and, where applicable, of its representative;

   (c) a statement of the extent to which the examination opinion is opposed, and of the grounds on which the opposition is based.

5. The opposition shall be examined by an opposition panel set up by the Office in accordance with the rules applicable to examination panels as referred to in Article 28. However, the opposition panel shall not include any examiner previously involved in the examination panel that examined the centralised application.

6. If the opposition panel notes that the notice of opposition does not comply with paragraphs 2, 3 or 4, it shall reject the opposition as inadmissible, and communicate this to opponent, unless these deficiencies have been remedied before expiry of the opposition filing period referred to in paragraph 1.

7. The decision to reject an opposition as inadmissible shall be communicated to the holder of the centralised application, together with a copy of the notice of opposition.

A notice of opposition shall be inadmissible where a previous appeal relating to the same subject matter and cause of action has been adjudicated on its merits by the Office, and the decision of the Office on that appeal has acquired the authority of a final decision.

8. Where the opposition is not rejected as inadmissible, the Office shall promptly transmit the notice of opposition to the applicant, and shall publish it in the Register. If several notices of opposition have been filed, the Office shall promptly communicate them to the other opponents.

9. The Office shall issue a decision on the opposition within 6 months, unless the complexity of the case requires a longer period.

10. If the opposition panel considers that no ground for opposition prejudices the maintenance of the examination opinion, it shall reject the opposition, and the Office shall mention this in the Register.

11. If the opposition panel considers that at least one ground for opposition prejudices the maintenance of the examination opinion, it shall adopt an amended opinion, and the Office shall mention this in the Register.

12. The Commission is empowered to adopt delegated acts in accordance with Article 54 to supplement this Regulation by specifying the details of the procedure for filing and examining an opposition.

Article 27

Role of competent national authorities

1. On a request made to the Office, any competent national authority may be appointed by the Office as a participating office in the examination procedure. Once a competent national authority is appointed in accordance with this Article, that authority shall designate one or more examiners to be involved in the examination of one or more centralised applications.

2. The Office and the competent national authority shall conclude an administrative agreement before that competent national authority is appointed as participating office as referred to in paragraph 1.

   The agreement shall specify the rights and obligations of the parties, in particular the formal undertaking by the competent national authority concerned to comply with this Regulation as regards the centralised examination procedure.

3. The Office may appoint a competent national authority as a participating office as referred to in paragraph 1 for 5 years. That appointment may be extended for further periods of 5 years.

4. The Office shall, before appointing a competent national authority, or extending its appointment, or before any such appointment expires, hear the competent national authority concerned.

5. Each competent national authority appointed under this Article shall provide the Office with a list identifying the individual examiners who are available for participation in examination and opposition proceedings. Each such competent national authority shall update that list in the event of a change.

Article 28

Examination panels

1. The assessments under Articles 23 and 26 shall be conducted by an examination panel including one member of the Office as well as two examiners as referred to in Article 27(1) from two different participating competent national authorities.

2. Examiners shall be impartial in the exercise of their duties and shall declare to the Office any real or perceived conflict of interest upon their designation.

3. When setting up an examination panel, the Office shall ensure the following:

   (a) geographical balance amongst the participating offices;

   (b) the respective workload of the examiners is taken into account;

   (c) no more than one examiner employed by a competent national authority making use of the exemption laid down in Article 10(5).

4. The Office shall publish a yearly overview of the number of procedures, including those for examination, opposition and appeal, each competent national authority participated in.

5. The Commission is empowered to adopt implementing acts to determine the criteria in the ways the panels are to be set up, and the criteria for the selection of examiners. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55.

Article 29

Appeals

1. Any party to proceedings under this Chapter, adversely affected by a decision of the Office, including the adoption of an examination opinion, may appeal the decision to the Boards of Appeal.

2. The filing of the appeal shall have suspensive effect. A decision of the Office that has not been contested shall take effect on the day following the date of expiry of the appeal period referred to in paragraph 3.

3. Notice of appeal shall be filed in writing at the Office within 2 months of the date of notification of the decision. The notice shall be deemed to have been filed only when the fee for appeal has been paid. In case of an appeal, a written statement setting out the grounds of appeal shall be filed within 4 months of the date of notification of the decision.

4. Following an examination of admissibility of the appeal, the Boards of Appeal shall decide on the merits of the appeal.

5. Where an appeal before the Boards of Appeal of the Office results in a decision which is not in line with the examination opinion and is remitted to the Office, the decision of the Boards may annul or alter that opinion before transmitting it to the competent national authorities of the designated Member States.

6. An action may be brought before the General Court of the European Union against a decision of the Boards of Appeal in relation to appeals, within 2 months of the date of notification of that decision, on grounds of infringement of an essential procedural requirement, infringement of the Treaty on the Functioning of the European Union, infringement of this Regulation or of any rule of law relating to their application or misuse of power. The action shall be open to any party to proceedings before the Board of Appeal adversely affected by its decision. The General Court shall have jurisdiction to annul or to alter the contested decision.

7. The decisions of the Boards of Appeal shall take effect on the day following the date of expiry of the period referred to in paragraph 6 or, if an action has been brought before the General Court within that period, as from the date following the day of dismissal of such action or of dismissal of any appeal filed with the Court of Justice of the European Union against the decision of the General Court. The Office shall take the necessary measures to comply with the judgement of the General Court or, in the event of an appeal against that judgement, the Court of Justice.

8. The Commission is empowered to adopt delegated acts in accordance with Article 54 to supplement this Regulation by specifying the content and form of the notice of appeal referred to in paragraph 3, the procedure for the filing and examination of an appeal and the content and the form of the Boards of Appeal's decision referred to in paragraph 4.

Article 30

Boards of Appeal

1. In addition to the powers conferred upon it by Article 165 of Regulation (EU) 2017/1001, the Boards of Appeal instituted by that Regulation shall be responsible

for deciding on appeals against decisions of the Office taken on the basis of Article 29(1).

2. A Board of Appeal in matters regarding centralised applications for certificates shall consist of three members, at least two of whom are legally qualified. Where the Board of Appeal considers that the nature of the appeal so requires, it may call up to two further members for that case.

3. There shall be no Grand Board as referenced in Article 165 (2), (3) and 4, as well as Article 167 (2) of Regulation (EU) 2017/1001 in matters regarding centralised applications for certificates. Decisions taken by a single member as under Article 165 (2) of Regulation (EU) 2017/1001 shall not be possible.

4. Members of the Boards of Appeal in matters regarding centralised applications for certificates shall be appointed in accordance with Article 166 (5) of Regulation (EU) 2017/1001.

Article 31

Delegation of power regarding the Boards of Appeal

The Commission is empowered to adopt delegated acts in accordance with Article 54 to supplement this Regulation by specifying the details concerning the organisation of the Boards of Appeal in proceedings relating to certificates under this Regulation.

Article 32

National implementation of a centralised examination opinion

1. After the period during which an appeal or an opposition may be filed has expired without any appeal nor opposition being filed, or after a final decision on the merits has been issued, the Office shall transmit the examination opinion and its translations to the competent national authority of each designated Member State.

2. In respect of a centralised application, where a positive examination opinion has been issued for one or more designated Member State, the competent national authority of each of those Member States shall grant a certificate in accordance with applicable national rules and procedures.

3. By way of derogation from paragraph 2, a Member State may decide not to grant a certificate, where material circumstances, in that Member State, have changed since the filing of the centralised application in respect of one or more of the conditions laid down in Article 15(1), points (b) or (c), or Article 14, first paragraph, point (d). In such a case that Member State shall reject the application insofar as that Member State is concerned.

4. A certificate granted by a competent national authority under this Article shall be subject to Articles 4, 5, 11 and 12 to 18, and to the applicable national legislation.

5. Where a negative examination opinion has been issued for one or more designated Member State, the competent national authority of each of these Member States shall issue a rejection decision according to its applicable national rules and procedures.

Article 33

Fees

1. The Office shall charge a fee for a centralised application for certificates.

2. The Office shall charge a fee for an appeal, and for an opposition.

3. The Commission is empowered to adopt implementing acts to determine the amounts of the fees charged by the Office, the time limits within which they have to be paid, and the ways in which those fees are to be paid. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55.

4. Article 12 shall apply to certificates granted under this Chapter.

Article 34

Register

1. As regards centralised applications for certificates for plant protection products, the Register set up under Article 35 of Regulation [COM(2023) 231][29] shall include, for each centralised application or certificate, all of the following information:

   (a) the name and address of the applicant or certificate holder;

   (b) the name and business address of the representative, other than a representative as referred to in Article 37(3);

   (c) the application as well as its date of lodging and date of publication;

   (d) whether the application relates to a medicinal product or to a plant protection product;

   (e) the designated Member States;

   (f) the number of the basic patent;

   (g) an identification of the product for which certificates are requested;

   (h) the numbers and dates of the authorisations to place the product on the market referred to in Article 3(1), point (b), and an identification of the product identified in each of them;

   (i) the number and date of the first authorisation to place the product on the market in the Union;

   (j) the date and a summary of the examination opinion in respect of each of the designated Member States;

   (k) where applicable, the duration of the certificates to be granted;

   (l) where applicable, the filing of an opposition, and its outcome, including where applicable a summary of the revised examination opinion;

   (m) where applicable, the filing of an appeal, and the outcome of the appeal proceedings, including where applicable a summary of the revised examination opinion;

[29] Regulation of the European Parliament and of the Council on the supplementary protection certificate for medicinal products [COM(2023) 231].

(n) where applicable and available, the particulars of the certificates granted in each of the designated Member States;

(o) where applicable, a mention that the centralised application was rejected in one or more of the designated Member States;

(p) where applicable, a mention that a certificate has lapsed or was declared invalid;

(q) information on the payment of annual fees, as provided by the relevant competent national authorities.

2. The Register shall contain changes to the information referred to in paragraph 1, including transfers, each accompanied by the date of recording of such entry.

3. The Register and information referred to in paragraphs 1 and 2 shall be available in all official languages of the Union. The Office may use verified machine translation for the information to be published in the register.

4. Competent national authorities shall promptly share with the Office information relating to the grant, lapse, invalidity or transfers of certificates and to the rejection of applications under Chapters II and III, and to the payment of related annual fees.

5. The Executive Director of the Office may determine that information other than those referred to in paragraphs 1 and 2 shall be entered in the Register.

6. The Office shall collect, organise, make public and store the information referred to in paragraphs 1 and 2, including any personal data, for the purposes laid down in paragraph 8. The Office shall keep the Register easily accessible for public inspection.

7. The Office shall provide certified or uncertified extracts from the Register on request and on payment of a fee.

8. The processing of the data concerning the entries set out in paragraphs 1 and 2, including any personal data, shall take place for the purposes of:

(a) administering the applications in accordance with this Chapter and the acts adopted pursuant to it;

(b) maintaining the Register and making it available for inspection by public authorities and economic operators;

(c) producing reports and statistics enabling the Office to optimise its operations and improve the functioning of the system.

9. All the data, including personal data, concerning the entries in paragraphs 1 and 2 shall be considered to be of public interest and may be accessed by any third party free of charge. For reasons of legal certainty, the entries in the Register shall be kept for an indefinite period of time.

Article 35

Database

1. In addition to the obligation to keep a Register, the Office shall collect and store in an electronic database all the particulars provided by applicants or any other third party observations pursuant to this Regulation or acts adopted pursuant to it.

2. The electronic database may include personal data, beyond those included in the Register, to the extent that such particulars are required by this Regulation or by acts adopted pursuant to it. The collection, storage and processing of such data shall serve the purposes of:

(a) administering the applications and/or certificate registrations as described in this Regulation and in acts adopted pursuant to it;

(b) accessing the information necessary for conducting the relevant proceedings more easily and efficiently;

(c) communicating with the applicants and other third parties;

(d) producing reports and statistics enabling the Office to optimise its operations and improve the functioning of the system.

3. The Executive Director shall determine the conditions of access to the electronic database and the manner in which its contents, other than the personal data referred to in paragraph 2 of this Article but including those listed in Article 34(3), may be made available in machine-readable form, including the charge for such access.

4. Access to the personal data referred to in paragraph 2 shall be restricted and such data shall not be made publicly available unless the party concerned has given his express consent.

5. All data shall be kept indefinitely. However, the party concerned may request the removal of any personal data from the database after 18 months from the expiry of the certificate or, the case being, the closure of the relevant *inter partes* procedure. The party concerned shall have the right to obtain the correction of inaccurate or erroneous data at any time.

Article 36

Transparency

1. Regulation (EC) No 1049/2001 of the European Parliament and of the Council[30] shall apply to documents held by the Office.

2. The Management Board of the Office shall adopt detailed rules for applying Regulation (EC) No 1049/2001 in the context of this Regulation.

3. Decisions taken by the Office under Article 8 of Regulation (EC) No 1049/2001 may be challenged through the European Ombudsman or form the subject of an action before the Court of Justice of the European Union, under the conditions laid down in Articles 228 and 263 TFEU respectively.

4. The processing of personal data by the Office shall be subject to Regulation (EC) No 45/2001 of the European Parliament and of the Council[31].

[30] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

[31] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

Article 37

Representation

1. Natural or legal persons having neither their domicile nor their principal place of business or a real and effective industrial or commercial establishment in the European Economic Area shall be represented before the Office in accordance with this Article in all proceedings provided for by Chapter III of this Regulation, other than the filing of a centralised application.

2. Natural or legal persons having their domicile or principal place of business or a real and effective industrial or commercial establishment in the European Economic Area may be represented before the Office by an employee.

   An employee of a legal person may also represent other legal persons which are economically linked with the legal person being represented by that employee.

   The second subparagraph also applies where those other legal persons have neither their domicile nor their principal place of business nor a real and effective industrial or commercial establishment within the Union.

   Employees who represent natural or legal persons shall, at the request of the Office or, where appropriate, of the party to the proceedings, file with the Office a signed authorisation for insertion in the files.

3. A common representative shall be appointed where there is more than one applicant or more than one third party acting jointly.

4. Only a practitioner established in the Union, entitled to act as a professional representative in patent matters before a national patent office or the European Patent Office, or a lawyer authorised to practise before the courts or tribunals of a Member State, may represent natural or legal persons before the Office.

Article 38

Combined applications

1. A centralised application may also include a request for the grant of a unitary certificate, as defined in Regulation [COM(2023) 221][32] ('combined application').

2. The combined application shall undergo a single centralised examination procedure, as well as a single opposition or appeal procedure, where it has been filed against an opinion or decision in respect of both the centralised application and the unitary certificate application.

3. The Member States for which the basic patent has unitary effect shall not be designated in the combined application for the parallel grant of national certificates. Any designation, in the combined application, of a Member State for which the basic patent has unitary effect shall be disregarded for the purpose of the examination of the combined application.

[32] Regulation of the European Parliament and of the Council concerning the unitary supplementary protection certificate for plant protection products [COM(2023) 221].

Article 39

Supplementary Protection Certificates Division

A Supplementary Protection Certificate Division ('SPC Division') shall be set up within the Office and shall be responsible for implementing the tasks set out in Chapter III of this Regulation and in Chapter III of Regulation [COM(2023) 231], as well as in Regulations [COM(2023) 222] and [COM(2023) 221], including in particular:

(a) receiving and supervising the examination of centralised applications for certificates, appeals and observations by third parties;

(b) adopting examination opinions on behalf of the Office in relation to centralised applications for certificates;

(c) deciding on oppositions against examination opinions;

(d) maintaining the Register and the database.

Article 40

Languages

1. All documents and information sent to the Office in respect of the procedures under this Regulation shall be in one of the official languages of the Union.

2. For the tasks conferred on the Office under this Regulation, the languages of the Office shall be all the official languages of the Union in accordance with Council Regulation No 1[33].

Article 41

Communications to the Office

1. Communications addressed to the Office may be effected by electronic means. The Executive Director shall determine to what extent and under which technical conditions those communications may be submitted electronically.

2. The Commission is empowered to adopt delegated acts in accordance with Article 54 to supplement this Regulation by specifying the rules on the means of communication, including the electronic means of communication, to be used by the parties to proceedings before the Office and the forms to be made available by the Office.

Article 42

Decisions and communications of the Office

1. Decisions of the Office under this Chapter shall include examination opinions and shall state the reasons on which they are based. They shall be based only on reasons or evidence on which the parties concerned have had an opportunity to present their comments. Where oral proceedings are held before the Office, the decision may be given orally. Subsequently, the decision or opinion shall be notified in writing to the parties.

[33] Council Regulation No 1 determining the languages to be used by the European Economic Community (OJ 17, 6.10.1958, p. 385).

2. Any decision, opinion, communication or notice from the Office under this Chapter shall indicate the SPC Division and the relevant panel as well as the name or the names of the examiners responsible. It shall be signed by these examiners, or, instead of a signature, carry a printed or stamped seal of the Office. The Executive Director may determine that other means of identifying the SPC Division and the name of the examiners responsible, or an identification other than a seal, may be used where decisions or other communications are transmitted by any technical means of communication.

3. Decisions of the Office under this Chapter which are open to appeal shall be accompanied by a written communication indicating that any notice of appeal is to be filed in writing at the Office within 2 months of the date of notification of the decision in question. That communication shall also draw the attention of the parties to the provisions laid down in Article 29. The parties may not plead any failure on the part of the Office to communicate the availability of appeal proceedings.

Article 43

Oral proceedings

1. If the Office considers that oral proceedings would be expedient they shall be held either at the instance of the Office or at the request of any party to the proceedings.

2. Oral proceedings before an examination panel or opposition panel shall not be public.

3. Oral proceedings before the Boards of Appeal, including delivery of the decision and, as the case may be, of a revised opinion, shall be public, unless the Boards of Appeal decide otherwise in cases where admission of the public could have serious and unjustified disadvantages, in particular for a party to the proceedings.

4. The Commission is empowered to adopt delegated acts in accordance with Article 54 to supplement this Regulation by setting out the detailed arrangements for oral proceedings.

Article 44

Taking of evidence

1. In any proceedings before the Office, the means of giving or obtaining evidence shall include the following:

   (a) hearing the parties;

   (b) requests for information;

   (c) the production of documents and items of evidence;

   (d) hearing witnesses;

   (e) opinions by experts;

   (f) statements in writing sworn or affirmed or having a similar effect under the law of the State in which the statement is drawn up.

2. The relevant panel may commission one of its members to examine the evidence adduced.

3. If the Office or the relevant panel considers it necessary for a party, witness or expert to give evidence orally, it shall issue a summons to the person concerned to appear before it. The period of notice provided in such summons shall be at least 1 month, unless they agree to a shorter period.

4. The parties shall be informed of the hearing of a witness or expert before the Office. They shall have the right to be present and to put questions to the witness or expert.

5. The Executive Director shall determine the amounts of expenses to be paid, including advances, as regards the costs of taking of evidence as referred to in this Article.

6. The Commission is empowered to adopt delegated acts in accordance with Article 54 to supplement this Regulation by setting out the detailed arrangements for the taking of evidence.

Article 45

Notification

1. The Office shall, as a matter of course, notify those concerned of decisions, including opinions, summonses and of any notice or other communication from which a time limit is reckoned, or of which those concerned are to be notified under other provisions of this Chapter or of acts adopted pursuant to this Chapter, or of which notification has been ordered by the Executive Director.

2. Notification may be effected by different means, including electronic means. The details regarding electronic means shall be determined by the Executive Director.

3. Where notification is to be effected by public notice, the Executive Director shall determine how the public notice is to be given and shall fix the beginning of the 1-month period on the expiry of which the document shall be deemed to have been notified.

4. The Commission is empowered to adopt delegated acts in accordance with Article 54 to supplement this Regulation by setting out the detailed arrangements for notification.

Article 46

Time limits

1. Time limits shall be laid down in terms of full years, months, weeks or days. Calculation shall start on the day following the day on which the relevant event occurred. The duration of time limits shall be no less than 1 month and no more than 6 months.

2. The Executive Director shall determine, before the commencement of each calendar year, the days on which the Office is not open for receipt of documents or on which ordinary post is not delivered in the locality in which the Office is located.

3. The Executive Director shall determine the duration of the period of interruption in the case of a general interruption in the delivery of post in the Member State where the Office is located or, in the case of an actual interruption of the Office's connection to admitted electronic means of communication.

4. If an exceptional occurrence, such as a natural disaster or strike, interrupts or interferes with proper communication from the parties to the proceedings to the Office or vice-versa, the Executive Director may determine that for parties to the proceedings having their residence or registered office in the Member State concerned or who have appointed a representative with a place of business in the Member State concerned all time limits that otherwise would expire on or after the date of commencement of such occurrence, as determined by the Executive Director, shall extend until a date to be determined by the Executive Director. When determining that date, the Executive Director shall assess when the exceptional occurrence comes to an end. If the occurrence affects the seat of the Office, such determination of the Executive Director shall specify that it applies in respect of all parties to the proceedings.

5. The Commission is empowered to adopt delegated acts in accordance with Article 54 to supplement this Regulation by specifying the details regarding the calculation and duration of time limits.

Article 47

Correction of errors and manifest oversights

1. The Office shall correct any linguistic errors or errors of transcription and manifest oversights in its decisions, including opinions, or technical errors in publishing information in the Register, of its own motion or at the request of a party.

2. Where the Office has made an entry in the Register or taken a decision which contains an obvious error attributable to the Office, it shall ensure that the entry is cancelled or the decision is revoked. The cancellation of the entry in the Register or the revocation of the decision shall be effected within 1 year of the date on which the entry was made in the Register or that decision was taken, after consultation with the parties to the proceedings.

3. The Office shall keep records of any such corrections or cancellations.

4. Corrections and cancellations shall be published by the Office.

Article 48

Restitutio in integrum

1. The applicant or any other party to proceedings before the Office under this Chapter, who, in spite of all due care required by the circumstances having been taken, was unable to comply with a time limit vis-à-vis the Office shall, upon application, have his rights re-established if the obstacle to compliance has the direct consequence, by virtue of the provisions of this Chapter, of causing the loss of any right or means of redress.

2. The application for re-establishment shall be filed in writing within 2 months of the removal of the obstacle to compliance with the time limit. The omitted act shall be completed within this period. The application shall only be admissible within the year immediately following the expiry of the unobserved time limit.

3. The application for re-establishment shall state the grounds on which it is based and shall set out the facts on which it relies. It shall not be deemed to be filed until the fee for re-establishment of rights has been paid.

4. The SPC Division, or where applicable the Boards of Appeal, shall decide upon the application.

5. This Article shall not be applicable to the time limits referred to in paragraph 2 of this Article, or in Article 26(1) and (3).

Article 49

Interruption of proceedings

1. Proceedings before the Office under this Chapter shall be interrupted:

   (a) in the event of the death or legal incapacity of the applicant or of the person authorised by national law to act on behalf of the applicant. To the extent that that death or incapacity does not affect the authorisation of a representative appointed under Article 37, proceedings shall be interrupted only on application by such representative;

   (b) in the event of the applicant being prevented, for legal reasons resulting from action taken against his property, from continuing the proceedings before the Office;

   (c) in the event of the death or legal incapacity of the representative of the applicant, or of that representative being prevented, for legal reasons resulting from action taken against his property, from continuing the proceedings before the Office.

2. Proceedings before the Office shall be resumed as soon as the identity of the person authorised to continue them has been established.

3. The Commission is empowered to adopt delegated acts in accordance with Article 54 to supplement this Regulation by setting out the detailed arrangements for the resumption of proceedings before the Office.

Article 50

Costs

1. The losing party in opposition proceedings, including in related appeal proceedings, shall bear the fees paid by the other party. The losing party shall also bear all costs incurred by the other party that are essential to the proceedings, including travel and subsistence and the remuneration of a representative, within the maximum rates set for each category of costs in the implementing act to be adopted in accordance with paragraph 7. The fees to be borne by the losing party shall be limited to the fees paid by the other party in those proceedings.

2. Where each party succeeds on some and fails on other heads, or if reasons of equity so dictate, the SPC Division or Board of Appeal shall decide a different apportionment of costs.

3. Where proceedings are terminated the costs shall be at the discretion of the SPC Division or Board of Appeal.

4. Where the parties conclude before the SPC Division or Board of Appeal a settlement of costs differing from that provided for in paragraphs 1 to 3, the body concerned shall take note of that agreement.

5. The SPC Division or Board of Appeal shall fix the amount of the costs to be paid pursuant to paragraphs 1 to 3 of this Article when the costs to be paid are limited to the fees paid to the Office and the representation costs. In all other cases, the registry of the Board of Appeal or SPC Division shall fix, on request, the amount of the costs to be reimbursed. The request shall be admissible only for the period of 2 months following the date on which the decision for which an application was made for the costs to be fixed becomes final and shall be accompanied by a bill and supporting evidence. For the costs of representation an assurance by the representative that the costs that have been incurred shall be sufficient. For other costs, it shall be sufficient if their plausibility is established. Where the amount of the costs is fixed pursuant to the first sentence of this paragraph, representation costs shall be awarded at the level laid down in the implementing act adopted pursuant to paragraph 7 of this Article and irrespective of whether they have been actually incurred.

6. Decisions on the fixing of costs adopted in accordance with paragraph 5 shall state the reasons on which they are based, and may be reviewed by a decision of the SPC Division or Board of Appeal on a request filed within 1 month of the date of notification of the awarding of costs. It shall not be deemed to be filed until the fee for reviewing the amount of the costs has been paid. The SPC Division or the Board of Appeal, as the case may be, shall take a decision on the request for a review of the decision on the fixing of costs without oral proceedings.

7. The Commission shall adopt implementing acts specifying the maximum rates for costs essential to the proceedings and actually incurred by the successful party. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55.

8. When specifying the maximum rates with respect to travel and subsistence costs, the Commission shall take into account the distance between the place of residence or business of the party, representative or witness or expert and the place where the oral proceedings are held, the procedural stage at which the costs have been incurred, and, as far as costs of representation are concerned, the need to ensure that the obligation to bear the costs may not be misused for tactical reasons by the other party. In addition, subsistence expenses shall be calculated in accordance with the Staff Regulations of Officials of the Union and the Conditions of Employment of Other Servants of the Union, laid down in Council Regulation (EEC, Euratom, ECSC) No 259/68[34]. The losing party shall bear the costs for one party in the proceedings only and, where applicable, one representative only.

Article 51

Enforcement of decisions fixing the amount of costs

1. Any final decision of the Office fixing the amount of costs shall be enforceable.

2. Enforcement shall be governed by the rules of civil procedure in force in the Member State in the territory of which it is carried out. Each Member State shall designate a single authority responsible for verifying the authenticity of the decision referred to

[34] Regulation (EEC, Euratom, ECSC) No 259/68 of the Council of 29 February 1968 laying down the Staff Regulations of Officials and the Conditions of Employment of Other Servants of the European Commission and instituting special measures temporarily applicable to officials of the Commission (OJ L 56, 4.3.1968, p. 1.)'

in paragraph 1 and shall communicate its contact details to the Office, the Court of Justice and the Commission. The order for enforcement shall be appended to the decision by that authority, with the verification of the authenticity of the decision as the sole formality

3. When these formalities have been completed on application by the party concerned, the latter may proceed to enforcement in accordance with the national law, by bringing the matter directly before the competent authority.

4. Enforcement may be suspended only by a decision of the Court of Justice. However, the courts of the Member State concerned shall have jurisdiction over complaints that enforcement is being carried out in an irregular manner.

Article 52

Financial provisions

1. The expenses incurred by the Office in carrying out the additional tasks given to it in accordance with this Regulation shall be covered by the procedural fees to be paid to it by applicants and, if needed, by a fraction of the annual fees paid to competent national authorities by the holders of certificates granted under this Chapter. That fraction shall initially be set at a certain value but shall be reviewed every 5 years, with the objective of achieving financial sustainability for the activities carried out by the Office under this Regulation as well as Regulations [COM(2023) 231], [COM(2023) 222] and [COM(2023) 221], insofar as expenses incurred by the Office are not covered by fees under these Regulations.

2. For the purposes of implementing paragraph 1, each competent national authority shall keep an account of the annual fees paid to it by holders of certificates granted under this Chapter.

3. The expenses incurred by a competent national authority participating in proceedings under this Chapter shall be covered by the Office and shall be paid annually, on the basis of the number of proceedings in which that competent national authority was involved during the preceding year.

4. The Commission is empowered to adopt implementing acts laying down rules on the financial transfers between the Office and Member States, the amounts of these transfers, and the remuneration to be paid by the Office regarding the participation of competent national authorities referred to in paragraph 3. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55.

↓ 1610/96 (adapted)

~~TRANSITIONAL PROVISIONS~~

~~Article 19~~

~~1. Any product which, on the date on which this Regulation enters into force, is protected by a valid basic patent and for which the first authorization to place it on the market as a plant protection product in the Community was obtained after 1 January 1985 under Article 4 of Directive 91/414/EEC or an equivalent national provision may be granted a certificate.~~

~~2. An application made under paragraph 1 for a certificate shall be submitted within six months of the date on which this Regulation enters into force.~~

↓ 2003 Act of Accession (adapted)

~~*Article 19a*~~

~~*Provisions relating to the enlargement of the Community*~~

~~Without prejudice to the other provisions of this Regulation, the following shall apply:~~

~~(a)~~

~~(1) (i) any plant protection product protected by a valid basic patent in the Czech Republic and for which the first authorisation to place it on the market as a plant protection product was obtained in the Czech Republic after 10 November 1999 may be granted a certificate, provided that the application for a certificate was lodged within six months of the date on which the first market authorisation was obtained,~~

~~(2) (ii) any plant protection product protected by a valid basic patent in the Czech Republic and for which the first authorisation to place it on the market as a plant protection product was obtained in the Community not earlier than six months prior to the date of accession may be granted a certificate, provided that the application for a certificate was lodged within six months of the date on which the first market authorisation was obtained;~~

~~(b) any plant protection product protected by a valid basic patent and for which the first authorisation to place it on the market as a plant protection product was obtained in Estonia prior to the date of accession may be granted a certificate, provided that the application for a certificate was lodged within six months of the date on which the first market authorisation was obtained or, in the case of those patents granted prior to 1 January 2000, within the six month period provided for in the Patents Act of October 1999;~~

~~(c) any plant protection product protected by a valid basic patent and for which the first authorisation to place it on the market as a plant protection product was obtained in Cyprus prior to the date of accession may be granted a certificate, provided that the application for a certificate was lodged within six months of the date on which the first market authorisation was obtained; notwithstanding the above, where the market authorisation was obtained before the grant of the basic patent, the application for a certificate must be lodged within six months of the date on which the patent was granted;~~

~~(d) any plant protection product protected by a valid basic patent and for which the first authorisation to place it on the market as a plant protection product was obtained in Latvia prior to the date of accession may be granted a certificate. In cases where the period provided for in Article 7(1) has expired, the possibility of applying for a certificate shall be open for a period of six months starting no later than the date of accession;~~

~~(e) any plant protection product protected by a valid basic patent applied for after 1 February 1994 and for which the first authorisation to place it on the market as a~~

~~plant protection product was obtained in Lithuania prior to the date of accession may be granted a certificate, provided that the application for a certificate is lodged within six months of the date of accession;~~

~~(f) any plant protection product protected by a valid basic patent and for which the first authorisation to place it on the market as a plant protection product was obtained after 1 January 2000 may be granted a certificate in Hungary, provided that the application for a certificate is lodged within six months of the date of accession;~~

~~(g) any plant protection product protected by a valid basic patent and for which the first authorisation to place it on the market as a plant protection product was obtained in Malta prior to the date of accession may be granted a certificate. In cases where the period provided for in Article 7(1) has expired, the possibility of applying for a certificate shall be open for a period of six months starting no later than the date of accession;~~

~~(h) any plant protection product protected by a valid basic patent and for which the first authorisation to place it on the market as a plant protection product was obtained after 1 January 2000 may be granted a certificate in Poland, provided that the application for a certificate is lodged within six months starting no later than the date of accession;~~

~~(i) any plant protection product protected by a valid basic patent and for which the first authorisation to place it on the market as a plant protection product was obtained in Slovenia prior to the date of accession may be granted a certificate, provided that the application for a certificate is lodged within six months of the date of accession, including in cases where the period provided for in Article 7(1) has expired;~~

~~(j) any plant protection product protected by a valid basic patent and for which the first authorisation to place it on the market as a plant protection product was obtained in Slovakia after 1 January 2000 may be granted a certificate, provided that the application for a certificate was lodged within six months of the date on which the first market authorisation was obtained or within six months of 1 July 2002 if the market authorisation was obtained before that date;~~

↓ 2005 Act of Accession (adapted)

~~(k) any plant protection product protected by a valid basic patent and for which the first authorisation to place it on the market as a plant protection product was obtained after 1 January 2000 may be granted a certificate in Bulgaria, provided that the application for a certificate is lodged within six months of the date of accession;~~

~~(l) any plant protection product protected by a valid basic patent and for which the first authorisation to place it on the market as a plant protection product was obtained after 1 January 2000 may be granted a certificate in Romania. In cases where the period provided for in Article 7(1) has expired, the possibility of applying for a certificate shall be open for a period of six months starting no later than the date of accession;~~

↓ 2012 Act of Accession (adapted)

~~(m) any plant protection product protected by a valid basic patent and for which the first authorisation to place it on the market as a plant protection product was obtained after 1 January 2003 may be granted a certificate in Croatia, provided that the application for a certificate is lodged within six months from the date of accession.~~

↓ 1610/96 (adapted)

Article ~~20~~53

⌦ Transitional provisions ⌫

↓ 2003 Act of Accession (adapted)

~~1. In those Member States whose national law did not, on 1 January 1990, provide for the patentability of plant protection products, this Regulation shall apply from 2 January 1998. Article 19 shall not apply in those Member States.~~

↓ 2012 Act of Accession (adapted)

~~2.~~ This Regulation shall apply to ~~supplementary protection~~ certificates granted in accordance with the national legislation of ⌦ Czechia ⌫ ~~the Czech Republic~~, Estonia, Croatia, Cyprus, Latvia, Lithuania, Malta, Poland, Romania, Slovenia and Slovakia prior to their respective date of accession.

⇩ new

CHAPTER IV
FINAL PROVISIONS

Article 54

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Articles 26(13), 29(8), 31, 41(2), 43(4), 44(6), 45(4), 46(5) and 49(3) shall be conferred on the Commission for an indeterminate period of time from the date of entry into force of this Regulation.

3. The delegation of power referred to in Articles 26(13), 29(8), 31, 41(2), 43(4), 44(6), 45(4), 46(5) and 49(3) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect on the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Articles 26(13), 29(8), 31, 41(2), 43(4), 44(6), 45(4), 46(5) and 49(3) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 55

Committee procedure

1. The Commission shall be assisted by a Committee on Supplementary Protection Certificates established by Regulation [COM(2023) 231]. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Article 56

Evaluation

By *[OP, please insert: five years after the date of application]*, and every five years thereafter, the Commission shall carry out an evaluation of the application of Chapter III.

↑

Article 57

Repeal

Regulation (EC) No 1610/96 is repealed.

References to the repealed Regulation shall be construed as references to this Regulation and read in accordance with the correlation table in Annex II.

↓ 1610/96 (adapted)

Article ~~21~~58

Entry into force ⌦ and application ⌫

This Regulation shall enter into force on the ⌦ twentieth day following that of⌫ ~~sixth month after~~ its publication in the *Official Journal of the European* ~~Communities~~ ⌦ *Union* ⌫.

⇩ new

Articles 19 to 52, 54 to 56 shall apply from *[OP: please insert: the first day of the 12th month after the entry into force]*.

↓ 1610/96

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

Council of the European Union

Brussels, 28 April 2023
(OR. en)

8894/23

Interinstitutional File: 2023/0130(COD)

PI 56
PHARM 68
COMPET 385
MI 353
IND 207
IA 89
CODEC 748

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	27 April 2023
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2023) 231 final
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the supplementary protection certificate for medicinal products (recast)

Delegations will find attached document COM(2023) 231 final.

Encl.: COM(2023) 231 final

EUROPEAN
COMMISSION

Brussels, 27.4.2023
COM(2023) 231 final

2023/0130 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the supplementary protection certificate for medicinal products (recast)

(Text with EEA relevance)

{SEC(2023) 172 final} - {SWD(2023) 117 final} - {SWD(2023) 118 final} -
{SWD(2023) 119 final}

EXPLANATORY MEMORANDUM

CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

Supplementary protection certificates (SPCs) are *sui generis* intellectual property (IP) rights that extend the 20-year term of patents for medicinal or plant protection products (PPPs) by up to 5 years[1]. They aim to offset the loss of effective patent protection due to the compulsory and lengthy testing required in the EU for the regulatory marketing authorisation of these products.

The unitary patent will enter into force on 1 June 2023, allowing for a single patent that covers all participating Member States in a unitary manner[2].

This proposal aims to simplify the EU's SPC system as regards national SPCs for medicinal products, as well as improve its transparency and efficiency. This initiative was announced in the Commission work programme for 2022 as initiative number 16 under Annex II (REFIT initiatives)[3].

Regulation (EC) No 469/2009 provides for SPCs for medicinal products (both human and veterinary medicinal products) to be granted at a national level on the basis of national applications, on a country-by-country basis. Similarly, Regulation (EC) No 1610/96 provides for SPCs for plant protection products. Together these two measures constitute the EU's SPC regime. As Regulation (EC) No 469/2009 has been amended several times, and since further amendments are to be made, that Regulation should, in the interest of clarity, be recast, which is the **first objective of this proposal** (and of the parallel proposal on PPPs (COM(2023) 223).

As confirmed by the evaluation carried out in 2020 (SWD(2020)292 final), today's purely national procedures for granting SPCs involve separate examination proceedings (in parallel or subsequent) in Member States. This entails duplication of work, resulting in high costs and more often discrepancies between Member States in decisions to grant or refuse SPCs including in litigation before national courts. Inconsistency between Member States in decisions to grant or refuse SPCs is the single reason most often cited by national courts for preliminary references to the Court of Justice of the European Union on the application of the EU's SPC regime. The current purely national procedures, therefore, lead to significant legal uncertainty.

The Commission's intellectual property action plan of November 2020 (COM(2020) 760 final), which builds on the SPC evaluation, highlighted the need to tackle the remaining fragmentation of the EU's intellectual property system. The plan noted that, for medicinal

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1 An additional 6-month period of protection is available, subject to specific conditions, for medicinal products for use in the paediatric population, as defined by Regulation (EC) 1901/2006.

2 The unitary patent (UP) is a legal title that will provide uniform protection across all participating countries on a one-stop-shop basis. As of April 2023, 17 Member States are expected to participate in the UP system. For updates and more information, see: https://ec.europa.eu/growth/industry/strategy/intellectual-property/patent-protection-eu/unitary-patent_en.

3 European Commission, Annexes to Commission communication – Commission work programme 2022, COM(2021) 645 final, 2021, p. 9 (https://eur-lex.europa.eu/resource.html?uri=cellar%3A9fb5131e-30e9-11ec-bd8e-01aa75ed71a1.0001.02/DOC_2&format=PDF#page=9).

products and PPPs, SPC protection is only available at national level. At the same time, there is a centralised procedure for granting European patents and a centralised procedure for obtaining marketing authorisations for medicinal products. In the same vein, the pharmaceutical strategy for Europe (COM(2020) 761 final) emphasised the importance of investing in R&D to create innovative medicines. The strategy stressed, however, that the differences between Member States in the implementation of intellectual property regimes, especially for SPCs, lead to duplications and inefficiencies that affect the competitiveness of the pharmaceutical industry. Both the Council[4] and the European Parliament[5] have called on the Commission to correct these deficiencies.

Therefore, a **second objective of this proposal** is to introduce a centralised procedure for granting SPCs for medicinal products. This would allow applicants to obtain SPCs in the respective designated Member States subject to marketing authorisations having been granted in/for each of them, by filing a single 'centralised SPC application' that would undergo a single centralised examination procedure.

While that examination would be conducted by a centralised authority, the actual grant of SPCs would be done by the respective national offices of the designated Member States, based on a positive opinion from the central examination authority. The opinion of the central examination authority would be binding upon the national offices of the designated Member States.

A parallel proposal (COM(2023) 223), with similar provisions to this one for medicinal products[6], concerns SPCs for PPPs.

- **Consistency with existing policy provisions in the policy area**

The core substantive features of the proposed centralised procedure – i.e. the conditions for obtaining certificates, as well as their legal effect – are the same as those of the existing SPC regime. This proposal introduces new procedural provisions as regards the centralised examination and is not intended to modify the scope nor the effect of the rights conferred by national SPCs currently granted according to Regulation (EC) No 469/2009. The same new procedural provisions are also inserted in the above-mentioned parallel proposal on SPCs for PPPs (COM(2023) 223).

At the same time, parallel proposals are being made to create unitary certificates for medicinal products (cf. COM(2023) 222) and for PPPs (cf. COM(2023) 221). Applications for these unitary certificates would undergo the same centralised examination procedure described in this proposal, especially in the event of 'combined' applications that request both a unitary certificate and national certificates, as explained below. This ensures complete consistency across the whole SPC reform package.

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4 Council conclusions on intellectual property policy of 10 November 2020 https://www.consilium.europa.eu/media/46671/st-12750-2020-init.pdf.

5 European Parliament, Committee on Legal Affairs, Report on an intellectual property action plan to support the EU's recovery and resilience (2021/2007(INI)), https://www.europarl.europa.eu/doceo/document/A-9-2021-0284_EN.html.

6 Human and veterinary medicinal products.

This table explains the purposes of the four related proposals:

Medicinal products		**Plant protection products**
PROPOSAL 1 Regulation on the SPC for medicinal products (recast)	← Art. 114 TFEU →	**PROPOSAL 2** Regulation on the SPC for plant protection products (recast)
PROPOSAL 3 Regulation on the unitary SPC for medicinal products	← Art. 118 TFEU →	**PROPOSAL 4** Regulation on the unitary SPC for plant protection products

Moreover, it should be noted that nothing will prevent national SPCs as defined in Regulation (EC) No 469/2009 and in Chapter II of this proposal from being granted on the basis of a unitary patent as the basic patent.

Finally, this proposal is part of the 'EU patent package' announced in 2023 which, besides the revision, modernisation and introduction of a system for unitary supplementary protection certificates, includes a new initiative on compulsory licensing and legislation on standard-essential patents. The proposal also complements the unitary patent system, which is a major step towards the completion of the single market for patents.

- **Consistency with other Union policies**

The COVID-19 pandemic has underlined the importance of having a strong and balanced IP system to provide the necessary incentives to develop new treatments and vaccines that patients will have access to. It has also highlighted the need for transparent and easily accessible information on the status of IP rights, including SPCs, to facilitate potential collaborations, licensing and freedom-to-operate analyses[7]. Patents and SPCs are key to supporting the EU in its efforts to build a European Health Union and to other related initiatives such as the new European Health Emergency Preparedness and Response Authority (HERA)[8], EU FAB[9] and the pharmaceutical strategy for Europe.

The proposed centralised procedure is therefore fully consistent with the existing pharmaceutical legislation and with other relevant legislation, in particular the European patent with unitary effect ('unitary patent') as set out in Regulation (EU) No 1257/2012, and the related Agreement on a Unified Patent Court (UPCA). The unitary patent system will enter into force on 1 June 2023.

In addition, this proposal is fully compatible with Regulation (EC) No 1901/2006 on medicinal products for paediatric use, which provides for a possible 'paediatric extension' of SPCs for medicinal products under specific conditions.

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7 Discussions in this regard have been taken to the World Intellectual Property Organisation (WIPO), where national/regional patent offices were invited to share information on their collaborations with publicly accessible databases of patent status information concerning medicines and vaccines, such as MedsPaL. See: WIPO, Standing Committee on the Law of Patents, 32nd session, SCP/32/7, 2020.

8 European Commission, Commission Communication – HERA Incubator: Anticipating together the threat of COVID-19 variants, COM/2021/78, 2021.

9 European Commission, 'Questions and answers : HERA incubator – Anticipating together the threat of COVID-19 variants', 2021 (https://ec.europa.eu/commission/presscorner/detail/en/qanda_21_642).

Moreover, this proposal complements the pharmaceutical strategy for Europe and its intention to promote both innovation in medicines and better access to them, including the related legislative changes that are contemplated as regards regulatory protections (*[OP, please add a reference to the ongoing reform of the pharmaceutical legislation]*).

Finally, the SPC reform and the other initiatives listed in the intellectual property action plan contribute to the broader innovation strategy of the EU.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

• Legal basis

This proposal is based on Article 114(1) of the Treaty on the Functioning of the European Union on the single (or 'internal') market. This is the same legal basis used for Regulations (EC) No 469/2009 and (EC) No 1610/96 (previously Articles 100a, and then 95, respectively, of the Treaty establishing the European Community, as it then was). It is once again necessary to have recourse to Article 114 to adapt the EU SPC regime in the light of how the existing system has been applied. Even though SPCs are already harmonised, there are still cases where some Member States have granted SPCs while identical applications have been refused in others or been granted with a different scope. SPC applicants thus face diverging decisions across the EU on the same product, while incurring costs for applying and maintaining SPCs in several Member States. Consequently, further EU action is needed to address these issues and can, unlike national intervention by Member States, ensure a consistent EU-wide framework, and reduce the total costs and burden of fees to be paid in multiple Member States. Further EU-level action would strengthen the integrity of the single market by providing a centralised, balanced and transparent SPC system across the EU, and mitigate the negative consequences of redundant and potentially diverging procedures that applicants face[10]. Hence, by its nature, action at EU level is also justified to ensure the smooth functioning of the single market for innovative medicinal products that are subject to marketing authorisations. EU-level action would also allow innovative and follow-on manufacturers to reap the benefits of an efficient intellectual property framework in the relevant product markets.

• Subsidiarity

The objectives underlying the proposal can only be achieved at Union level. The Union-wide approach implemented by the centralised procedure envisaged in this proposal will ensure that the applicable rules and procedures are consistent across the Union, ensuring legal certainty for all relevant market participants.

• Proportionality

This initiative does not go beyond what is necessary to achieve the identified objectives. Its scope is limited to those aspects that Member States cannot achieve satisfactorily on their own and where EU action can produce better results, e.g. in terms of consistent decisions on SPC applications to reduce administrative burdens and costs, and improve transparency and legal certainty.

[10] Case C-58/08 ECLI:EU:C:2010:321.

- **Choice of the instrument**

As the current SPC legislation is only governed by regulations, no other instrument can be envisioned for recasting the existing EU SPC legislation (Regulations (EC) No 469/2009 and (EU) No 2019/933) and introducing a centralised procedure.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Ex-post evaluations and fitness checks of existing legislation**

An evaluation of the SPC regime was carried out in 2020 (SWD(2020) 292). It found that SPCs promote innovation and the availability of new medicines and PPPs because they help companies recoup their R&D investments. Although the SPC Regulations provide a common framework within the EU, they are administered at national level. This fragmentation leads to high costs and imposes an administrative burden on applicants (especially SMEs) and national administrations. It also leads to legal uncertainty, as the scope of protection can differ across the EU. This has a negative impact on SPC users and makers of generics. These negative effects are amplified by a lack of transparency, especially from a cross-border perspective, making it difficult to trace what SPC protection exists for which products in which Member States. This affects both SPC holders and generics manufacturers.

An evaluation of the SPC manufacturing waiver, which is an exception introduced by Regulation (EU) 2019/933, which amended Regulation (EC) No 469/2009, and is included in this proposal, will be undertaken in the near future (as foreseen in Article 21a of Regulation (EC) No 469/2009).

- **Stakeholder consultations**

The Commission conducted a public consultation during the evaluation of the SPC regime (between 12 October 2017 and 4 January 2018)[11]. In addition, the Max Planck Institute study mentioned below included a survey of stakeholders in the Member States, conducted in 2017 by the Allensbach Institute ('the Allensbach survey'), which included several questions on the operation of the current (national) SPC regimes. Moreover, from 8 March to 5 April 2022 interested parties could provide feedback to Commission's Call for Evidence. For further information, see Annex 2 of the impact assessment (SWD(2023) 118).

- **Collection and use of expertise**

The study[12] carried out in 2018 by the Max Planck Institute on the legal aspects of SPCs in the EU (especially Chapter 22) provides key findings on the operation of the current SPC regime (for medicinal products). The additional Max Planck Institute study completed in 2022[13] provides a deeper analysis of the design of a centralised procedure.

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11 https://ec.europa.eu/docsroom/documents/29464

12 https://ec.europa.eu/docsroom/documents/29524

13 https://op.europa.eu/en/publication-detail/-/publication/94cb20ea-2ff0-11ed-975d-01aa75ed71a1/language-en

- **Impact assessment**

An impact assessment was carried out and submitted to the Regulatory Scrutiny Board in late 2022 and, after resubmission, received a positive opinion on 16 December 2022 (SWD(2023) 118).

The following options were identified:

– Option 0: No policy change.

– Option 1: Guidelines for the application of the current SPC regimes. This option would provide common guidelines/recommendations to national patent offices (NPOs) on the application of the SPC Regulation, building on their experience and the case law of the Court of Justice of the European Union (CJEU). These guidelines would also recommend common rules for the publication and accessibility of SPC information in national registers.

– Option 2: Mutual recognition of national decisions. This would enable applicants to file an SPC application with a designated NPO, known as the reference office, whose decision would be recognised by all other NPOs.

– Option 3: Centralised filing and examination of SPC applications, resulting in a non-binding opinion. This would create a central authority for filing SPC applications in the EU, which would examine applications and issue an opinion on whether or not to grant an SPC. NPOs could follow this opinion or, alternatively, conduct their own examination. Therefore, the decision on granting SPC protection would be kept at the national level. Only holders of a European patent – and, for medicinal products, of a centralised marketing authorisation – could use this system.

– Option 4: Centralised filing and examination of SPC applications, resulting in a binding opinion. This is identical to option 3, 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 a central authority.

– Option 5: A 'unitary SPC' complementing the unitary patent. The central authority, in addition to examining applications, would grant a 'unitary SPC' to applicants with a European patent with unitary effect. The unitary SPC would be valid only in the territory of the (initially 17) Member States party to the UPCA.

These options would not replace national SPCs, but would provide alternative routes to obtaining SPC protection across the EU.

A combination of options 4 and 5 constitutes the preferred choice. It would provide for a centralised procedure that could result in the grant of national SPCs in some or all Member States, and/or of a unitary SPC (covering those Member States in which the basic unitary patent has effect). When deciding on who should act as the examination authority, several criteria were considered: accountability (in particular, to the European Parliament), alignment with the EU's overarching political values and current policy priorities, and experience with substantive SPC assessment. It is therefore proposed that the EU Intellectual Property Office (EUIPO) should become the central examination authority, supported by national offices.

Option 1, on guidelines for examining national SPC applications, would not be sufficient alone to overcome discrepancies between national practices, as the guidance would be non-binding. Nevertheless, in the context of the preferred options 4 and 5, EUIPO should develop guidelines that reflect its practice. These guidelines would be of practical use both to officials in charge of the SPC-related procedures and to their users, including professional advisers

who assist applicants (e.g. by offering examples). This guidance would take stock of the practices developed by the examination panels, especially since they will include examiners from several different Member States, to improve consistency between examination practices under the new centralised procedure. Moreover, national offices may also benefit from guidelines developed by the examination authority for their own (national) examination procedures.

Option 2 may not provide enough predictability, as some reference offices could be more lenient than others, thus leading to 'forum shopping', while Option 3 alone would allow offices to re-examine the SPC application, and has thus the potential to result in divergences on the decision to grant or refuse an SPC, leading to further fragmentation in the single market.

- **Regulatory fitness and simplification**

Enabling holders of European patents to obtain several (national) SPCs across the EU through a centralised procedure would represent a considerable simplification compared to the current situation in which national SPCs need to be applied for and granted separately in each Member State. The proposed new centralised procedure is expected to result in significant reductions in costs and administrative burden for applicants, and in improved legal certainty and transparency, including for third parties (e.g. makers of generics).

In addition, as regards medicinal products, this proposal will result in a single SPC Regulation instead of three, as would have resulted from proposing the creation of a centralised procedure through a stand-alone Regulation while leaving the existing Regulation (EC) No 469/2009 (as amended by Regulation (EU) 2019/933) unaffected. In other words, this proposal – that will recast and repeal Regulation (EC) No 469/2009, which was amended by Regulation (EU) No 2019/933 – will achieve a 'one in, two out' outcome.

- **Fundamental rights**

This proposal will have no impact on fundamental rights, especially since it is not proposed to alter the substantive features of the existing SPC regimes (e.g. conditions for grant, scope, effects). The initiative is consistent with the Charter of Fundamental Rights as it offers greater legal certainty to applicants for the grant of an intellectual property right and where necessary for third parties, by providing for the procedural conditions for the examination, opposition and appeal before the centralised authority.

In particular, where a centralised examination opinion is negative, the applicant may file an appeal before the Boards of Appeal of the EUIPO. Oppositions to applications may also be filed by third parties.

In addition, a national office may decide to not grant an SPC, despite a positive examination opinion, in certain narrowly defined situations, namely where material circumstances in that Member State have changed since the filing of the centralised application (such as the basic patent being no longer in force). Moreover, examiners from national offices will play a key role in the centralised examination procedure and participate in the substantive examination of the application, as well as may take part in opposition proceedings.

On the other hand, third parties will be able to submit observations during the examination of a centralised application, and to initiate an opposition against an examination opinion. Where national SPCs are granted by national offices on the basis of a positive opinion, third parties will also be able to challenge their validity before the respective national courts or other competent bodies, as already possible today pursuant to Regulation (EC) No 469/2009.

As further explained below under 'Basic patent', legal certainty concerns call for closing the national route when SPC protection is sought for a given product, where the conditions are fulfilled for the centralised procedure – i.e., in such a case, the filing of separate national applications before national offices should be prohibited. This is intended to avoid divergences between national decisions as such divergences would be avoided by using the centralised procedure, and to prevent users from filing national SPC applications only before national offices whose examination practice is less rigorous. This practice is akin to forum shopping and undermines the SPC system. Applicants may seek to file weak applications at national level in the hope of receiving SPCs from more lenient offices.

Conversely, as further explained below under 'Unitary SPC', this proposal does not exclude centralised SPC applications designating one or more Member States participating in the unitary patent system, potentially resulting in national SPCs being granted in these Member States, as long as double protection is excluded, even where the conditions are met for the grant of a unitary SPC.

A comparison of these two proposed measures does not show any unjustified difference of treatment. Indeed, there may be cases where an applicant, while holding a unitary patent, has no interest in obtaining SPCs in all the Member States which that patent covers, and therefore that applicant should not be forced to apply for a unitary SPC, even if the conditions thereof were fulfilled. On the other hand, the closing of the national route for the centralised procedure never creates an obligation to designate all Member States for which the centralised procedure can be used in given circumstances, as the applicant is free to choose which Member States should be designated.

4. BUDGETARY IMPLICATIONS

This proposal will have no impact on the EU budget, since the system will remain fully self-funded by applicants' fees, as is already the case for the existing SPCs regimes governed by Regulations (EC) No 469/2009 and (EC) No 1610/96, and will be implemented by the examination authority, the EUIPO. The necessary set-up costs of the tasks conferred to the EUIPO, including the costs of new digital systems, will be financed from the EUIPO's accumulated budgetary surplus. A breakdown of the budgetary impact on the examination authority is provided in Annex 5D of the impact assessment.

The financial impacts on Member States (national offices) will also remain low. Indeed, while the number of SPCs applied for each year is likely to increase, it is quite low for the time being, even in large Member States. For instance, in 2017, 70 SPC applications were filed in Germany and 72 in France. The largest number of applications (95) were filed in Ireland. The average cost varies by country. Based on current average coverage (20 Member States) and duration (3.5 years), SPC protection for a given product would cost around EUR 98 500 on average. In order to cover all 27 Member States for 5 years one would pay nearly EUR 192 000 in total (not including any fees charged by patent lawyers). For a breakdown of the costs, see Annex 5B of the impact assessment (SWD(2023) 118).

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

It is envisaged that an evaluation will be carried out every 5 years.

- **Detailed explanation of the specific provisions of the proposal**

Overall structure of the proposal

Chapter I of the proposal includes definitions and other general provisions.

Chapter II of the proposal includes most of the existing provisions of Regulation (EC) No 469/2009 regarding national applications for certificates, filed at national offices[14] (as amended by Regulation (EU) 2019/933), without changing their substance, except for minor technical adaptations that bring the recast regulation up to current drafting standards and ensure better alignment with certain provisions of the corresponding proposal on plant protection products (COM(2023) 223), derived from Regulation (EC) No 1610/96.

Chapter III includes new provisions defining the new centralised procedure.

Chapter IV contains final provisions, including the repeal of Regulation (EC) No 469/2009.

Basic patent

The existing SPC Regulations do not impose any limitation on the types of ('basic') patents on which a national SPC application must rely, which may thus be: (1) a national patent resulting from either a national patent application or from a European patent application; or (2) a unitary patent (a 'European patent with unitary effect'). To remove any residual legal uncertainty, the option to rely on this second type of patent will be clarified through minor amendments, in the recitals of this proposal, that explicitly refer to unitary patents. In this respect it should be noted that paragraph 21 of the explanatory memorandum of the first proposal for a Council Regulation concerning the creation of a supplementary protection certificate for medicinal products (COM(90)101) envisaged that '*when use is made of the European procedure to obtain a Community patent, it will likewise be necessary that the certificate can apply equally to medicinal products protected by a Community patent*' (now referred to as a 'European patent with unitary effect' or, more informally, a 'unitary patent').

It is proposed that applications for SPCs filed under the new centralised procedure (Chapter III of this proposal) must be based on European patents only as 'basic patents', including a European patent with unitary effect. This will facilitate the examination of centralised SPC applications because the filing and examination of a European patent application, if positive, results in the grant of a European patent having, with a few exceptions, identical claims for all designated countries, which is required for unitary patents.

Moreover, today most inventions, and in particular medicinal products, patented in the EU are protected by European patents, which are granted only as the result of a thorough examination procedure, and not by national patents, which in several Member States are not subject to an in-depth substantive examination.

Therefore, under the proposed centralised procedure, allowing centralised SPC applications to be based on national patents would be more demanding as regards the examination of such applications, as it would be necessary to examine separately, for each of the designated Member States, whether the product concerned is indeed protected by each of the respective national patents in force, which will not necessarily have the same claims. This may also affect legal certainty.

[14] More precisely, filed with the competent industrial property office of the Member State concerned, unless another authority was designated for that purpose.

A requirement that the claims of the basic (European) patent must be identical for all Member States designated in a centralised SPC application would make it easier to examine the application. However, the cases where a European patent includes two or more sets of claims for different Member States are quite rare, and it is very exceptional that there are more than two sets of claims. For this reason, this proposal does not include a requirement that the claims of the basic patent must be identical for all Member States designated in a centralised SPC application.

In those situations where a centralised application could be filed, namely where the basic patent is a European patent and the marketing authorisation is a centralised one, the choice could have been made to also allow applicants to file national SPC applications. Based on the findings of the evaluation completed in 2020, which revealed discrepancies between the granting practices of various national offices, this might have resulted, however, in applicants applying for certificates in Member States with less strict examination standards, to avoid filing a centralised application that may be rejected due to a stricter examination. Such a situation would be detrimental to consistency and legal certainty, could promote forum shopping, and would result in a higher total workload across the EU from examining applications. To avoid these drawbacks, it is considered preferable to examine applications under the centralised procedure in all cases where the conditions for using this procedure are met. Accordingly, this proposal requires that a national SPC application, filed in a Member State, be rejected where the requirements for filing a centralised application are fulfilled (‘closing of the national route’).

Examination/granting authority

Under the proposed centralised procedure, a central examination authority will carry out a substantive examination of a centralised SPC application, especially as regards the conditions for grant defined in Article 3 of the existing SPC Regulations. The Commission proposes that the EUIPO should be the central examination authority, in particular because it is an EU agency and therefore part of the EU legal order.

After assessing the formal admissibility of the centralised SPC application, the central examination authority would entrust the substantive examination of the application to a panel. This panel would be made up of a member of that central authority and two qualified examiners, experienced in SPC matters, from two different national patent offices in Member States. Before designating examiners qualified to examine SPC issues, these national patent offices will have agreed, through an ad hoc agreement with the central examination authority, to participate in this centralised examination system. Competencies and skills in SPC matters are scarce and qualified SPC examiners can be found today in national patent offices. Moreover, the relatively low number of products for which SPC applications are made each year (less than 100) justifies making recourse to existing qualified examiners in Member States, as opposed to creating an entirely new body of experts. During the examination, third parties may submit their observations on the validity of a certain centralised SPC application after its publication.

Examination procedure and remedies

After examining the centralised SPC application, the central examination authority will issue an examination opinion stating, for each of the designated Member States, whether a national SPC fulfilling the applicable criteria (and in the first place those defined in Article 3) should be granted or refused. The applicant can file an appeal against a negative or partly negative opinion (as further explained below).

In order to account for the need to have a complete system of remedies and avoid the need for third parties challenging a positive examination opinion in national courts which would then in turn have to make reference to the EU Courts, third parties will be able to challenge a positive (or partly positive) opinion by initiating an opposition procedure during 2 months after the publication of the examination opinion. Such an opposition may result in the examination opinion being amended.

Challenges against the examination opinion can be appealed to the Boards of Appeal, and subsequently to the General Court and, possibly, ultimately before the Court of Justice subject to the system of leave to appeal under Articles 170a and following of the Rules of Procedure of the Court of Justice, or under the review procedure in accordance with Article 256, paragraph 2, TFEU, Article 62 of the Statute of the Court and Articles 191 and following of the Rules of Procedure of the CJEU.

The opinion (including where amended following an opposition) will then be transmitted to the national offices of each of the designated Member States. Where the opinion is positive the designated Member States will grant a national SPC in accordance with their national rules, e.g. as regards publication, registration in relevant databases and the payment of annual (renewal) fees, unless circumstances have changed, such as the basic patent no longer being in force in a certain Member State. Subject to the outcome of any appeal before the Boards of Appeal or the EU courts, if the examination opinion is negative, the national office concerned must reject the application.

After the grant of SPCs at a national level, third parties will still be able to initiate invalidity proceedings before the body responsible under national law for the revocation of the corresponding basic patents, or the competent courts of the Member States, including the Unified Patent Court, as applicable. The same applies to a possible counterclaim for a declaration of invalidity of an SPC.

Marketing authorisations concerned

It is proposed that only a centralised marketing authorisation (as defined in Regulation (EC) No 726/2004 and in Regulation (EU) No 2019/6) could serve as the basis for a centralised SPC application for medicinal products made under the centralised procedure proposed in Chapter III. Today, most medicinal products are authorised under that centralised marketing authorisation procedure. A centralised SPC application based on national marketing authorisations, such as those granted under the decentralised or mutual recognition procedures, would have significant drawbacks. These would include a bigger examination workload, potential differences between the various national marketing authorisations granted for the product concerned in different Member States, including language issues.

Substantive features of the SPC regime

This reform does not intend to modify, nor further clarify in view of the relevant case law of the Court of Justice, the substantive features currently laid down in Regulation (EC) No 469/2009 for the existing national SPC regimes or the new centralised procedure, since:

– the case law[15] on SPCs is progressively converging, and steadily reducing uncertainty about the interpretation of the SPC regime[16], while further amendments

[15] For a full list of cases, see Table 5.5. of the second MPI study.

[16] Further clarifications are, however, necessary in certain areas as indicated by two referrals in 2022, cases C-119/22 and C-149/22.

might trigger new fluctuations and uncertainty as regards the proper interpretation of the amended rules;

– respondents to the Allensbach survey did not call for Article 3 of the SPC Regulations to be amended (question 48) even if they consider that the case law is unclear in some respects (question 46).

New recitals

It was noted that there were no relevant recitals in Regulation (EC) No 469/2009 that could assist in interpretation of Article 3. Accordingly, certain recitals concern the conditions in Article 3 for the grant of SPCs, and incorporate the case law of the Court of Justice. The aim is to ensure consistency. In particular the judgements in cases C- 121/17 and C-673/18 interpret Article 3(a) and 3(d) of Regulation (EC)No 469/2009, respectively, and should be considered settled case law. This is also the case for judgement C-471/14, whereby the date of the first marketing authorisation in the Union, within the meaning of Article 13, is the date on which notification of the decision granting the authorisation was given to the addressee of the decision.

The requirement that the product should be protected by the basic patent means that the product should fall within the scope of one or more claims of that patent, as properly interpreted at the basic patent's filing date. This also includes situations where the product corresponds to a general functional definition used by one of the claims of the basic patent, and necessarily comes within the scope of the invention covered by that patent, even if it is not indicated in individualised form as a specific embodiment in the patent, provided that it is specifically identifiable from the patent.

Many general objectives set out in the Explanatory Memorandum of the proposal (COM(90)101) for what became Council Regulation 1768/92/EEC, i.e. the predecessor of Regulation (EC) No 469/2009, remain fully relevant today and should continue to be used as a guide to interpretation, where relevant. This includes the objective that *only one certificate may be granted for any one product, a product being understood to mean an active substance in the strict sense. Minor changes to the medicinal product such as a new dose, the use of a different salt or ester or a different pharmaceutical form will not lead to the issue of a new certificate*.

Furthermore, as regards the rights conferred by a certificate, *the certificate confers the same protection as the basic patent, but only protects the product covered by the authorisation, for all pharmaceutical uses authorised, until the expiry of the basic patent.*

As regards the rights conferred by a certificate, and in line with the earlier statements regarding derivatives, it could be appropriate to consider that the protection conferred by a certificate on a product extends to the therapeutically equivalent derivatives of the product.

For biological products, the application of the rules, both as regards the conditions for grant and the effects of a certificate, should take into account the fact that minor differences may be unavoidable between a subsequent biosimilar and the product initially authorised, given the nature of biological products.

Language regime

This Regulation envisages the possibility of filing a centralised SPC application in any official EU language. In this regard, the amount of text in an SPC application is extremely small, especially compared to patents and this would not present a burden for applicants. Certain matters would not require any translation, such as the identification of the basic patent and the relevant marketing authorisation, the relevant dates, and the identification of the applicant(s)

and the product concerned. The translation costs are, therefore, expected to be considerably lower than would be the case for patent applications. See the impact assessment (SWD(2023) 118) for an exact calculation.

Appeals

Decisions of the central examination authority are subject to appeal. This also applies to a negative (or partly negative) examination opinion issued by the central examination authority, an appeal could be filed by an applicant before the central examination authority, during a limited period after the issuance of the examination opinion. This also applies to other decisions of that authority; for instance, the decision relating to an opposition may be appealed by any of its parties. An appeal may result in the examination opinion being amended.

In the event of a 'combined' SPC application as referred to below – namely an SPC application which requests the grant of a unitary SPC and also of national SPCs –, such an appeal would also be applicable to the (common) examination opinion relating to the combined SPC application.

The appeal would take place before the Boards of Appeal of the EUIPO. Members from the Boards of Appeal should be appointed in accordance with Article 166 (5) of Regulation 2017/1001. These members may also be national examiners, but they may not be the same examiners already involved in the examination of the centralised applications or applications for unitary certificates.

In terms of workload, SPC applications are made for less than 100 products each year on average, for medicinal products and PPPs together, and introducing third-party observations should help keep the number of appeals at a very low level.

Fees

An application fee and possibly other procedural fees, such as the fee for oppositions and appeals, will have to be paid to the central examination authority. For national SPCs granted under the centralised procedure, renewal fees would have to be paid to the national patent offices of all the Member States where such certificates have been granted. This would differ, however, for unitary certificates granted under the parallel proposals COM(2023) 222 and COM(2023) 221, whereby the examination authority shall charge application and annual (renewal) fees. The level of fees to be paid to the central examination authority will be set in an implementing act.

Financial transfers between the central authority and national patent offices (NPOs)

As the procedural fees paid by applicants to the central examination authority may not be sufficient to cover the costs incurred by that authority under the new centralised procedure, it is necessary to ensure that a fraction of the renewal fees collected by national offices for SPCs granted on the basis of the centralised procedure will be transferred to the central examination authority. This already happens between national patent offices and the European Patent Office (EPO) in respect of renewal fees for European patents. At the same time, it is necessary to ensure that those national offices that participate in the new centralised procedure as regards the substantive examination of centralised SPC applications are properly remunerated for their participation.

Litigation

Whether it was obtained under today's current national procedures or under the newly proposed centralised procedure, an SPC based on an European patent, including a unitary patent, will be able to be litigated before the body responsible under national law for the

revocation of the corresponding basic patent, which is typically a national court, and may also, for those Member States participating in the unitary patent system (i.e. that have ratified the UPCA), be the Unified Patent Court ('UPC') where the applicable conditions are fulfilled (cf. Article 3(b) of the UPCA, together with Article 2(g) and Article 32)[17].

National aspects

As the proposed centralised procedure results in the grant of national certificates (SPCs), many existing national requirements and procedures, currently applicable to the SPCs applied for nationally, will be equally applicable to the certificates granted under the proposed centralised procedure. This relates in particular to publication requirements, national registers, the payment of renewal fees and the SPC manufacturing waiver introduced by Regulation (EU) 2019/933 and the paediatric extension defined in Regulation (EC) No 1901/2006.

No changes are proposed to the judicial procedures applicable to nationally granted SPCs, whether granted on the basis of a national application or of a centralised application, e.g. as regards revocation and enforcement, subject to the provisions of the UPCA, for its parties, where applicable. In other words, invalidity actions and infringement actions may be brought before the UPC also in respect of a nationally granted SPC based on a European patent, subject to the applicable conditions, in particular the requirement that neither the patent nor the SPC has been opted-out from the jurisdiction of the UPC.

Extension of SPCs for paediatric medicinal products

SPC applicants and holders should be able to use the centralised SPC granting procedure to apply for extensions of SPCs for paediatric medicinal products, under the conditions currently provided for by Regulation (EC) No 1901/2006.

Unitary SPCs

A parallel proposal (COM(2023) 222) is intended to create a unitary SPC for medicinal products. This unitary certificate would be available only on the basis of a European patent with unitary effect ('unitary patent'), as a basic patent, and would exert its effects uniformly in all the Member States in which the basic patent has unitary effect (17 initially).

The procedure for the centralised filing and examination of applications for such unitary certificates would be the same *mutatis mutandis* as the centralised procedure set out in this proposal. In this manner, a 'combined' SPC application could possibly include both a request for the grant of a unitary SPC (for the Member States covered by the basic patent) and a request for the grant of national SPCs in other Member States. This 'combined' application would undergo a single examination procedure, ruling out any discrepancies, and considerably reducing costs and the administrative burden for applicants. For the sake of clarity, this proposal does not exclude centralised SPC applications designating one or more Member States participating in the unitary patent system, as long as no unitary SPC is simultaneously requested in such a case.

[17] Where the related basic patent or the SPC itself has not been opted-out from the competence of the UPC and where no action has already been brought before a national court (as far as those Member States in which the patent has unitary effect are concerned).

↓ 469/2009 (adapted)

2023/0130 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the supplementary protection certificate for medicinal products (recast)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty ~~establishing the European Community~~ ⌦ on the Functioning of the European Union ⌫, and in particular Article ~~95~~ ⌦ 114(1) ⌫ thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[18],

Having regard to the opinion of the Committee of the Regions[19],

Acting in accordance with the ordinary legislative procedure,

Whereas:

↓ 469/2009 recital 1 (adapted)

~~Council Regulation (EC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products has been substantially amended several times[20]. In the interests of clarity and rationality the said Regulation should be codified.~~

⇩ new

(1) Regulation (EC) No 469/2009 of the European Parliament and of the Council[21] has been substantially amended[22]. Since further amendments are to be made, that Regulation should be recast in the interests of clarity.

18 OJ C […], […], p. […].

19 OJ C […], […], p. […].

20 ~~See Annex I.~~

21 Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ L 152, 16.6.2009, p. 1).

↓ 469/2009 recital 2

(2) Pharmaceutical research plays a decisive role in the continuing improvement in public health.

↓ 469/2009 recital 3 (adapted)

(3) Medicinal products, ~~especially~~ ⌦ in particular ⌫ those that are the result of long, costly research will not continue to be developed in the ~~Community~~ ⌦ Union ⌫ ~~and in Europe~~ unless they are covered by favourable rules that provide for sufficient protection to encourage such research.

↓ 469/2009 recital 4 (adapted)

(4) ~~At the moment,~~ T~~t~~he period that elapses between the filing of an application for a patent for a new medicinal product and ⌦ the ⌫ authorisation to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research.

↓ 469/2009 recitals 5 and 6 (adapted)

(5) ⌦ That ⌫ ~~This~~ situation leads to a lack of protection which penalises pharmaceutical research ⌦ and there is ⌫ ~~. There exists~~ a risk ~~of~~ ⌦ that ⌫ research centres situated in the Member States ⌦ relocate ⌫ ~~relocating~~ to countries that offer greater protection.

↓ 469/2009 recital 7 (adapted)

(6) A uniform solution at ~~Community~~ ⌦ Union ⌫ level should be provided for, thereby preventing the heterogeneous development of national laws leading to further disparities which would be likely to create obstacles to the free movement of medicinal products within the ~~Community~~ ⌦ Union ⌫ and thus directly affect the functioning of the internal market.

[22] See Annex I.

↓ 469/2009 recital 8 (adapted)
⇨ new

(7) Therefore, the provision of a supplementary protection certificate ⌦ ('certificate') ⌫ granted, under the same conditions, by each of the Member States at the request of the holder of a national ⌦ patent ⌫ or European patent ⇨, with or without unitary effect, ⇦ relating to a medicinal product for which marketing authorisation has been granted is necessary. ~~A regulation is therefore the most appropriate legal instrument.~~ ⇨ The certificate should provide its holder with an adequate additional period of effective protection subsequent to the expiry of the basic patent. An application for such a certificate should be filed with the competent industrial property office ('competent national authority') of the Member State concerned. ⇦

⇩ new

(8) One of the conditions for the grant of a certificate should be that the product is protected by the basic patent, in the sense that the product should fall within the scope of one or more claims of that patent, as interpreted by the person skilled in the art by the description of the patent on its filing date. This should not necessarily require that the active ingredient of the product be explicitly identified in the claims. Or, in the event of a combination product, this should not necessarily require that each of its active ingredients be explicitly identified in the claims, provided that each of them is specifically identifiable in the light of all the information disclosed by that patent.

(9) To avoid overprotection, it should be provided that no more than one certificate, whether national or unitary, may protect the same product in a Member State. Therefore it should be required that the product, or any therapeutically equivalent derivative such as salts, esters, ethers, isomers, mixtures of isomers, complexes or biosimilars, should not have already been the subject of a prior certificate, either alone or in combination with one or more additional active ingredients, whether for the same therapeutic indication or for a different one.

(10) Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate should extend only to the product, namely the active ingredient or combinations thereof, covered by the authorisation to place it on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate.

(11) To ensure balanced protection, however, a certificate should entitle its holder to prevent a third party from manufacturing not only the product identified in the certificate but also therapeutically equivalent derivatives of that product, such as salts, esters, ethers, isomers, mixtures of isomers or complexes, as well as biosimilars, even where such derivatives are not explicitly mentioned in the product description on the certificate. There is therefore a need to consider that the protection conferred by the certificate extends to such equivalent derivatives, within the limits of the protection conferred by the basic patent.

(12) As a further measure to ensure that no more than one certificate may protect the same product in any Member State, the holder of more than one patent for the same product should not be granted more than one certificate for that product. However, where two patents protecting the product are held by two holders, one certificate for that product

should be allowed to be granted to each of those holders, where they can demonstrate that they are not economically linked. Furthermore, no certificate should be granted to the proprietor of a basic patent in respect of a product which is the subject of an authorisation held by a third party, without that party's consent.

(13) Where the marketing authorisation submitted in support of the application for a certificate for a biological medicinal product identifies that product by means of its International Nonproprietary Name (INN), the protection conferred by the certificate should extend to all therapeutically equivalent products having the same International Nonproprietary Name as the product referred to in the marketing authorisation, irrespective of possible minor differences between a subsequent biosimilar and the product authorised, which are usually unavoidable given the nature of biological products.

(14) In order to ensure maximum flexibility and not unduly discriminate between holders of different types of patents, there should be no limitation on the type of patent on which a national certificate can be applied for before a competent national authority. Therefore, this should continue to be possible on the basis of a national patent or of a European patent and, in particular, this should also be possible in respect of a European patent with unitary effect ('unitary patent').

↓ 469/2009 recital 9 (adapted)

(15) The duration of the protection granted by the certificate should be such as to provide adequate effective protection. For this purpose, the holder of both a patent and a certificate should be able to enjoy an overall maximum of 15 years of exclusivity from the time the medicinal product in question first obtains ⌦ an ⌫ authorisation to be placed on the market in the ~~Community~~ ⌦ Union ⌫.

↓ 469/2009 recital 10 (adapted)
⇨ new

(16) All the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector should nevertheless be taken into account. For ~~this~~ ⌦ that ⌫ purpose, ⌦ it should not be possible to grant a ⌫ ~~the~~ certificate ~~cannot be granted~~ for a period exceeding ⌦ 5 ⌫ years. The protection granted should furthermore be strictly confined to the product which obtained authorisation to be placed on the ⌦ Union ⌫ market as a medicinal product. ⇨ In addition, the timely entry of generics and biosimilars into the Union market is also important, particularly in order to increase competition, to reduce prices and to ensure that national healthcare systems are sustainable and that patients in the Union have better access to affordable medicines. ⇦

↓ 469/2009 recital 11

~~Provision should be made for appropriate limitation of the duration of the certificate in the special case where a patent term has already been extended under a specific national law.~~

⇩ new

(17) In order to promote the development of paediatric medicinal products, it should be possible to extend the period of overall maximum exclusivity of 15 years and the maximum period of validity of the certificate of 5 years where the paediatric extension provided for in Article 36 of Regulation (EC) No 1901/2006 of the European Parliament and of the Council[23] applies.

(18) Since the creation of supplementary protection, certificates were only applied for and granted nationally, thus requiring several similar applications to be filed and examined in parallel in a number of Member States. This has resulted in duplication of work for both applicants and competent industrial property offices ('competent national authorities') conducting separate examination proceedings in respect of a given product, as well as in occasional discrepancies in the decisions taken by the competent national authorities in different Member States. Such differences usually pertain to the conditions for the grant or refusal of a certificate and include the grant of a certificate in one Member State but the refusal in another Member State regarding the same product or differences in the application of the conditions that apply to prior marketing authorisation or whether the product has already been the subject of a supplementary protection certificate. This leads to legal uncertainty and is inconsistent with the aims of the internal market.

(19) There is a centralised procedure for granting European patents, as well as a centralised procedure for obtaining marketing authorisations for medicinal products. In addition, the 'unitary patent' as laid down in Regulation (EU) No 1257/2012 of the European Parliament and of the Council[24] is to enter into force in June 2023 in respect of the Member States having ratified the Agreement on a Unified Patent Court ('UPC').

(20) Therefore, it is necessary to complement the existing national procedures for the grant of certificates for medicinal products with a centralised procedure. That procedure should make it possible, where the basic patent is a European patent, including a unitary patent, to request the grant of national certificates for two or more designated Member States through the filing and examination of a single 'centralised' application. Following the grant of certificates under the centralised procedure, those certificates should be equivalent to the certificates granted under national procedures and be subject to the same rules.

(21) Regulation (EU) No 2017/1001 of the European Parliament and of the Council[25] has established, under its Article 2, a European Union Intellectual Property Office ('the Office'). In the interest of the internal market, the centralised procedure should be carried out by a single examining authority. This can be achieved by the Office being

[23] Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1).

[24] Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection (OJ L 361, 31.12.2012, p. 1).

[25] Regulation (EU) 2017/1001 of the European Parliament and of the Council of 14 June 2017 on the European Union trade mark (OJ L 154, 16.6.2017, p. 1).

given the task of examining applications for certificates under the centralised procedure in accordance with this Regulation.

(22) In order to provide for a simplified examination of a centralised application, its filing should be available only on the basis of a European patent, including a unitary patent. The centralised application should not be available on the basis of a set of independent national patents, as their claims are likely to be different, resulting in greater complexity in examination compared to the situations where the basic patent is a European patent.

(23) The centralised procedure should apply only to a medicinal product that is based on a centralised marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council[26] or Regulation (EU) No 2019/6 of the European Parliament and of the Council[27]. These authorisations refer to human medicinal and veterinary medicinal products respectively. Such an authorisation, unlike national authorisations, relates to the same medicinal product throughout the Union, and will facilitate the examination of centralised applications.

(24) The Office should have the possibility to charge a fee for the centralised application for a certificate and for an application for the extension of duration of certificates in the case of paediatric medicinal products, as well as other procedural fees such as a fee for opposition or appeal. The fees charged by the Office should be laid down by an implementing act.

(25) To ensure consistency amongst the certificates granted based on the same basic patent and for the same product in Member States, to reduce the global examination workload, and to ensure an appropriate application of the conditions for grant in all Member States where protection is sought for a given product, it is necessary that the centralised procedure be the only option available as regards those Member States for which the related requirements are fulfilled, namely that the basic patent be a European patent, including a unitary patent, and that the marketing authorisation be a centralised one. To this end, a national application for a certificate filed with a competent national authority, should be rejected by that national office where the requirements to use the centralised procedure are met. This measure is proportionate considering the risk of divergences, and does not apply to those situations where those requirements do not apply, in which case national applications may still be filed.

(26) An applicant should also be allowed to lodge a ‘combined application’ that would include an application for a unitary certificate as set out in Regulation [COM(2023) 222]. Such a combined application should undergo a single examination procedure.

(27) In order to avoid double protection, it should not be possible to grant certificates – whether national certificates or unitary certificates – for the same product in the same Member State based on both a national application and a centralised application.

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[26] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

[27] Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).

(28) To guarantee a fair and transparent process, ensure legal certainty and reduce the risk of subsequent validity challenges, third parties should have the possibility, after the publication of the centralised application, to submit within 3 months observations to the Office while the centralised examination is being performed. These third parties allowed to submit observations should also include Member States. This, however, should not affect the rights of third parties to initiate invalidity proceedings before the body responsible under national law for the revocation of the corresponding basic patent. These provisions are necessary to ensure involvement of third parties both before and after the grant of certificates.

(29) The Office should examine the centralised application for certificates and issue an examination opinion. That opinion should state the reasons for which it is positive or negative in respect of each of the designated Member States.

(30) The examination of a centralised application for a certificate should be conducted, under supervision of the Office, by an examination panel including one member of the Office as well as two examiners employed by the national patent offices. This would ensure that optimal use be made of expertise in supplementary protection certificates matters, located today at national offices only. To ensure an optimal quality of the examination, suitable criteria should be laid down in respect of the participation of specific examiners in the centralised procedure, in particular as regards qualification and conflicts of interest.

(31) Where the Office finds that the conditions for grant of a certificate are fulfilled in one or more of the Member States designated in a centralised application, but are not fulfilled in one or more of the other ones, including where in one of the designated Member States the basic European patent has different claims which do not cover the product, the Office should issue a positive opinion for those designated Members States in which the conditions for obtaining a certificate are fulfilled, and a negative opinion for those in which the conditions are not fulfilled.

(32) To safeguard third parties' procedural rights and ensure a complete system of remedies, third parties should be able to challenge an examination opinion, by initiating opposition proceedings within a short duration following the publication of that opinion, and that opposition may result in that opinion being amended.

(33) After the completion of the examination of a centralised application, and after the time limits for appeal and opposition have expired, or, the case being, after a final decision on the merits has been issued, the opinion should be transmitted to the respective national patent offices of the designated Member States.

(34) Where the examination opinion is positive for one or several Member States, the respective competent national authorities should grant a certificate in accordance with the applicable domestic rules, in particular as regards publication, registration in relevant databases and the payment of annual fees.

(35) Where the examination opinion is negative for one or several Member States, the respective competent national authorities should reject the application in accordance with the applicable domestic rules.

(36) For the sake of coherence and legal certainty, the same substantive provisions should apply to national applications and to centralised applications regarding in particular the scope, the conditions for obtaining certificates, the subject-matter of protection and effect of certificates, and their publication. The centralised procedure would result in

the grant of national certificates fully identical to those granted on the basis of national applications.

(37) Since certain competent national authorities may have limited administrative capacity to conduct a full substantive examination of applications for certificates, competent national authorities should remain able to not verify all the conditions for granting a certificate on the basis of a national application. However, to ensure the quality and uniformity of the certificates granted under the centralised procedure, the Office should examine all of the conditions for grant of a certificate under the centralised procedure.

(38) Where the applicant or another party is adversely affected by a decision of the Office, the applicant or that party should have the right, subject to a fee, to file within 2 months an appeal against the decision, before a Board of Appeal of the Office. This also applies to the examination opinion, that may be appealed by the applicant. Decisions of that Board of Appeal should, in turn, be amenable to actions before the General Court, which has jurisdiction to annul or to alter the contested decision. In case of a combined application including a request for a unitary certificate, a common appeal may be filed.

(39) When appointing members of the Boards of Appeal in matters regarding centralised applications for certificates, their prior experience in supplementary protection certificate or patent matters should be taken into account.

(40) Any person may challenge the validity of a certificate granted following the centralised procedure before a competent court of a Member State, which includes the Unified Patent Court where the conditions are met.

(41) To reduce administrative burden and costs for certificate holders, there is a need for the centralised procedure to provide for a swift way of applying for, and granting, an extension of the duration of a set of equivalent certificates for a given medicinal product, granted under the new centralised procedure, in accordance with Regulation (EC) No 1901/2006. As for certificates, such extensions should be granted by competent national authorities, subject to a positive examination of the centralised application for an extension of the duration.

(42) In 2019, the Union introduced an exception in Regulation (EU) 2019/933 of the European Parliament and of the Council[28] from the protection granted to holders of supplementary protection certificates for medicinal products. It noted the absence of any exception to the protection conferred by the certificate has had the unintended consequence of preventing makers of generics and biosimilars established in the Union from making generics and biosimilars in the Union, even for the purpose of export to third country markets in which protection does not exist or has expired or for the purpose of storing with a view to day-one placement on the Union market entry. Those circumstances put makers of generics and biosimilars established in the Union at a significant competitive disadvantage in comparison with makers based in third countries that offer less or no protection. The reasons for the introduction for the waiver and the conditions for its application remain applicable at the present time.

[28] Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products (OJ L 153, 11.6.2019, p. 1).

↓ 2019/933 recital 5 (adapted)

(43) ~~Those circumstances put makers of generics and biosimilars established in the Union at a significant competitive disadvantage in comparison with makers based in third countries that offer less or no protection. The Union should strike~~ A~~a~~ balance ⌦ should be struck ⌫ between restoring a level playing field between ~~those~~ makers ⌦ of generics and biosimilars established in the Union and makers based in third countries that offer less or no protection ⌫ and ensuring that the essence of the exclusive rights of holders of certificates ('certificate holders') is guaranteed in relation to the Union market.

↓ 2019/933 recital 8 (adapted)

(44) ~~The aim of this Regulation is to promote the competitiveness of the Union, thereby enhancing growth and job creation in the internal market and contributing to a wider supply of products under uniform conditions, by allowing makers of generics and biosimilars established in the Union to make in the Union products, or medicinal products containing those products, for the purpose of export to third-country markets in which protection does not exist or has expired, thereby also helping those makers to compete effectively in those third-country markets.~~ ~~This Regulation should also allow such~~ M~~m~~akers ⌦ of generics and biosimilars established in the Union should be allowed ⌫ to make and store products, or medicinal products containing those products, in a Member State for a defined period pending the expiry of the certificate, for the purpose of entering the market of any Member State upon expiry of the corresponding certificate, thereby helping those makers to compete effectively in the Union immediately after protection has expired ('EU day-one entry'). ~~This Regulation should also complement the efforts of the Union's trade policy to ensure open markets for makers of products, or medicinal products containing those products, established in the Union. Over time, this Regulation should benefit the entire pharmaceutical sector in the Union by allowing all players, including newcomers, to reap the benefits of the new opportunities opening up in the fast-changing global pharmaceutical market. Furthermore, the general interest of the Union would be promoted given that, by reinforcing Union-based supply chains for medicines and by allowing storing with a view to entry into the Union market upon expiry of the certificate, medicines would become more accessible to patients in the Union after the expiry of the certificate.~~

↓ 2019/933 recital 9 (adapted)

(45) In those specific and limited circumstances, and in order to create a level playing field between makers established in the Union and third-country makers, it is appropriate to provide for an exception to the protection conferred by a certificate so as to allow the making of a product, or a medicinal product containing that product, for the purpose of export to third countries or of storing, and any related acts in the Union strictly necessary for that making or for the actual export or the actual storing ⌦ ('related acts') ⌫, where such acts would otherwise require the consent of ⌦ the ⌫ ~~a~~ certificate holder~~ ('related acts')~~. For instance, such related acts could include~~:~~ ⌦ the ⌫ possessing~~,~~ offering to supply~~,~~ supplying~~,~~ importing~~,~~ using or

synthesising ⌦ of ⌫ an active ingredient for the purpose of making a medicinal product.~~;~~ ~~or~~ ⌦They could also consist of ⌫ temporary storing or advertising ⌦ of the product ⌫ for the exclusive purpose of export to third-country destinations. ~~That~~ ⌦ The ⌫ exception should also apply to related acts performed by third parties who are in a contractual relationship with the maker.

↓ 2019/933 recital 10 (adapted)

(46) The exception should apply to a product, or a medicinal product containing that product, protected by a certificate~~. It~~ ⌦ and ⌫ should cover the making of the product protected by ⌦ the ⌫ ~~a~~ certificate in the territory of a Member State and the making of the medicinal product containing that product.

↓ 2019/933 recital 11

(47) The exception should not cover placing a product, or a medicinal product containing that product, which is made for the purpose of export to third countries or of storing with a view to EU day-one entry, on the market of a Member State where a certificate is in force, either directly or indirectly after export, nor should it cover re-importation of such a product, or medicinal product containing that product, into the market of a Member State in which a certificate is in force. Moreover, it should not cover any act or activity carried out for the purpose of import of products, or medicinal products containing those products, into the Union merely for the purposes of repackaging and re-exporting. In addition, the exception should not cover any storing of products, or medicinal products containing those products, for any purposes other than those set out in this Regulation.

↓ 2019/933 recital 12 (adapted)
⇨ new

(48) By limiting the scope of the exception to ⌦ the ⌫ making ⌦ of a product, or a medicinal product containing that product, ⌫ for the purpose of export outside the Union or to making for the purpose of storing, and to acts strictly necessary for such making or for the actual export or the actual storing, the exception ~~provided for in this Regulation~~ ~~should~~ ⇨ will ⇦ not conflict with the normal exploitation of the product, or the medicinal product containing that product, in the Member State in which the certificate is in force, namely with the core exclusive right of the certificate holder to make that product for the purpose of placing it on the Union market during the term of the certificate. In addition, that exception should not unreasonably prejudice the legitimate interests of the certificate holder, whilst taking account of the legitimate interests of third parties.

↓ 2019/933 recital 13 (adapted)

(49) Effective and proportionate safeguards should apply in relation to the exception in order to increase transparency, to help the ~~holder of a~~ certificate ⌦ holder to ⌫

enforce its protection in the Union and check compliance with ~~the conditions set out in~~ this Regulation, and to reduce the risk of illicit diversion onto the Union market during the term of the certificate.

↓ 2019/933 recital 14 (adapted)
⇨ new

(50) ~~This Regulation should~~ ⇨ To ensure better transparency and legal certainty, it is necessary to ⇦ impose an information obligation on the maker, namely the person established in the Union, on whose behalf the making of a product, or a medicinal product containing that product, for the purpose of export or storing, is carried out. ~~It is possible that the maker directly carries out the making~~ ⌦ That obligation should apply also where the making is directly carried out by the maker ⌫. ~~That information obligation should consist of requiring the maker to provide certain information to the competent industrial property office, or another designated authority, which granted the certificate ('the authority') in the Member State where the making is to take place. A standard form for notification should be provided for this purpose. The information should be provided before the making of a product, or a medicinal product containing that product, starts for the first time in that Member State, or before any related act prior to that making, whichever is the earlier. The information should be updated as and when appropriate. The making of a product, or a medicinal product containing that product, and the related acts, including those performed in Member States other than the one of making in cases where the product is also protected by a certificate in those other Member States, should only fall within the scope of the exception where the maker has sent the notification to the authority of the Member State of making, and where the maker has informed the holder of the certificate granted in that Member State. Where making takes place in more than one Member State, a notification should be required in each of those Member States. In the interests of transparency, the authority should be required to publish, as soon as possible, the information received, together with the date of notification of that information. Member States should be allowed to require that notifications, and updates to notifications, be subject to the payment of a one-off fee. That fee should be set at a level which does not exceed the administrative cost of processing notifications and updates.~~

↓ 2019/933 recital 18

(51) ~~For reasons of proportionality, failure to comply with the requirement regarding a third country should only affect exports to that country, and exports to that country should, thus, not benefit from the exception provided for in this Regulation.~~ It should be the responsibility of the maker established in the Union to verify that protection does not exist or has expired in a country of export, or whether that protection is subject to any limitations or exemptions in that country.

↓ 2019/933 recital 20 (adapted)
⇨ new

(52) ~~This Regulation should impose c~~Certain due diligence requirements ⌦should be imposed⌫ on the maker as a condition to use the exception ⇨ , so as to ensure better transparency and legal certainty ⇦. ~~The maker should be required to inform persons within its supply chain in the Union, including the exporter and the person carrying out the storing, through appropriate and documented means, in particular contractual means, that the product, or the medicinal product containing that product, is covered by the exception provided for in this Regulation and that the making is intended for the purpose of export or storing. A maker who fails to comply with those due diligence requirements should not benefit from the exception, nor should any third party performing a related act in the Member State of making or in a different Member State in which a certificate conferring protection for the product is in force.~~ The holder of the relevant certificate ⌦ will ⌫ ~~would~~, therefore, be entitled to enforce its rights under the certificate, while having due regard to the general obligation, provided for in Directive 2004/48/EC of the European Parliament and of the Council[29], not to engage in abusive litigation.

↓ 2019/933 recital 21 (adapted)

(53) ~~This Regulation should impose labelling requirements on the maker in respect of products, or medicinal products containing those products, to be exported, in order to facilitate, by means of a logo, identification of such products or such medicinal products as being exclusively intended for the purpose of export to third countries. Making for the purpose of export and related acts should only fall within the scope of the exception if the product, or the medicinal product containing that product, is labelled in the manner provided for in this Regulation.~~ ~~That l~~Labelling ~~obligation~~ ⌦ in this Regulation ⌫ should be without prejudice to labelling requirements of third countries.

↓ 2019/933 recital 22

(54) Any act not covered by the exception provided for in this Regulation should remain within the scope of the protection conferred by a certificate. Any diversion onto the Union market, during the term of the certificate, of any product, or any medicinal product containing that product, made under the exception, should remain prohibited.

[29] Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (OJ L 157, 30.4.2004, p. 45).

↓ 2019/933 recital 23
⇨ new

(55) This ~~Regulation~~ ⇨ exception ⇦ is without prejudice to other intellectual property rights that could protect other aspects of a product, or a medicinal product containing that product. This ~~Regulation~~ ⇨ exception ⇦ does not affect the application of Union acts that aim to prevent infringements, and facilitate enforcement, of intellectual property rights, including Directive 2004/48/EC and Regulation (EU) No 608/2013 of the European Parliament and of the Council[30] ~~(7)~~.

↓ 2019/933 recital 24
⇨ new

(56) This ~~Regulation~~ ⇨ exception ⇦ does not affect the rules on the unique identifier, provided for in Directive 2001/83/EC of the European Parliament and of the Council[31]. The maker should ensure that any medicinal product made for the purpose of export~~, pursuant to this Regulation,~~ does not bear an active unique identifier within the meaning of Commission Delegated Regulation (EU) 2016/161[32] ⇨ , to ensure that such a product may be identified if it were illicitly re-imported into the Union ⇦. However, under that Delegated Regulation, the requirement to carry such an active unique identifier applies to medicinal products intended to be placed on the market of a Member State upon expiry of the corresponding certificate ⇨ ; accordingly, the prohibition of a unique identifier does not apply to such products ⇦.

↓ 2019/933 recital 25
⇨ new

(57) This ~~Regulation~~ ⇨ exception ⇦ does not affect the application of Directive~~s 2001/82/EC and~~ 2001/83/EC and Regulation (EU) 2019/6, in particular the requirements relating to the manufacturing authorisation of medicinal products made for export. This includes compliance with the principles and guidelines of good manufacturing practices for medicinal products and using only active substances which have been manufactured in accordance with good manufacturing practices for active substances and distributed in accordance with good distribution practices for active substances.

30 Regulation (EU) No 608/2013 of the European Parliament and of the Council of 12 June 2013 concerning customs enforcement of intellectual property rights and repealing Council Regulation (EC) No 1383/2003 (OJ L 181, 29.6.2013, p. 15).

31 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

32 Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use (OJ L 32, 9.2.2016, p. 1).

↓ 2019/933 recital 26 (adapted)
⇨ new

(58) To safeguard the rights of certificate holders, the exception provided for in this Regulation should not apply to a certificate that ~~has~~ ⌦ had ⌫ already taken effect at the date of entry into force of ~~this~~ Regulation ⌦ (EU) 2019/933 of the European Parliament and of the Council ⌫. ~~In order t~~To ensure that the rights of certificate holders are not excessively restricted, the exception should apply to certificates that are applied for on or after the date of entry into force of ~~this~~ Regulation ⌦ (EU) No 2019/933 ⌫. Given that a certificate takes effect at the end of the lawful term of the basic patent, which can be a relatively long time after the date of filing of the application for the certificate, ~~and in order to achieve the aim of this Regulation,~~ it is justified that ⇨ the exception set out in ⇦ this Regulation also ~~cover~~ ⌦ covers ⌫, over a certain period of time, a certificate that was applied for before the date of entry into force of ~~this~~ Regulation ⌦ (EU) No 2019/933 ⌫, but ~~has~~ ⌦ had ⌫ not yet taken effect before that date, irrespective of whether or not that certificate was granted before that date. The exception ⌦ applied ⌫ ~~should apply~~, therefore, from 2 July 2022 to a certificate that ~~takes~~ ⌦ took ⌫ effect from the date of entry into force of ~~this~~ Regulation ⌦ (EU) No 2019/933⌫. The concept of 'certain period of time' for each individual certificate that takes effect after the date of entry into force of ⌦ that ⌫ ~~this~~ Regulation should ensure that the exception ~~is~~ ⌦ be ⌫ applied, on a progressive basis, to such a certificate, depending on the date on which it ~~takes~~ ⌦ took ⌫ effect and on its duration. Such application of the exception would allow the holder of a certificate that ~~has~~ ⌦ had ⌫ been granted, but that ~~has~~ ⌦ had ⌫ not yet taken effect by the date of the entry into force of ~~this~~ Regulation ⌦ (EU) 2019/933 ⌫, a reasonable period of transition to adapt to the changed legal context, while at the same time ensuring that makers of generics and biosimilars can benefit effectively, without excessive delay, from the exception.

↓ 2019/933 recital 27 (adapted)

(59) ~~Typically, an applicant for a certificate files an application at approximately the same date in each Member State of filing. However, due to differences in national procedures for the examination of applications, the date of grant of the certificate might vary significantly from one Member State to another, thereby creating disparities in the legal situation of the applicant in the Member States in which the certificate was applied for. Introducing t~~The exception ⌦ should apply ⌫ on the basis of the date of the filing of the application for a certificate ~~would, therefore~~, ⌦ in order to ⌫ promote uniformity and limit the risk of disparities.

⇩ new

(60) To ensure transparency, a register should be set up that can serve as a single access point providing information on applications for certificates under the centralised procedure, including on certificates granted on that basis by competent national authorities, which should share with the Office any related information. The register should be available in all official languages of the Union.

(61) Regulation [COM(2023) 222][33] creates a unitary supplementary protection certificate for medicinal products, which may be requested for those Member States in which the basic patent has unitary effect. The request for such a unitary certificate may be made in a combined application for a certificate under the centralised procedure covered by this Regulation. In such a case, the combined application including both requests should be subject to a single centralised examination procedure. Double protection by both a unitary certificate and a certificate granted pursuant to this Regulation should be excluded.

(62) For the tasks conferred on the Office under this Regulation, the languages of the Office should be all official languages of the Union. The Office should accept verified translations, into one of the official languages of the Union, of documents and information. The Office may, if appropriate, use verified machine translations.

(63) Financial provision should be made to ensure that competent national authorities that participate in the centralised procedure are adequately remunerated for their participation.

(64) The necessary set-up costs related to the tasks conferred to the Office, including the costs of new digital systems, should be financed from the Office's accumulated budgetary surplus.

(65) In order to supplement certain non-essential elements of this Regulation, the power to adopt acts, in accordance with Article 290 of the Treaty on the Functioning of the European Union, should be delegated to the Commission in respect of: (i) specifying the content and form of the notice of appeal and the content and the form of the Boards of Appeal's decision, (ii) specifying the details concerning the organisation of the Boards of Appeal in proceedings relating to certificates, (iii) specifying the rules on the means of communication, including the electronic means of communication, to be used by the parties to proceedings before the Office and the forms to be made available by the Office, (iv) setting out the detailed arrangements for oral proceedings, (v) setting out the detailed arrangements for the taking of evidence, (vi) setting out the detailed arrangements for notification, (vii) specifying the details regarding the calculation and duration of time limits and (viii) setting out the detailed arrangements for the resumption of proceedings. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016.[34] In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

(66) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards: (i) the application forms to be used; (ii) rules on procedures relating to the filing, and

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[33] Regulation of the European Parliament and of the Council on the unitary supplementary protection certificate for medicinal products [COM(2023) 222].

[34] Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making (OJ L 123, 12.5.2016, p. 1).

procedures regarding the way in which examination panels examine centralised applications and prepare examination opinions, as well as the issuance of examination opinions by the Office, (iii) the criteria in the ways the examination panels are to be set up, and the criteria for the selection of examiners, (iv) the amounts of the applicable fees to be paid to the Office, (v) specifying the maximum rates for costs essential to the proceedings and actually incurred by the successful party, and (vi) rules on the financial transfers between the Office and Member States, the amounts of these transfers, and the remuneration to be paid by the Office regarding the participation of competent national authorities. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[35].

↓ 2019/933 recital 28 (adapted)
⇨ new

(67) The Commission should carry out a regular evaluation of this Regulation ⇨, in particular in order to assess the impact on the exception on the competitiveness of the pharmaceutical sector of the Union⇦. ~~Pursuant to the Interinstitutional Agreement of 13 April 2016 on Better Law-Making, that evaluation should be based on the five criteria of effectiveness, efficiency, relevance, coherence and added value and should provide the basis for impact assessments of possible further measures.~~ That evaluation should take into account, on the one hand, exports to outside the Union, and on the other ⌦ hand ⌫, the effects of storing on the swifter entry of generics and especially biosimilars into markets in the Union as soon as possible after a certificate expires. Such regular evaluation should also address the effects of this ~~Regulation~~ ⇨ exception ⇦ on the making of generics and biosimilars in the Union by makers of generics and biosimilars established in the Union. In that context, it ⌦ is ⌫~~would be~~ important to ascertain whether making that was previously taking place outside of the Union ~~would be~~ ⌦ are being ⌫ moved to within Union territory. In particular, ⌦ the ⌫ ~~that~~ evaluation should review the effectiveness of the exception in the light of the aim to restore a global level playing field for makers of generics and biosimilars in the Union. ⌦ The evaluation ⌫ ~~It~~ should also study the impact of the exception on research and production of innovative medicines in the Union by certificate holders and consider the balance between the different interests at stake, in particular as regards public health, public expenditure and, in ⌦ that ⌫ ~~this~~ context, access to medicines within the Union. It should also study whether the period provided for as regards the making of generics and biosimilars for the purpose of storing is sufficient to achieve the objective of EU day-one entry, including its effects on public health. ⇨ The Commission should also regularly evaluate the centralised procedure. ⇦

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[35] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

↓ 2019/933, recital 30 (adapted)
⇨ new

(68) This Regulation respects fundamental rights and observes the principles recognised by the Charter of Fundamental Rights of the European Union ('the Charter'). ⇨ The rules in this Regulation should be interpreted and applied in accordance with those rights and principles. ⇦ In particular, this Regulation seeks to ensure full respect for the right to property and the right to health care ⇨ and the right to an effective remedy ⇦ ~~set out respectively~~ in Articles 17 and 35 ⇨ and 47 ⇦ of the Charter. This Regulation should maintain the core rights of the certificate, by limiting the exception provided for in this Regulation to the making of a product, or a medicinal product containing that product, only for the purpose of export outside the Union or for the purpose of storing for a limited period of time with a view to entry into the Union market upon expiry of the protection, and to the acts strictly necessary for such making or for the actual export or the actual storing. In the light of those fundamental rights and principles, the exception provided for in this Regulation does not go beyond what is necessary and appropriate in the light of the overall objective of this Regulation, which is to promote the competitiveness of the Union by avoiding relocation and allowing makers of generics and biosimilars established in the Union to compete, on the one hand, on fast-growing global markets where protection does not exist or has already expired, and on the other, on the Union market upon expiry of the certificate. ~~Indeed, it is necessary to benefit from the positive economic effects arising from the exception, as otherwise the Union would risk substantially weakening its position as a hub for pharmaceutical development and manufacturing. It is, therefore, appropriate to introduce that exception in order to increase the competitive position of makers of generics and biosimilars established in the Union in third countries whose markets are in any event open to competition, whilst leaving the scope and duration of the protection granted by the certificate in the Union untouched. The appropriateness of the measure is further ensured by providing for appropriate safeguards regulating the use of the exception. This Regulation should allow sufficient time for public authorities to put in place the necessary arrangements to receive and publish notifications.~~ ⇨ In addition, the removal of the possibility to file a national application for a certificate with a competent national authority, where the requirements to use the centralised procedure are met, is proportionate in the light of the risk of divergences. Where the requirements do not apply, national applications may still be filed. ⇦

⇩ new

(69) The establishment of a centralised procedure for the grant of certificates should not affect in any manner the national applications for certificates still pending before competent national authorities, nor the certificates granted on the basis of national applications.

(70) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States but can rather, with a view to ensuring that the applicable rules and procedures are consistent across the Union, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality

as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

(71) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 of the European Parliament and of the Council[36] and delivered an opinion on XXX *[OP, please add reference once available]*.

(72) Appropriate arrangements should be made to facilitate a smooth transition from the rules provided for in Regulation (EC) No 469/2009 to the rules laid down in this Regulation. To allow for sufficient time for the Office to implement and launch the centralised procedure, the provisions on centralised applications should apply from *[OP – insert the date - one year after the entry into force of this Regulation]*,

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↓ 469/2009 (adapted)
⇨ new

HAVE ADOPTED THIS REGULATION:

CHAPTER I

⌦ GENERAL PROVISIONS ⌫

Article ~~2~~ 1

***~~Scope~~* ⌦ Subject matter ⌫**

~~Any product~~ ⌦ This Regulation lays down rules on the supplementary protection certificate ('certificate') for medicinal products ⌫ protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure as laid down in Directive 2001/83/EC ~~of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use~~[(6)] ⇨ , Regulation (EC) No 726/2004 ⇦ or ~~Directive 2001/82 of the European Parliament and of the Council 6 November 2001 on the Community code relating to veterinary medicinal products (7)~~ Regulation (EU) 2019/6 ~~may, under the terms and conditions provided for in this Regulation, be the subject of a certificate~~.

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[36] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

↓ 469/2009 (adapted)

Article ~~1~~ 2

Definitions

For the purposes of this Regulation, the following definitions shall apply:

(1) ‘medicinal product’ means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals;

(2) ‘product’ means the active ingredient or combination of active ingredients of a medicinal product;

(3) ‘basic patent’ means a patent which protects a product as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate;

~~‘certificate’ means supplementary protection certificate;~~

(4) ‘application for an extension of the duration’ means an application for an extension of the duration of the certificate pursuant to Article 13(3) of this Regulation and Article 36 of Regulation (EC) No 1901/2006 ~~of 12 December 2006 on medicinal products for paediatric use~~ [37];

↓ 2019/933 Art. 1 pt. 1

(5) ‘maker’ means the person, established in the Union, on whose behalf the making of a product, or a medicinal product containing that product, for the purpose of export to third countries or for the purpose of storing, is carried out.

⇩ new

(6) ‘national application’ means an application for a certificate made before a competent national authority pursuant to Article 9;

(7) ‘centralised application’ means an application made before the Office pursuant to Article 20 with a view to the grant of certificates, for the product identified in the application, in the designated Member States;

[37] Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1) OJ L 378, 27.12.2006, p. 1.

(8) ‘centralised application for an extension of the duration’ means an application for an extension of the duration of the certificate pursuant to Article 30 of this Regulation and Article 36 of Regulation (EC) No 1901/2006;

(9) ‘designated Member State’ means a Member State for which a certificate is sought under the centralised examination procedure laid down in Chapter III, as identified in a centralised application for a certificate;

(10) ‘European patent’ means a patent granted by the European Patent Office (EPO) under the rules and procedures laid down in the European Patent Convention (‘EPC’)[38];

(11) ‘unitary patent’ means a European patent which benefits from unitary effect in those Member States participating in the enhanced cooperation laid down in Regulation (EU) No 1257/2012;

(12) ‘competent national authority’ means the national authority that is competent, in a given Member State, for the grant of certificates and for the rejection of applications for certificates, as referred to in Article 9(1).

CHAPTER II
NATIONAL APPLICATIONS FOR A CERTIFICATE

↓ 469/2009 ⇨ new

Article 3

Conditions for obtaining a certificate

1. A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application ⇨ , all of the following conditions are fulfilled ⇦:

   (a) the product is protected by a basic patent in force;

   (b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC, ⇨ Regulation (EC) No 726/2004 ⇦ or ~~Directive 2001/82/EC~~ Regulation (EU) 2019/6, as appropriate;

   (c) the product has not already been the subject of a certificate;

   (d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.

[38] Convention on the Grant of European Patents of 5 October 1973, as revised on 17 December 1991 and on 29 November 2000

⇩ new

2. By way of derogation from paragraph 1, a certificate shall not be granted under this Chapter, in a Member State, on the basis of a national application where the requirements of Article 20(1) are fulfilled for the filing of a centralised application in which that Member State would be designated.

3. The holder of more than one patent for the same product shall not be granted more than one certificate for that product. However, where two or more applications concerning the same product and emanating from two or more holders of different patents are pending, one certificate for that product may be issued to each of those holders, where they are not economically linked.

🡻 469/2009 (adapted)

Article 4

⌦ Scope ⌫ ~~Subject matter~~ of ⌦ the ⌫ protection

Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate.

🡻 933/2019 Art. 1 pt. 2 (adapted)

Article 5

Effects of the certificate

1. ~~Subject to the provisions of Article 4,~~ T~~t~~he certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations.

2. By way of derogation from paragraph 1, the certificate ~~referred to in paragraph 1~~ shall not confer protection against certain acts which would otherwise require the consent of the ~~holder of the certificate (~~‘the certificate holder’~~)~~, if ⌦ all of ⌫ the following conditions are met:

   (a) the acts comprise ⌦ any of the following ⌫:

      (i) the making of a product, or a medicinal product containing that product, for the purpose of export to third countries; ~~or~~

      (ii) any related act that is strictly necessary for the making, in the Union, referred to in point (i), or for the actual export; ~~or~~

      (iii) the making, no earlier than ⌦ 6 ⌫ ~~six~~ months before the expiry of the certificate, of a product, or a medicinal product containing that product, for the purpose of storing it in the Member State of making, in order to place that product, or a medicinal product containing that product, on the

market of Member States after the expiry of the corresponding certificate; ~~or~~

(iv) any related act that is strictly necessary for the making, in the Union, referred to in point (iii), or for the actual storing, provided that such related act is carried out no earlier than ⌦ 6 ⌫ ~~six~~ months before the expiry of the certificate.

(b) the maker, through appropriate and documented means, notifies the authority referred to in Article 9(1) in the Member State in which that making is to take place, and informs the certificate holder, of the information ⌦ referred to ⌫ ~~listed~~ in paragraph 5 ~~of this Article~~ no later than ⌦ 3 ⌫ ~~three~~ months before the start date of the making in that Member State, or no later than ⌦ 3 ⌫ ~~three~~ months before the first related act, prior to that making, that would otherwise be prohibited by the protection conferred by a certificate, whichever is the earlier;

(c) if the information ⌦ referred to ⌫ ~~listed~~ in paragraph 5 of this Article changes, the maker notifies the authority referred to in Article 9(1) and informs the certificate holder, before those changes take effect;

(d) in the case of products, or medicinal products containing those products, made for the purpose of export to third countries, the maker ensures that a logo, in the form set out in Annex ~~Ia~~ II, is affixed to the outer packaging of the product, or the medicinal product containing that product, referred to in point (a)(i) of this paragraph, and, where feasible, to its immediate packaging;

(e) the maker complies with paragraph 9 of this Article and, if applicable, with Article 12(2).

3. ~~The exception laid down referred to in p~~Paragraph 2 shall not apply to any act or activity carried out for the import of products, or medicinal products containing those products, into the Union merely for the purpose of repackaging, re-exporting or storing.

4. The information provided to the certificate holder for the purposes of paragraph 2, points (b) and (c), ~~of paragraph 2~~ shall be used exclusively for the purposes of verifying whether the requirements of this Regulation have been met and, where applicable, initiating legal proceedings for non-compliance.

5. ~~The information to be provided by the maker f~~For the purposes of paragraph 2, point (b), ~~of paragraph 2~~ ⌦ the maker shall provide all of the following information ⌫ ~~shall be as follows~~:

(a) the name and address of the maker;

(b) an indication of whether the making is for the purpose of export, for the purpose of storing, or for the purpose of both export and storing;

(c) the Member State in which the making and, if applicable, also the storing is to take place, and the Member State in which the first related act, if any, prior to that making is to take place;

(d) the number of the certificate granted in the Member State of making, and the number of the certificate granted in the Member State of the first related act, if any, prior to that making; ~~and~~

(e) for medicinal products to be exported to third countries, the reference number of the marketing authorisation, or the equivalent of such authorisation, in each third country of export, as soon as it is publicly available.

6. For the purposes of notification to the authority under paragraph 2, points (b) and (c), ~~of paragraph 2,~~ the maker shall use the standard form for notification ~~contained~~ ⌦ set out ⌫ in Annex ~~Ia~~ III.

7. Failure to ~~comply with the requirements of~~ ⌦ provide the information referred to in ⌫ paragraph 5, point (e), ~~of paragraph 5~~ with regard to a third country shall only affect exports to that ⌦ third ⌫ country, and those exports shall~~, therefore,~~ not benefit from the exception ⌦ laid down in paragraph 2 ⌫.

8. The maker shall ensure that medicinal products made pursuant to paragraph 2, point (a) (i), ~~of paragraph 2~~ do not bear an active unique identifier within the meaning of ~~Commission~~ Delegated Regulation (EU) 2016/161[39].

9. The maker shall ensure, through appropriate and documented means, that any person in a contractual relationship with the maker ~~who~~ ⌦that⌫ performs acts falling under paragraph 2, point (a), ~~of paragraph 2~~ is fully informed and aware of ⌦ all of ⌫ the following:

(a) that those acts are subject to paragraph 2;

(b) that the placing on the market, import or re-import of the product, or the medicinal product containing that product, referred to in paragraph 2, point (a)(i), ~~of paragraph 2~~ or the placing on the market of the product, or the medicinal product containing that product, referred to in paragraph 2, point (a)(iii), ~~of paragraph 2~~ could infringe the certificate referred to in ⌦ that ⌫ paragraph ~~2~~ where, and for as long as, that certificate applies.

10. Paragraph 2 shall apply to certificates that are applied for on or after 1 July 2019.

Paragraph 2 shall also apply to certificates that have been applied for before 1 July 2019 and that take effect on or after that date. Paragraph 2 shall only apply to such certificates from 2 July 2022.

Paragraph 2 shall not apply to certificates that have taken effect before 1 July 2019.

⬇ 469/2009 (adapted)
⇨ new

Article 6

Entitlement to the certificate

1. The certificate shall be granted to the holder of the basic patent or ~~his~~ ⌦ to the ⌫ successor in title ⌦ of that holder ⌫.

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[39] ~~Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use (OJ L 32, 9.2.2016, p. 1).';~~

⇩ new

2. Notwithstanding paragraph 1, where a basic patent has been granted in respect of a product that is the subject of an authorisation held by a third party, a certificate for that product shall not be granted to the holder of the basic patent without the consent of that third party.

🡻 469/2009 (adapted)
⇨ new

Article 7

Application for a certificate

1. The application for a certificate shall be lodged within ⌦ 6 ⌫ ~~six~~ months of the date on which the authorisation referred to in Article 3(1), point (b), to place the product on the market as a medicinal product was granted.

2. Notwithstanding paragraph 1, where the authorisation to place the product on the market is granted before the basic patent is granted, the application for a certificate shall be lodged within ⌦ 6 ⌫ ~~six~~ months of the date on which the patent is granted.

3. The application for an extension of the duration may be ~~made~~ ⌦ lodged at the same time ⌫when lodging the application for a certificate or when the application for the certificate is pending and the appropriate requirements of Article 8(1), point (d), or Article 8(2), respectively, are fulfilled.

4. The application for an extension of the duration of a certificate already granted shall be lodged not later than ⌦ 2 ⌫ ~~two~~ years before the expiry of the certificate.

~~Notwithstanding paragraph 4, for five years following the entry into force of Regulation (EC) No 1901/2006, the application for an extension of the duration of a certificate already granted shall be lodged not later than six months before the expiry of the certificate.~~

Article 8

Content of the application for a certificate

1. The application for a certificate shall contain ⌦ the following ⌫:

   (a) a request for the grant of a certificate, stating in particular:

      (i) the name and address of the applicant;

      (ii) if ⌦ the applicant ⌫ ~~he~~ has appointed a representative, the name and address of ⌦ that ⌫ ~~the~~ representative;

      (iii) the number of the basic patent and the title of the invention;

      (iv) the number and date of the first authorisation to place the product on the market, as referred to in Article 3⌦ (1), point ⌫(b), and, if this authorisation is not the first authorisation for placing the product on the market in the ⌦ Union ⌫ ~~Community~~, the number and date of that authorisation;

(b) a copy of the authorisation to place the product on the market, as referred to in Article 3(1), point (b), in which the product is identified, containing in particular the number and date of the authorisation and the summary of the product characteristics listed in Article 11 of Directive 2001/83/EC or Article 35 ~~14~~ of ~~Directive 2001/82/EC~~ Regulation (EU) 2019/6;

(c) ⌦ where ⌫ ~~if~~ the authorisation referred to in point (b) is not the first authorisation for placing the product on the market as a medicinal product in the ⌦ Union ⌫ ~~Community~~, information regarding the identity of the product thus authorised and the legal provision under which the authorisation procedure took place, together with a copy of the notice publishing the authorisation in the appropriate official publication ⇨ or, in the absence of such a notice, any other document proving that the authorisation has been issued, the date on which it was issued and the identity of the product authorised ⇦;

(d) where the application for a certificate for a medicinal product includes a request for an extension of the duration:

(i) a copy of the statement indicating compliance with an agreed completed paediatric investigation plan as referred to in Article 36(1) of Regulation (EC) No 1901/2006;

(ii) where necessary, in addition to the copy of the authorisation to place the product on the market as referred to in point (b), proof of possession of authorisations to place the product on the market of all other Member States, as referred to in Article 36(3) of Regulation (EC) No 1901/2006.

2. Where an application for a certificate is pending, an application for an extension of the duration in accordance with Article 7(3) shall include the particulars referred to in paragraph 1, point (d), of this Article and a reference to the application for a certificate already filed.

3. The application for an extension of the duration of a certificate already granted shall contain the particulars referred to in paragraph 1, point (d), and a copy of the certificate already granted.

4. Member States may provide that a fee is to be payable upon application for a certificate and upon application for the extension of the duration of a certificate.

Article 9

Lodging of an application for a certificate

1. The application for a certificate shall be lodged with the competent industrial property office of the Member State which granted the basic patent or on whose behalf it was granted and in which the authorisation referred to in Article 3(1), point (b), to place the product on the market was obtained, unless the Member State designates another authority for ⌦ that ⌫ ~~the~~ purpose.

The application for an extension of the duration of a certificate shall be lodged with the competent authority of the Member State concerned.

2. Notification of the application for a certificate shall be published by the authority referred to in paragraph 1. The notification shall contain ~~at least~~ ⇨ all of ⇦ the following information:

(a) the name and address of the applicant;

(b) the number of the basic patent;

(c) the title of the invention;

(d) the number and date of the authorisation to place the product on the market, referred to in Article 3(1), point (b), and the product identified in that authorisation;

(e) where relevant, the number and date of the first authorisation to place the product on the market in the ⌦ Union ⌫ ~~Community~~;

(f) where applicable, an indication that the application includes an application for an extension of the duration.

3. Paragraph 2 shall apply to the notification of the application for an extension of the duration of a certificate already granted or where an application for a certificate is pending. The notification shall additionally contain an indication of the application for an extended duration of the certificate.

Article 10

Grant of the certificate or rejection of the application for a certificate

1. Where the application for a certificate and the product to which it relates meet the conditions laid down in this Chapter~~Regulation~~, the authority referred to in Article 9(1) shall grant the certificate.

2. The authority referred to in Article 9(1) shall, subject to paragraph 3 ⌦ of this Article ⌫, reject the application for a certificate if the application or the product to which it relates does not meet the conditions laid down in this Chapter~~Regulation~~.

3. Where the application for a certificate does not meet the conditions laid down in Article 8, the authority referred to in Article 9(1) shall ask the applicant to rectify the irregularity, or to settle the fee, within a stated time.

4. If the irregularity is not rectified or the fee is not settled under paragraph 3 within the stated time, the authority shall reject the application.

5. Member States may provide that the authority referred to in Article 9(1) is to grant certificates without verifying that the conditions laid down in Article 3(1), points (c) and (d), are met.

6. Paragraphs 1 to 4 shall apply *mutatis mutandis* to the application for an extension of the duration.

Article 11

Publication

1. ⌦ The authority referred to in Article 9(1) shall publish, as soon as possible, ⌫ n~~N~~otification of the fact that a certificate has been granted ~~shall be published by the authority referred to in Article 9(1)~~. The notification shall contain ~~at least~~ ⇨ all of ⇦ the following information:

(a) the name and address of the holder of the certificate;

(b) the number of the basic patent;

(c) the title of the invention;

(d) the number and date of the authorisation to place the product on the market referred to in Article 3 (1), point (b), and the product identified in that authorisation;

(e) where relevant, the number and date of the first authorisation to place the product on the market in the ⌦ Union ⌫ ~~Community~~;

(f) the duration of the certificate.

2. ⌦ The authority referred to in Article 9(1) shall publish, as soon as possible, ⌫ nN~~n~~otification of the fact that the application for a certificate has been rejected ~~shall be published by the authority referred to in Article 9(1)~~. The notification shall contain at least the information listed in Article 9(2).

3. Paragraphs 1 and 2 shall apply to the notification of the fact that an extension of the duration of a certificate has been granted or of the fact that the application for an extension has been rejected.

↓ 2019/933 Art. 1 pt. 3

4. The authority referred to in Article 9(1) shall publish, as soon as possible, the information listed in Article 5(5), together with the date of notification of that information. It shall also publish, as soon as possible, any changes to the information notified in accordance with Article 5(2), point (c) ~~of Article 5(2)~~.

↓ 933/2019 Art. 1 pt. 4 (adapted)

Article 12

Fees

1. Member States may require that the certificate be subject to the payment of annual fees.

2. Member States may require that the notifications to in Article 5(2), points (b) and (c), ~~of Article 5(2)~~ be subject to the payment of a fee.

↓ 469/2009 (adapted)
⇨ new

Article 13

Duration of the certificate

1. The certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorisation to place the product on the market in the ⌦ Union ⌫ ~~Community~~, reduced by a period of ⌦ 5 ⌫ ~~five~~ years.

2. Notwithstanding paragraph 1, the duration of the certificate may not exceed ⌦ 5 ⌫ ~~five~~ years from the date on which it takes effect.

3. The periods laid down in paragraphs 1 and 2 ⌦ of this Article ⌫ shall be extended by ⌦ 6 ⌫ ~~six~~ months in the case where Article 36 of Regulation (EC) No 1901/2006 applies. In that case, the duration of the period laid down in paragraph 1 of ⌦ that ⌫ ~~this~~ Article may be extended only once.

~~Where a certificate is granted for a product protected by a patent which, before 2 January 1993, had its term extended or for which such extension was applied for, under national law, the term of protection to be afforded under this certificate shall be reduced by the number of years by which the term of the patent exceeds 20 years.~~

Article 14

Expiry of the certificate

The certificate shall lapse ⌦ in any of the following events ⌫:

(a) at the end of the period provided for in Article 13;

(b) if the certificate holder surrenders it;

(c) if the annual fee laid down in accordance with Article 12 is not paid in time;

(d) if and as long as the product covered by the certificate may no longer be placed on the market following the withdrawal of the appropriate authorisation or authorisations to place on the market in accordance with Directive 2001/83/EC or ~~Directive 2001/82/EC~~ Regulation (EU) 2019/6.

⇨ For the purposes of point (d), ⇦ ~~T~~the authority referred to in Article 9(1) ~~of this Regulation~~ may decide on the lapse of the certificate either of its own motion or at the request of a third party.

Article 15

Invalidity of the certificate

1. The certificate shall be invalid ⌦ in any of the following events ⌫ ~~if~~:

(a) ⌦ the certificate ⌫ ~~it~~ was granted contrary to ~~the provisions of~~ Article 3;

(b) the basic patent has lapsed before its lawful term expires;

(c) the basic patent is revoked or limited to the extent that the product for which the certificate was granted would no longer be protected by the claims of the basic patent or, after the basic patent has expired, grounds for revocation exist which would have justified such revocation or limitation.

2. Any person may submit an application or bring an action for a declaration of invalidity of the certificate before the body responsible under national law for the revocation of the corresponding basic patent ⇨ , or before a competent court of a Member State ⇦.

Article 16

Revocation of an extension of the duration of a certificate for a medicinal product

1. The extension of the duration may be revoked if it was granted contrary to ~~the provisions of~~ Article 36 of Regulation (EC) No 1901/2006.

2. Any person may submit an application for revocation of the extension of the duration ⌦ granted under this Chapter ⌫ to the body responsible under national law for the revocation of the corresponding basic patent.

Article 17

Notification of lapse or invalidity

1. If the certificate lapses in accordance with ~~point (b), (c) or (d) of~~ Article 14, points (b), (c) or (d), or is invalid in accordance with Article 15, ⌦ the authority referred to in Article 9(1) shall publish ⌫ notification thereof ~~shall be published by the authority referred to in Article 9(1)~~.

2. If the extension of the duration is revoked in accordance with Article 16, ⌦ the authority referred to in Article 9(1) shall publish ⌫ notification thereof ~~shall be published by the authority referred to in Article 9(1)~~.

Article 18

Appeals

1. The decisions of the authority referred to in Article 9(1) or of the bodies referred to in Article 15(2) and Article 16(2) taken under this ~~Regulation~~ Chapter shall be open to the same appeals as those provided for in national law against similar decisions taken in respect of national patents.

⇩ new

2. The decision to grant the certificate shall be open to an appeal aimed at rectifying the duration of the certificate where the date of the first authorisation to place the product on the market in the Union, contained in the application for a certificate as provided for in Article 8, is incorrect.

🡻 469/2009 (adapted)

Article 19

Procedure

1. In the absence of procedural provisions in this Regulation, the procedural provisions applicable under national law to the corresponding basic patent shall apply to the certificate, unless the national law lays down special procedural provisions for certificates.

2. Notwithstanding paragraph 1, the procedure for opposition to the grant~~ing~~ of a certificate shall be excluded.

⇩ new

CHAPTER III
CENTRALISED PROCEDURE FOR CERTIFICATES

Article 20

Scope of the centralised application

1. Where the basic patent is a European patent, including a unitary patent, and the authorisation to place the product on the market has been granted through the centralised procedure under Regulation (EC) No 726/2004 or Regulation (EU) 2019/6, the procedure in this Chapter shall apply.

2. When the conditions under paragraph 1 are met, the filing of national applications shall be prohibited, in respect of the same product, in those Member States in which that basic patent is in force.

3. A centralised application shall be lodged with the European Union Intellectual Property Office established by Article 2 of Regulation (EU) 2017/1001 ('the Office').

4. Articles 1 to 7 and 13 to 18 shall apply to centralised applications.

5. The centralised application shall be lodged by using a specific application form.

The Commission is empowered to adopt implementing acts laying down rules on the application form to be used to lodge a centralised application. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 56.

Article 21

Content of the centralised application

The centralised application shall contain the following:

(a) designation of the Member States in which certificates are sought under the centralised procedure;

(b) the information referred to in Article 8(1).

Article 22

Examination of the admissibility of a centralised application

1. The Office shall examine the following:

(a) whether the centralised application complies with Article 21;

(b) whether the centralised application complies with Article 7;

(c) whether the application fee referred to in Article 34(1) has been paid within the prescribed period.

2. Where the centralised application does not satisfy the requirements referred to in paragraph 1, the Office shall request the applicant to take the measures necessary to satisfy those requirements, and shall set a deadline for such compliance.

3. Where the fee referred to in paragraph 1, point (c), has not been paid or has not been paid in full, the Office shall inform the applicant accordingly.

4. If the applicant does not satisfy the requirements referred to in paragraph 1 within the deadline referred to in paragraph 2, the Office shall reject the application.

Article 23

Publication of the centralised application

If the centralised application complies with Article 22, or if an application for an extension of the duration of certificates complies with Article 33(2), the Office shall publish the application, without undue delay, in the Register.

Article 24

Examination of the centralised application

1. The Office shall assess the application on the basis of all the conditions in Article 3(1) for each of the designated Member States.

2. Where the centralised application for a certificate and the product to which it relates comply with Article 3(1) in respect of all or some of the designated Member States, the Office shall adopt a reasoned positive examination opinion in respect of such Member States. The Office shall notify that opinion to the applicant.

3. Where the centralised application for a certificate and the product to which it relates does not comply with Article 3(1) in respect of all or some of the designated Member States, the Office shall adopt a reasoned negative examination opinion in respect of such Member States. The Office shall notify that opinion to the applicant.

4. The Office shall translate the examination opinion in the official languages of all designated Member States. The Office may use verified machine translation to that effect.

5. The Commission is empowered to adopt implementing acts laying down rules on procedures relating to the filing, and procedures regarding the way in which examination panels examine centralised applications and prepare examination opinions, as well as the issuance of examination opinions by the Office. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 56.

Article 25

Observations by third parties

1. Any natural or legal person may submit written observations to the Office concerning the eligibility for supplementary protection of the product to which the application relates in one or more of the Member States designated therein.

2. A natural or legal person that has submitted the written observations in accordance with paragraph 1 shall not be a party to the proceedings.

3. Third party observations shall be submitted within 3 months after publication of the centralised application in the Register.

4. Any observations by a third party shall be submitted in writing in one of the official languages of the Union and state the grounds on which they are based.

5. Any observations by a third party shall be notified to the applicant. The applicant may comment on the observations within a time limit set by the Office.

Article 26

Opposition

1. Within a period of 2 months following the publication of the examination opinion in respect of a centralised application, any person ('opponent') may file with the Office a notice of opposition to that opinion.

2. Opposition may only be filed on the grounds that one or more of the conditions set out in Article 3 are not fulfilled for one or more of the designated Member States.

3. Opposition shall be filed in writing, and shall specify the grounds on which it is made. It shall not be considered as duly filed until the opposition fee has been paid.

4. The notice of opposition shall contain:

   (a) the references of the centralised application against which opposition is filed, the name of its holder, and the identification of the product;

   (b) the particulars of the opponent and, where applicable, of its representative;

   (c) a statement of the extent to which the examination opinion is opposed, and of the grounds on which the opposition is based.

5. The opposition shall be examined by an opposition panel set up by the Office in accordance with the rules applicable to examination panels as referred to in Article 28. However, the opposition panel shall not include any examiner previously involved in the examination panel that examined the centralised application.

6. If the opposition panel notes that the notice of opposition does not comply with paragraphs 2, 3 or 4, it shall reject the opposition as inadmissible, and communicate this to opponent, unless these deficiencies have been remedied before expiry of the opposition filing period referred to in paragraph 1.

7. The decision to reject an opposition as inadmissible shall be communicated to the holder of the centralised application, together with a copy of the notice of opposition.

A notice of opposition shall be inadmissible where a previous appeal relating to the same subject matter and cause of action has been adjudicated on its merits by the Office, and the decision of the Office on that appeal has acquired the authority of a final decision.

8. Where the opposition is not rejected as inadmissible, the Office shall promptly transmit the notice of opposition to the applicant, and shall publish it in the Register. If several notices of opposition have been filed, the Office shall promptly communicate them to the other opponents.

9. The Office shall issue a decision on the opposition within 6 months, unless the complexity of the case requires a longer period.

10. If the opposition panel considers that no ground for opposition prejudices the maintenance of the examination opinion, it shall reject the opposition, and the Office shall mention this in the Register.

11. If the opposition panel considers that at least one ground for opposition prejudices the maintenance of the examination opinion, it shall adopt an amended opinion, and the Office shall mention this in the Register.

12. The Commission is empowered to adopt delegated acts in accordance with Article 55 to supplement this Regulation by specifying the details of the procedure for filing and examining an opposition.

Article 27

Role of competent national authorities

1. On a request made to the Office, any competent national authority may be appointed by the Office as a participating office in the examination procedure. Once a competent national authority is appointed in accordance with this Article, that authority shall designate one or more examiners to be involved in the examination of one or more centralised applications.

2. The Office and the competent national authority shall conclude an administrative agreement before that competent national authority is appointed as participating office as referred to in paragraph 1.

   The agreement shall specify the rights and obligations of the parties, in particular the formal undertaking by the competent national authority concerned to comply with this Regulation as regards the centralised examination procedure.

3. The Office may appoint a competent national authority as a participating office as referred to in paragraph 1 for 5 years. That appointment may be extended for further periods of 5 years.

4. The Office shall, before appointing a competent national authority, or extending its appointment, or before any such appointment expires, hear the competent national authority concerned.

5. Each competent national authority appointed under this Article shall provide the Office with a list identifying the individual examiners who are available for participation in examination and opposition proceedings. Each such competent national authority shall update that list in the event of a change.

Article 28

Examination panels

1. The assessments under Articles 24, 26 and 33 shall be conducted by an examination panel including one member of the Office as well as two examiners as referred to in Article 27(1) from two different participating competent national authorities.

2. Examiners shall be impartial in the exercise of their duties and shall declare to the Office any real or perceived conflict of interest upon their designation.

3. When setting up an examination panel, the Office shall ensure the following:

   (a) geographical balance amongst the participating offices;

(b) the respective workload of the examiners is taken into account;

(c) no more than one examiner employed by a competent national authority making use of the exemption laid down in Article 10(5).

4. The Office shall publish a yearly overview of the number of procedures, including those for examination, opposition and appeal, each competent national authority participated in.

5. The Commission is empowered to adopt implementing acts to determine the criteria in the ways the panels are to be set up, and the criteria for the selection of examiners. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 56.

Article 29

Appeals

1. Any party to proceedings under this Chapter, adversely affected by a decision of the Office, including the adoption of an examination opinion, may appeal the decision to the Boards of Appeal.

2. The filing of the appeal shall have suspensive effect. A decision of the Office that has not been contested shall take effect on the day following the date of expiry of the appeal period referred to in paragraph 3.

3. Notice of appeal shall be filed in writing at the Office within 2 months of the date of notification of the decision. The notice shall be deemed to have been filed only when the fee for appeal has been paid. In case of an appeal, a written statement setting out the grounds of appeal shall be filed within 4 months of the date of notification of the decision.

4. Following an examination of admissibility of the appeal, the Boards of Appeal shall decide on the merits of the appeal.

5. Where an appeal before the Boards of Appeal of the Office results in a decision which is not in line with the examination opinion and is remitted to the Office, the decision of the Boards may annul or alter that opinion before transmitting it to the competent national authorities of the designated Member States.

6. An action may be brought before the General Court of the European Union against a decision of the Boards of Appeal in relation to appeals, within 2 months of the date of notification of that decision, on grounds of infringement of an essential procedural requirement, infringement of the Treaty on the Functioning of the European Union, infringement of this Regulation or of any rule of law relating to their application or misuse of power. The action shall be open to any party to proceedings before the Board of Appeal adversely affected by its decision. The General Court shall have jurisdiction to annul or to alter the contested decision.

7. The decisions of the Boards of Appeal shall take effect on the day following the date of expiry of the period referred to in paragraph 6 or, if an action has been brought before the General Court within that period, as from the date following the day of dismissal of such action or of dismissal of any appeal filed with the Court of Justice of the European Union against the decision of the General Court. The Office shall take the necessary measures to comply with the judgement of the General Court or, in the event of an appeal against that judgement, the Court of Justice.

8. The Commission is empowered to adopt delegated acts in accordance with Article 55 to supplement this Regulation by specifying the content and form of the notice of appeal referred to in paragraph 3, the procedure for the filing and examination of an appeal and the content and the form of the Boards of Appeal's decision referred to in paragraph 4.

Article 30

Boards of Appeal

1. In addition to the powers conferred upon it by Article 165 of Regulation (EU) 2017/1001, the Boards of Appeal instituted by that Regulation shall be responsible for deciding on appeals against decisions of the Office taken on the basis of Article 29(1).

2. A Board of Appeal in matters regarding centralised applications for certificates shall consist of three members, at least two of whom are legally qualified. Where the Board of Appeal considers that the nature of the appeal so requires, it may call up to two further members for that case.

3. There shall be no Grand Board as referenced in Article 165 (2), (3) and 4, as well as Article 167 (2) of Regulation (EU) 2017/1001 in matters regarding centralised applications for certificates. Decisions taken by a single member as under Article 165 (2) of Regulation (EU) 2017/1001 shall not be possible.

4. Members of the Boards of Appeal in matters regarding centralised applications for certificates shall be appointed in accordance with Article 166 (5) of Regulation (EU) 2017/1001.

Article 31

Delegation of power regarding the Boards of Appeal

The Commission is empowered to adopt delegated acts in accordance with Article 55 to supplement this Regulation by specifying the details concerning the organisation of the Boards of Appeal in proceedings relating to certificates under this Regulation.

Article 32

National implementation of a centralised examination opinion

1. After the period during which an appeal or an opposition may be filed has expired without any appeal nor opposition being filed, or after a final decision on the merits has been issued, the Office shall transmit the examination opinion and its translations to the competent national authority of each designated Member State.

2. In respect of a centralised application, where a positive examination opinion has been issued for one or more designated Member State, the competent national authority of each of those Member States shall grant a certificate in accordance with applicable national rules and procedures.

3. By way of derogation from paragraph 2, a Member State may decide not to grant a certificate, where material circumstances, in that Member State, have changed since the filing of the centralised application in respect of one or more of the conditions laid down in Article 15(1), points (b) or (c), or Article 14, first paragraph, point (d).

In such a case that Member State shall reject the application insofar as that Member State is concerned.

4. A certificate granted by a competent national authority under this Article shall be subject to Articles 4, 5, 11 and 12 to 19, and to the applicable national legislation.

5. Where a negative examination opinion has been issued for one or more designated Member State, the competent national authority of each of those Member States shall issue a rejection decision according to its applicable national rules and procedures.

Article 33

Centralised application for an extension of the duration of certificates

1. Where certificates for a given medicinal product have been granted through the centralised procedure, their holder may request an extension of the duration of those certificates by filing a centralised application for an extension of the duration of those certificates with the Office. That centralised application shall specify the designation of the Member States for which the extension is requested.

2. The centralised application for an extension of the duration of certificates shall be filed in accordance with Article 7(3) and (4), Article 8(1), point (d), Article 8(2), (3) and (4).

3. Articles 10, 11 and 17 shall apply, whereby references to 'the authority referred to in Article 9(1)' shall be understood as references to the Office.

4. Third parties may also submit observations in respect of a centralised application for an extension of the duration of certificates.

Article 34

Fees

1. The Office shall charge a fee for a centralised application for certificates, and for a centralised application for the extension of the duration of a certificate.

2. The Office shall charge a fee for an appeal, and for an opposition.

3. The Commission is empowered to adopt implementing acts to determine the amounts of the fees charged by the Office, the time limits within which they have to be paid, and the ways in which those fees are to be paid. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 56.

4. Article 12 shall apply to certificates granted under this Chapter.

Article 35

Register

1. The Office shall develop, keep and maintain an electronic Register, providing up-to-date information regarding the status of all published centralised applications, and of all centralised applications for an extension of the duration of certificates.

2. The Register shall include, for each centralised application or certificate, all of the following information:

(a) the name and address of the applicant or certificate holder;

(b) the name and business address of the representative, other than a representative as referred to in Article 37(3);

(c) the application as well as its date of lodging and date of publication;

(d) whether the application relates to a medicinal product or to a plant protection product;

(e) where applicable, an indication that the application includes an application for an extension of the duration;

(f) the designated Member States;

(g) the number of the basic patent;

(h) an identification of the product for which certificates are requested;

(i) the number and date of the authorisation to place the product on the market referred to in Article 3(1), point (b), and an identification of the product identified therein;

(j) the number and date of the first authorisation to place the product on the market in the Union;

(k) the date and a summary of the examination opinion in respect of each of the designated Member States;

(l) where applicable, the duration of the certificates to be granted;

(m) where applicable, the date and a summary of the examination opinion relating to an application for an extension of the duration of a certificate;

(n) where applicable, the filing of an opposition, and its outcome, including where applicable a summary of the revised examination opinion;

(o) where applicable, the filing of an appeal, and the outcome of the appeal proceedings, including where applicable a summary of the revised examination opinion;

(p) where applicable and available, the particulars of the certificates granted in each of the designated Member States;

(q) where applicable, a mention that the centralised application was rejected in one or more of the designated Member States;

(r) where applicable, a mention that a certificate has lapsed or was declared invalid;

(s) information on the payment of annual fees, as provided by the relevant competent national authorities.

3. The Register shall contain changes to the information in paragraph 2, including transfers, each accompanied by the date of recording of such entry.

4. The Register and information referred to in paragraphs 2 and 3 shall be available in all official languages of the Union. The Office may use verified machine translation for the information to be published in the Register.

5. Competent national authorities shall promptly share with the Office information relating to the grant, lapse, invalidity or transfers of certificates and to the rejection of applications under Chapters II and III, and to the payment of related annual fees.

6. The Executive Director of the Office may determine that information other than those referred to in paragraphs 2 and 3 shall be entered in the Register.

7. The Office shall collect, organise, make public and store the information referred to in paragraphs 2 and 3, including any personal data, for the purposes laid down in paragraph 10. The Office shall keep the Register easily accessible for public inspection.

8. The Office shall provide certified or uncertified extracts from the Register on request and on payment of a fee.

9. The processing of the data concerning the entries set out in paragraphs 2 and 3, including any personal data, shall take place for the purposes of the following:

(a) administering the applications in accordance with this Chapter and the acts adopted pursuant to it;

(b) maintaining the Register and making it available for inspection by public authorities and economic operators;

(c) producing reports and statistics enabling the Office to optimise its operations and improve the functioning of the system.

10. All the data, including personal data, concerning the entries in paragraphs 2 and 3 shall be considered to be of public interest and may be accessed by any third party free of charge. For reasons of legal certainty, the entries in the Register shall be kept for an indefinite period of time.

11. The Register set up under this Article shall also be used to publish information relating to certificates for plant protection products under Regulation [COM(2023) 223], and relating to unitary certificates under Regulation [COM(2023) 222] and Regulation [COM(2023) 221].

Article 36

Database

1. In addition to the obligation to keep a Register, the Office shall collect and store in an electronic database all the particulars provided by applicants or any other third party observations pursuant to this Regulation or acts adopted pursuant to it.

2. The electronic database may include personal data, beyond those included in the Register, to the extent that such particulars are required by this Regulation or by acts adopted pursuant to it. The collection, storage and processing of such data shall serve the purposes of:

(a) administering the applications and/or certificate registrations as described in this Regulation and in acts adopted pursuant to it;

(b) accessing the information necessary for conducting the relevant proceedings more easily and efficiently;

(c) communicating with the applicants and other third parties;

(d) producing reports and statistics enabling the Office to optimise its operations and improve the functioning of the system.

3. The Executive Director shall determine the conditions of access to the electronic database and the manner in which its contents, other than the personal data referred

to in paragraph 2 of this Article but including those listed in Article 35(3), may be made available in machine-readable form, including the charge for such access.

4. Access to the personal data referred to in paragraph 2 shall be restricted and such data shall not be made publicly available unless the party concerned has given his express consent.

5. All data shall be kept indefinitely. However, the party concerned may request the removal of any personal data from the database after 18 months from the expiry of the certificate or, the case being, the closure of the relevant *inter partes* procedure. The party concerned shall have the right to obtain the correction of inaccurate or erroneous data at any time.

Article 37

Transparency

1. Regulation (EC) No 1049/2001 of the European Parliament and of the Council[40] shall apply to documents held by the Office.

2. The Management Board of the Office shall adopt detailed rules for applying Regulation (EC) No 1049/2001 in the context of this Regulation.

3. Decisions taken by the Office under Article 8 of Regulation (EC) No 1049/2001 may be challenged through the European Ombudsman or form the subject of an action before the Court of Justice of the European Union, under the conditions laid down in Articles 228 and 263 TFEU respectively.

4. The processing of personal data by the Office shall be subject to Regulation (EC) No 45/2001 of the European Parliament and of the Council[41].

Article 38

Representation

1. Natural or legal persons having neither their domicile nor their principal place of business or a real and effective industrial or commercial establishment in the European Economic Area shall be represented before the Office in accordance with this Article in all proceedings provided for by Chapter III of this Regulation, other than the filing of a centralised application.

2. Natural or legal persons having their domicile or principal place of business or a real and effective industrial or commercial establishment in the European Economic Area may be represented before the Office by an employee.

An employee of a legal person may also represent other legal persons which are economically linked with the legal person being represented by that employee.

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[40] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

[41] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

The second subparagraph also applies where those other legal persons have neither their domicile nor their principal place of business nor a real and effective industrial or commercial establishment within the Union.

Employees who represent natural or legal persons shall, at the request of the Office or, where appropriate, of the party to the proceedings, file with the Office a signed authorisation for insertion in the files.

3. A common representative shall be appointed where there is more than one applicant or more than one third party acting jointly.

4. Only a practitioner established in the Union, entitled to act as a professional representative in patent matters before a national patent office or the European Patent Office, or a lawyer authorised to practise before the courts or tribunals of a Member State, may represent natural or legal persons before the Office.

Article 39

Combined applications

1. A centralised application may also include a request for the grant of a unitary certificate, as defined in Regulation [COM(2023) 222][42] ('combined application').

2. The combined application shall undergo a single centralised examination procedure, as well as a single opposition or appeal procedure, where it has been filed against an opinion or decision in respect of both the centralised application and the unitary certificate application.

3. The Member States for which the basic patent has unitary effect shall not be designated in the combined application for the parallel grant of national certificates. Any designation, in the combined application, of a Member State for which the basic patent has unitary effect shall be disregarded for the purpose of the examination of the combined application.

Article 40

Supplementary Protection Certificates Division

A Supplementary Protection Certificate Division ('SPC Division') shall be set up within the Office and shall be responsible for implementing the tasks set out in Chapter III of this Regulation and in Chapter III of Regulation [COM(2023) 223], as well as in Regulations [COM(2023) 222] and [COM(2023) 221], including in particular:

(a) receiving and supervising the examination of centralised applications for certificates, centralised applications for an extension of the duration of certificates, appeals and observations by third parties;

(b) adopting examination opinions on behalf of the Office in relation to centralised applications for certificates, as well as in relation to centralised applications for an extension of the duration of certificates;

[42] Regulation of the European Parliament and of the Council concerning the unitary supplementary protection certificate for medicinal products [COM(2023) 222].

(c) deciding on oppositions against examination opinions;

(d) maintaining the register and the database.

Article 41

Languages

1. All documents and information sent to the Office in respect of the procedures under this Regulation shall be in one of the official languages of the Union.

2. For the tasks conferred on the Office under this Regulation, the languages of the Office shall be all the official languages of the Union in accordance with Council Regulation No 1[43].

Article 42

Communications to the Office

1. Communications addressed to the Office may be effected by electronic means. The Executive Director shall determine to what extent and under which technical conditions those communications may be submitted electronically.

2. The Commission is empowered to adopt delegated acts in accordance with Article 55 to supplement this Regulation by specifying the rules on the means of communication, including the electronic means of communication, to be used by the parties to proceedings before the Office and the forms to be made available by the Office.

Article 43

Decisions and communications of the Office

1. Decisions of the Office under this Chapter shall include examination opinions and shall state the reasons on which they are based. They shall be based only on reasons or evidence on which the parties concerned have had an opportunity to present their comments. Where oral proceedings are held before the Office, the decision may be given orally. Subsequently, the decision or opinion shall be notified in writing to the parties.

2. Any decision, opinion, communication or notice from the Office under this Chapter shall indicate the SPC Division and the relevant panel as well as the name or the names of the examiners responsible. It shall be signed by these examiners, or, instead of a signature, carry a printed or stamped seal of the Office. The Executive Director may determine that other means of identifying the SPC Division and the name of the examiners responsible, or an identification other than a seal, may be used where decisions or other communications are transmitted by any technical means of communication.

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[43] Council Regulation No 1 determining the languages to be used by the European Economic Community (OJ 17, 6.10.1958, p. 385).

3. Decisions of the Office under this Chapter which are open to appeal shall be accompanied by a written communication indicating that any notice of appeal is to be filed in writing at the Office within 2 months of the date of notification of the decision in question. That communication shall also draw the attention of the parties to the provisions laid down in Article 29. The parties may not plead any failure on the part of the Office to communicate the availability of appeal proceedings.

Article 44

Oral proceedings

1. If the Office considers that oral proceedings would be expedient they shall be held either at the instance of the Office or at the request of any party to the proceedings.

2. Oral proceedings before an examination panel or opposition panel shall not be public.

3. Oral proceedings before the Boards of Appeal, including delivery of the decision and, as the case may be, of a revised opinion, shall be public, unless the Boards of Appeal decide otherwise in cases where admission of the public could have serious and unjustified disadvantages, in particular for a party to the proceedings.

4. The Commission is empowered to adopt delegated acts in accordance with Article 55 to supplement this Regulation by setting out the detailed arrangements for oral proceedings.

Article 45

Taking of evidence

1. In any proceedings before the Office, the means of giving or obtaining evidence shall include the following:

   (a) hearing the parties;

   (b) requests for information;

   (c) the production of documents and items of evidence;

   (d) hearing witnesses;

   (e) opinions by experts;

   (f) statements in writing sworn or affirmed or having a similar effect under the law of the State in which the statement is drawn up.

2. The relevant panel may commission one of its members to examine the evidence adduced.

3. If the Office or the relevant panel considers it necessary for a party, witness or expert to give evidence orally, it shall issue a summons to the person concerned to appear before it. The period of notice provided in such summons shall be at least 1 month, unless they agree to a shorter period.

4. The parties shall be informed of the hearing of a witness or expert before the Office. They shall have the right to be present and to put questions to the witness or expert.

5. The Executive Director shall determine the amounts of expenses to be paid, including advances, as regards the costs of taking of evidence as referred to in this Article.

6. The Commission is empowered to adopt delegated acts in accordance with Article 55 to supplement this Regulation by setting out the detailed arrangements for the taking of evidence.

Article 46

Notification

1. The Office shall, as a matter of course, notify those concerned of decisions, including opinions, summonses and of any notice or other communication from which a time limit is reckoned, or of which those concerned are to be notified under other provisions of this Chapter or of acts adopted pursuant to this Chapter, or of which notification has been ordered by the Executive Director.

2. Notification may be effected by different means, including electronic means. The details regarding electronic means shall be determined by the Executive Director.

3. Where notification is to be effected by public notice, the Executive Director shall determine how the public notice is to be given and shall fix the beginning of the 1-month period on the expiry of which the document shall be deemed to have been notified.

4. The Commission is empowered to adopt delegated acts in accordance with Article 55 to supplement this Regulation by setting out the detailed arrangements for notification.

Article 47

Time limits

1. Time limits shall be laid down in terms of full years, months, weeks or days. Calculation shall start on the day following the day on which the relevant event occurred. The duration of time limits shall be no less than 1 month and no more than 6 months.

2. The Executive Director shall determine, before the commencement of each calendar year, the days on which the Office is not open for receipt of documents or on which ordinary post is not delivered in the locality in which the Office is located.

3. The Executive Director shall determine the duration of the period of interruption in the case of a general interruption in the delivery of post in the Member State where the Office is located or, in the case of an actual interruption of the Office's connection to admitted electronic means of communication.

4. If an exceptional occurrence, such as a natural disaster or strike, interrupts or interferes with proper communication from the parties to the proceedings to the Office or vice-versa, the Executive Director may determine that for parties to the proceedings having their residence or registered office in the Member State concerned or who have appointed a representative with a place of business in the Member State concerned all time limits that otherwise would expire on or after the date of commencement of such occurrence, as determined by the Executive Director, shall extend until a date to be determined by the Executive Director. When determining that date, the Executive Director shall assess when the exceptional occurrence comes to an end. If the occurrence affects the seat of the Office, such determination of the Executive Director shall specify that it applies in respect of all parties to the proceedings.

5. The Commission is empowered to adopt delegated acts in accordance with Article 55 to supplement this Regulation by specifying the details regarding the calculation and duration of time limits.

Article 48

Correction of errors and manifest oversights

1. The Office shall correct any linguistic errors or errors of transcription and manifest oversights in its decisions, including opinions, or technical errors in publishing information in the Register, of its own motion or at the request of a party.

2. Where the Office has made an entry in the Register or taken a decision which contains an obvious error attributable to the Office, it shall ensure that the entry is cancelled or the decision is revoked. The cancellation of the entry in the Register or the revocation of the decision shall be effected within 1 year of the date on which the entry was made in the Register or that decision was taken, after consultation with the parties to the proceedings.

3. The Office shall keep records of any such corrections or cancellations.

4. Corrections and cancellations shall be published by the Office.

Article 49

Restitutio in integrum

1. The applicant or any other party to proceedings before the Office under this Chapter, who, in spite of all due care required by the circumstances having been taken, was unable to comply with a time limit vis-à-vis the Office shall, upon application, have his rights re-established if the obstacle to compliance has the direct consequence, by virtue of the provisions of this Chapter, of causing the loss of any right or means of redress.

2. The application for re-establishment shall be filed in writing within 2 months of the removal of the obstacle to compliance with the time limit. The omitted act shall be completed within this period. The application shall only be admissible within the year immediately following the expiry of the unobserved time limit.

3. The application for re-establishment shall state the grounds on which it is based and shall set out the facts on which it relies. It shall not be deemed to be filed until the fee for re-establishment of rights has been paid.

4. The SPC Division, or where applicable the Boards of Appeal, shall decide upon the application.

5. This Article shall not be applicable to the time limits referred to in paragraph 2 of this Article, or in Article 26(1) and (3).

Article 50

Interruption of proceedings

1. Proceedings before the Office under this Chapter shall be interrupted:

   (a) in the event of the death or legal incapacity of the applicant or of the person authorised by national law to act on behalf of the applicant. To the extent that that death or incapacity does not affect the authorisation of a representative

appointed under Article 38, proceedings shall be interrupted only on application by such representative;

(b) in the event of the applicant being prevented, for legal reasons resulting from action taken against his property, from continuing the proceedings before the Office;

(c) in the event of the death or legal incapacity of the representative of the applicant, or of that representative being prevented, for legal reasons resulting from action taken against his property, from continuing the proceedings before the Office.

2. Proceedings before the Office shall be resumed as soon as the identity of the person authorised to continue them has been established.

3. The Commission is empowered to adopt delegated acts in accordance with Article 55 to supplement this Regulation by setting out the detailed arrangements for the resumption of proceedings before the Office.

Article 51

Costs

1. The losing party in opposition proceedings, including in related appeal proceedings, shall bear the fees paid by the other party. The losing party shall also bear all costs incurred by the other party that are essential to the proceedings, including travel and subsistence and the remuneration of a representative, within the maximum rates set for each category of costs in the implementing act to be adopted in accordance with paragraph 7. The fees to be borne by the losing party shall be limited to the fees paid by the other party in those proceedings.

2. Where each party succeeds on some and fails on other heads, or if reasons of equity so dictate, the SPC Division or Board of Appeal shall decide a different apportionment of costs.

3. Where proceedings are terminated the costs shall be at the discretion of the SPC Division or Board of Appeal.

4. Where the parties conclude before the SPC Division or Board of Appeal a settlement of costs differing from that provided for in paragraphs 1 to 3, the body concerned shall take note of that agreement.

5. The SPC Division or Board of Appeal shall fix the amount of the costs to be paid pursuant to paragraphs 1 to 3 of this Article when the costs to be paid are limited to the fees paid to the Office and the representation costs. In all other cases, the registry of the Board of Appeal or SPC Division shall fix, on request, the amount of the costs to be reimbursed. The request shall be admissible only for the period of 2 months following the date on which the decision for which an application was made for the costs to be fixed becomes final and shall be accompanied by a bill and supporting evidence. For the costs of representation an assurance by the representative that the costs that have been incurred shall be sufficient. For other costs, it shall be sufficient if their plausibility is established. Where the amount of the costs is fixed pursuant to the first sentence of this paragraph, representation costs shall be awarded at the level laid down in the implementing act adopted pursuant to paragraph 7 of this Article and irrespective of whether they have been actually incurred.

6. Decisions on the fixing of costs adopted in accordance with paragraph 5 shall state the reasons on which they are based, and may be reviewed by a decision of the SPC Division or Board of Appeal on a request filed within 1 month of the date of notification of the awarding of costs. It shall not be deemed to be filed until the fee for reviewing the amount of the costs has been paid. The SPC Division or the Board of Appeal, as the case may be, shall take a decision on the request for a review of the decision on the fixing of costs without oral proceedings.

7. The Commission shall adopt implementing acts specifying the maximum rates for costs essential to the proceedings and actually incurred by the successful party. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 56.

8. When specifying the maximum rates with respect to travel and subsistence costs, the Commission shall take into account the distance between the place of residence or business of the party, representative or witness or expert and the place where the oral proceedings are held, the procedural stage at which the costs have been incurred, and, as far as costs of representation are concerned, the need to ensure that the obligation to bear the costs may not be misused for tactical reasons by the other party. In addition, subsistence expenses shall be calculated in accordance with the Staff Regulations of Officials of the Union and the Conditions of Employment of Other Servants of the Union, laid down in Council Regulation (EEC, Euratom, ECSC) No 259/68[44]. The losing party shall bear the costs for one party in the proceedings only and, where applicable, one representative only.

Article 52

Enforcement of decisions fixing the amount of costs

1. Any final decision of the Office fixing the amount of costs shall be enforceable.

2. Enforcement shall be governed by the rules of civil procedure in force in the Member State in the territory of which it is carried out. Each Member State shall designate a single authority responsible for verifying the authenticity of the decision referred to in paragraph 1 and shall communicate its contact details to the Office, the Court of Justice and the Commission. The order for enforcement shall be appended to the decision by that authority, with the verification of the authenticity of the decision as the sole formality

3. When these formalities have been completed on application by the party concerned, the latter may proceed to enforcement in accordance with the national law, by bringing the matter directly before the competent authority.

4. Enforcement may be suspended only by a decision of the Court of Justice. However, the courts of the Member State concerned shall have jurisdiction over complaints that enforcement is being carried out in an irregular manner.

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[44] Regulation (EEC, Euratom, ECSC) No 259/68 of the Council of 29 February 1968 laying down the Staff Regulations of Officials and the Conditions of Employment of Other Servants of the European Commission and instituting special measures temporarily applicable to officials of the Commission (OJ L 56, 4.3.1968, p. 1.).

Article 53

Financial provisions

1. The expenses incurred by the Office in carrying out the additional tasks given to it in accordance with this Regulation shall be covered by the procedural fees to be paid to the Office by applicants and, if needed, by a fraction of the annual fees paid to competent national authorities by the holders of certificates granted under Chapter III. That fraction shall initially be set at a certain value but shall be reviewed every 5 years, with the objective of achieving financial sustainability for the activities carried out by the Office under this Regulation as well as Regulations [COM(2023) 223], [COM(2023) 222] and [COM(2023) 221], insofar as expenses incurred by the Office are not covered by fees under these Regulations.

2. For the purposes of paragraph 1, each competent national authority shall keep an account of the annual fees paid to it by holders of certificates granted under this Chapter.

3. The expenses incurred by a competent national authority participating in proceedings under this Chapter shall be covered by the Office and shall be paid annually, on the basis of the number of proceedings in which that competent national authority was involved during the preceding year.

4. The Commission is empowered to adopt implementing acts laying down rules on the financial transfers between the Office and Member States, the amounts of these transfers, and the remuneration to be paid by the Office regarding the participation of competent national authorities referred to in paragraph 3. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 56.

↓ 469/2009 (adapted)

~~*Article 20*~~

~~*Additional provisions relating to the enlargement of the Community*~~

~~Without prejudice to the other provisions of this Regulation, the following provisions shall apply:~~

~~(a) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained after 1 January 2000 may be granted a certificate in Bulgaria, provided that the application for a certificate was lodged within six months from 1 January 2007;~~

~~(b) any medicinal product protected by a valid basic patent in the Czech Republic and for which the first authorisation to place it on the market as a medicinal product was obtained:~~

~~(i) in the Czech Republic after 10 November 1999 may be granted a certificate, provided that the application for a certificate was lodged within six months of the date on which the first market authorisation was obtained;~~

~~(ii) in the Community not earlier than six months prior to 1 May 2004 may be granted a certificate, provided that the application for a certificate was~~

~~lodged within six months of the date on which the first market authorisation was obtained;~~

~~(e) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained in Estonia prior to 1 May 2004 may be granted a certificate, provided that the application for a certificate was lodged within six months of the date on which the first market authorisation was obtained or, in the case of those patents granted prior to 1 January 2000, within the six months provided for in the Patents Act of October 1999;~~

~~(d) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained in Cyprus prior to 1 May 2004 may be granted a certificate, provided that the application for a certificate was lodged within six months of the date on which the first market authorisation was obtained; notwithstanding the above, where the market authorisation was obtained before the grant of the basic patent, the application for a certificate must be lodged within six months of the date on which the patent was granted;~~

~~(e) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained in Latvia prior to 1 May 2004 may be granted a certificate. In cases where the period provided for in Article 7(1) has expired, the possibility of applying for a certificate shall be open for a period of six months starting no later than 1 May 2004;~~

~~(f) any medicinal product protected by a valid basic patent applied for after 1 February 1994 and for which the first authorisation to place it on the market as a medicinal product was obtained in Lithuania prior to 1 May 2004 may be granted a certificate, provided that the application for a certificate was lodged within six months from 1 May 2004;~~

~~(g) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained after 1 January 2000 may be granted a certificate in Hungary, provided that the application for a certificate was lodged within six months from 1 May 2004;~~

~~(h) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained in Malta prior to 1 May 2004 may be granted a certificate. In cases where the period provided for in Article 7(1) has expired, the possibility of applying for a certificate shall be open for a period of six months starting no later than 1 May 2004;~~

~~(i) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained after 1 January 2000 may be granted a certificate in Poland, provided that the application for a certificate was lodged within six months starting no later than 1 May 2004;~~

~~(j) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained after 1 January 2000 may be granted a certificate in Romania. In cases where the period provided for in Article 7(1) has expired, the possibility of applying~~

~~for a certificate shall be open for a period of six months starting no later than 1 January 2007;~~

~~(k) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained in Slovenia prior to 1 May 2004 may be granted a certificate, provided that the application for a certificate was lodged within six months from 1 May 2004, including in cases where the period provided for in Article 7(1) has expired;~~

~~(l) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained in Slovakia after 1 January 2000 may be granted a certificate, provided that the application for a certificate was lodged within six months of the date on which the first market authorisation was obtained or within six months of 1 July 2002 if the market authorisation was obtained before that date.~~

↓ 2012 Act of Accession (adapted)

~~(m) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained after 1 January 2003 may be granted a certificate in Croatia, provided that the application for a certificate is lodged within six months from the date of accession.~~

↓ 469/2009 (adapted)

Article 54~~21~~

Transitional provisions

~~1. This Regulation shall not apply to certificates granted in accordance with the national legislation of a Member State before 2 January 1993 or to applications for a certificate filed in accordance with that legislation before 2 July 1992.~~

~~With regard to Austria, Finland and Sweden, this Regulation shall not apply to certificates granted in accordance with their national legislation before 1 January 1995.~~

↓ 2012 Act of Accession (adapted)

~~2.~~ This Regulation shall apply to ~~supplementary protection~~ certificates granted in accordance with the national legislation of ⌦ Czechia ⌫ ~~the Czech Republic~~, Estonia, Croatia, Cyprus, Latvia, Lithuania, Malta, Poland, Romania, Slovenia and Slovakia prior to their respective date of accession.

⇩ new

CHAPTER IV
FINAL PROVISIONS

Article 55

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Articles 26(13), 29(8), 31, 42(2), 44(4), 45(6), 46(4), 47(5) and 50(3) shall be conferred on the Commission for an indeterminate period of time from the date of entry into force of this Regulation.

3. The delegation of power referred to in Articles 26(13), 29(8), 31, 42(2), 44(4), 45(6), 46(4), 47(5) and 50(3) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect on the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Articles 26(13), 29(8), 31, 42(2), 44(4), 45(6), 46(4), 47(5) and 50(3) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 56

Committee procedure

1. The Commission shall be assisted by a Committee on Supplementary Protection Certificates. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

↓ 2019/933 Art. 1 pt. 5 (adapted)

Article 57~~21a~~

Evaluation

1. No later than five years after the date referred to in Article 5(10), and every ~~five~~ ⌦ 5 ⌫ years thereafter, the Commission shall carry out an evaluation of Article 5(2) to (9) and Article 11 in order to assess whether the objectives of those provisions have been achieved, and present a report on the main findings to the European Parliament, the Council and the European Economic and Social Committee. In addition to evaluating the impact of the exception of making for the purpose of export, special account shall be taken of the effects of making for the purpose of storing in order to place that product, or a medicinal product containing that product, on the market of Member States after the expiry of the corresponding certificate on access to medicines and on public health expenditure, and of whether the waiver and in particular the period provided for in Article 5(2), point (a)(iii), ~~of Article 5(2)~~ is sufficient to achieve the objectives referred to in Article 5, including public health.

⇩ new

2. By *[OP, please insert: five years after the date of application]*, and every 5 years thereafter, the Commission shall also carry out an evaluation of the application of Chapter III.

Article 58

Transitional provisions for pending applications

Article 20(2) shall not apply to national applications for certificates that are pending before competent national authorities on the xxxxxx *[OP – please insert the date of application of this Regulation]* and that meet the conditions under Article 20(1).

↓ 469/2009 (adapted)

Article 59~~22~~

Repeal

Regulation ⌦ (EC) No 469/2009 ⌫ ~~(EEC) No 1768/92, as amended by the acts listed in Annex I,~~ is repealed.

References to the repealed Regulation shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex IV~~II~~.

↓ (adapted)

Article 60~~23~~

Entry into force ⌦ and application ⌫

This Regulation shall enter into force on the ~~20th~~ ⌦ twentieth ⌫ day following its publication in the *Official Journal of the European Union*.

⇩ new

Articles 20 to 53 and 55 to 57 shall apply from xxxxx *[OP: please insert: the first day of the 12th month after the entry into force]*.

↓ 469/2009

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

Council of the European Union

Brussels, 28 April 2023
(OR. en)

8900/23

Interinstitutional File: 2023/0133(COD)

PI 57
COMPET 386
MI 354
IND 208
IA 90
CODEC 750
RC 11

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	27 April 2023
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2023) 232 final
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on standard essential patents and amending Regulation (EU)2017/1001

Delegations will find attached document COM(2023) 232 final.

Encl.: COM(2023) 232 final

EUROPEAN
COMMISSION

Brussels, 27.4.2023
COM(2023) 232 final

2023/0133 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on standard essential patents and amending Regulation (EU)2017/1001

(Text with EEA relevance)

{SEC(2023) 174 final} - {SWD(2023) 123 final} - {SWD(2023) 124 final} -
{SWD(2023) 125 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

Standardisation is a key contributor to industrial innovation and competitiveness. Successful standards rest on cutting-edge technologies, which require substantial investments in research and development. Under the rules of many standards development organisations (SDOs), such as the ETSI[1] and the IEEE[2], companies and individuals may patent their technical contributions to a standard. Patents that protect technology essential to a standard are known as standard-essential patents (SEPs). Typically, SDOs require that any person or company wishing to have their patented technology included in a standard commit to licensing the relevant patents to others who may wish to use the standard (firms using/implementing a standard are also known as 'implementers'[3]). These licences must be granted to implementers on fair, reasonable and non-discriminatory (FRAND) terms and conditions. If the patent holder refuses to make such a commitment, their patented technology cannot be included in the standard.

The overall objectives of this proposed initiative are to: (i) ensure that end users, including small businesses and EU consumers benefit from products based on the latest standardised technologies; (ii) make the EU attractive for standards innovation; and (iii) encourage both SEP holders and implementers to innovate in the EU, make and sell products in the EU and be competitive in non-EU markets. The initiative aims to incentivise participation by European firms in the standard development process and the broad implementation of such standardised technologies, particularly in IoT industries.

In this context, the initiative seeks to: (i) make available detailed information on SEPs and existing FRAND terms and conditions to facilitate licensing negotiations; (ii) raise awareness of SEP licensing in the value chain and (iii) provide for an alternative dispute resolution mechanism for setting FRAND terms and conditions.

The Commission's 2017 Communication 'Setting out the EU approach to Standard Essential Patents'[4], called for a comprehensive and balanced approach to SEP licensing to incentivise the contribution of best technology to global standardisation efforts and foster efficient access to standardised technologies. The Commission acknowledged the need for increased transparency and addressed certain aspects of FRAND licensing and SEP enforcement. The Commission's views were supported by Council conclusions 6681/18[5], with the Council stressing the importance of increased transparency.

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1 European Telecommunications Standards Institute.

2 Institute of Electrical and Electronics Engineers.

3 In certain cases, a SEP holders can be an implementer and vice versa – in fact, many companies participating in standards development are vertically integrated and therefore fall under both categories. Thus, it is not fully accurate to divide the world of SEPs into two entirely separate groups – SEP holders and implementers. However, for ease of reference in this impact assessment, those terms will be used to refer to companies that own SEPs (i.e., SEP owner) and those that implement SEPs in their products (i.e., implementer).

4 Communication on Setting out the EU approach to Standard Essential Patents, COM(2017)712 final, 29.11.2017.

5 Council conclusions on the enforcement of Intellectual Property Rights, as approved by the Council (Internal Market, Industry, Research and Space) at its meeting on 12 March 2018

On 10 November 2020, by Council conclusions 12339/20[6], the Council invited the Commission to present proposals for future EU IP policy. The Council encouraged the Commission to swiftly present the announced IP action plan, with initiatives to make IP protection more effective and more affordable, especially for small and medium-sized EU enterprises ('SMEs')[7], and to promote the effective sharing of IP, in particular critical assets such as SEPs, while ensuring adequate and fair compensation for technology developers.

On 25 November 2020, the Commission published the intellectual property action plan[8], where it announced its goals of promoting transparency and predictability in SEP licensing, including by improving the SEP licensing system, for the benefit of EU industry and consumers, and in particular SMEs. The action plan noted increases in SEP licensing disputes in the automotive sector and the potential for other IoT sectors to become subject of such disputes as they begin using connectivity and other standards. The plan was supported by Council conclusions of 18 June 2021[9] and by the European Parliament (EP) in its Resolution[10]. The EP acknowledged the need for a strong, balanced and robust IPR system and agreed with the Commission's position that the transparency necessary for fair licensing negotiations depends in large part on the availability of information about the existence, scope and essentiality of SEPs. The EP also asked the Commission to provide more clarity on various aspects of FRAND, and to consider possible incentives for more efficient SEP licensing negotiations and reducing litigation.

In parallel with this initiative, the Commission has updated the Standardisation strategy[11] and is revising the Horizontal guidelines[12]. The new Standardisation strategy, published in February 2022, aims to strengthen the EU's role as global standard-setter, driving international competitiveness and enabling a resilient, green and digital economy. The present SEPs initiative is complementary to the Standardisation strategy and the Horizontal guidelines[13], currently under review.

This initiative is also important in the context of global developments. For example, certain emerging economies are taking a much more aggressive approach in promoting home-grown standards and providing their industries with a competitive edge in terms of market access and technology roll-out.Courts in the UK, US and China have, with their own particular characteristics, also decided that they have jurisdiction to determine global FRAND terms and

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6 Council conclusions on Intellectual property policy and the revision of the industrial designs system in the Union, as adopted at its meeting on 10 November 2020

7 https://single-market-economy.ec.europa.eu/smes/sme-definition_en

8 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Making the most of the EU's innovative potential An intellectual property action plan to support the EU's recovery and resilience of 25 November 2020, COM(2020) 760 final.

9 Council conclusions on intellectual property policy, as approved by the Council (Economic and Financial Affairs) at its meeting on 18 June 2021.

10 European Parliament resolution of 11 November 2021 on an intellectual property action plan to support the EU's recovery and resilience (2021/2007(INI))

11 COM(2022) 31 final, 2.2.2022, An EU Strategy on Standardisation. Communication on An EU Strategy on Standardisation - Setting global standards in support of a resilient, green and digital EU single market. COM(2022) 31 final. Brussels 02.02.2022.

12 Communication from the Commission – Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements, OJ C 11, 14.01.2011, pp. 1 (currently under review)

13 Chapter 7, para 263

conditions in specific cases which may impact the EU industry.[14] Some countries have released[15] or are considering guidelines governing SEP licensing negotiations as well.[16]

- **Consistency with existing policy provisions in the policy area**

Standardisation agreements usually produce significant positive economic effects. The 'potential SEP' holder need to declare to the SDO whether they are willing to license their patents on FRAND terms and conditions when the standard is implemented in products or relevant components thereof. If a patent holder does not provide a FRAND commitment in line with SDO' IPR policy, their SEP contributions may not be included in the standard. However, by including a patented technology in a standard, the SEP holder has a strong economic position vis-à-vis a potential standard implementer, because implementers that want to incorporate standards cannot work around these patents and must either pay for a licence or forego manufacturing of products that use the standard. The more widespread the application of the standard is, the stronger the position of the holder can become, which again might lead to anticompetitive behaviour of the SEP holder.

The Horizontal Guidelines provide guidance for SDOs on how to self-assess compliance with Article 101(1) and Article 101(3) TFEU for standardisation agreements. They set out the following four principles to be considered by SDOs in their self-assessment: (i) participation in the standard-setting is unrestricted; (ii) the procedure for adopting the standard is transparent; (iii) there is no obligation to comply with the standard; (iv) there is effective access to the standard on FRAND terms. In light of this, SDO's IPR policies typically require that participants in standard development disclose the existence of patents (including pending patent applications) that may be or become essential to the relevant standard. In principle, implementers would need a licence from the patent holders to practice the standard. Typically, SEP holders would invite the implementers to take such a licence on FRAND terms and conditions. In its landmark judgment in *Huawei v. ZTE*[17], the Court of Justice of the European Union (CJEU) recognised the right of the SEP holder to seek to enforce its patents in national courts and set out the conditions (steps) that must be fulfilled to prevent an abuse of dominant position by the SEP holder when seeking an injunction. Since a patent confers on its owner the exclusive right to prevent any third party from using the invention without the owner's consent only in the jurisdiction for which it is issued (i.e. Germany, France, the US,

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14 Judgment of the United Kingdom's Supreme Court of 26 August 2020, Unwired Planet v. Huawei, UKSC 2018/0214, [2020] UKSC 37, Decision of the United States District Court for the Central District of California, TCL v Ericsson, Case No 8:14-cv-00341-JVS-DFM with consent of both parties. Chinese Supreme Court's ruling of 19 August 2021, OPPO v Sharp, Zui Gao Fa Zhi Min Xia Zhong No. 517, Order of the Wuhan Intermediate Court of 23 September 2020, Xiaomi v. Interdigital, (2020) E 01 Zhi Min Chu 169 No 1; Order of the Wuhan Intermediate Court, Samsung v Ericsson [2020], Case E 01 Zhi Min Chu No 743.

15 Japanese Patent Office Guide to Licensing Negotiations Involving Standard Essential Patents; South Korean Guidelines on unfair exercise of Intellectual Property Rights; Singapore's Competition & Consumers Commission Guidelines on the treatment of Intellectual Property Rights

16 The United States of America withdrew its Policy Statement on Licensing Negotiations and Remedies for Standards-Essential Patents Subject to F/RAND Commitments and concluded a Memorandum of Understanding with the WIPO Arbitration and Mediation Centre. The UK has launched a process in 2021 on SEPs and innovation, which is ongoing. India's Department of Telecommunications is discussing a proposal to set up a Digicom Intellectual Property Management Board to facilitate IPR licensing and IP management in the telecommunication sector. China has consulted on the draft amendments to the implementing regulations of its Anti Monopoly Law. Japan's Patent Office is revising its guidelines and METI launched a Study Group on Licensing Environment of SEPs.

17 Judgment of the Court of justice of 16 July 2015, Huawei Technologies Co. Ltd v ZTE Corp. and ZTE Deutschland GmbH, C-170/13, ECLI:EU:C:2015:477.

China, etc.), patent disputes are governed by national patent laws and civil proceedings or enforcement laws.[18]

- **Consistency with other Union policies**

The Commission has recently updated its standardisation strategy.[19] The new EU Strategy on Standardisation, published in February 2022, aims to strengthen the EU's global competitiveness, to enable a resilient, green and digital economy and to enshrine democratic values in technology applications while preserving the high-quality output of European standards. This initiative is complementary to the Standardisation Strategy in that it aims to encourage, and reward the continued contribution of cutting-edge technologies to standards by facilitating the licensing of the patented technologies incorporated in the standards.

The initiative is also complementary to the Horizontal guidelines, currently under review. The latter address issues related to the standardisation process and ensure access to the standard on FRAND terms and conditions. The initiative provides tools to facilitate the SEP licensing process after the publication of the standard without taking a position on competition-related issues.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- **Legal basis**

The initiative relates to standards to which a patent holder has contributed a patented technology and for which it has committed to an SDO to license on FRAND terms and conditions. Standards for which patent holders make FRAND commitments are applied cross-border among Member States and globally. SEP licensing is also seldom national. Usually, licensing contracts are global and may take into account certain regional aspects. The international standards in question cover technologies such as 4G, 5G, Wi-Fi, HEVC, AVC, DVB and others that ensure interoperability of products worldwide.

Article 114 TFEU constitutes the appropriate legal basis as the objective is to improve the conditions for the establishment and functioning of the single market. The initiative seeks to ensure the efficiency of SEPs licensing, facilitating lawful access to the standards and promoting wider adoption of standards. There are no specific EU or national rules on SEPs apart from certain specific competition law related guidance or court judgments[20]. In addition, as acknowledged by the CJEU in *Huawei v ZTE*, apart from common rules relating to the grant of a European patent, a European patent remains governed by the national law of each of the Contracting States for which it has been granted as is also the case for national patents.

The CJEU has confirmed[21] that recourse to Article 114 TFEU is possible if the aim is to prevent the emergence of obstacles to trade between Member States resulting from the

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18 Harmonised by Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights ('IPRED'), OJ L 157, 30.4.2004, p. 45.

19 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - An EU Strategy on Standardisation; Setting global standards in support of a resilient, green and digital EU single market, 2.2.2022, COM(2022) 31 final.

20 Communication from the Commission – Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements, OJ C 11, 14.01.2011, pp. 1-72, CELEX: and CJEU case-law., in particular Huawei v. ZTE, Case C-170/13, EU:C:2015:477

21 Judgment of the Court of Justice of 12 December 2006, Germany v. Parliament and Council, C- 380/03, EU:C:2006:772, para. 38 and the case-law cited, and judgment of the Court of Justice of 10 February 2009, Ireland v. Parliament and Council, C- 301/06, EU:C:2009:68, para. 64; see also, to that effect, judgment of the Court of Justice of 2 May 2006, United Kingdom v. Parliament and Council, C-217/04, EU:C:2006:279, paras. 60 to 64.

divergent development of national laws. However, the emergence of such obstacles must be considered likely and the measure in question must be designed to prevent them. Certain courts in Member States, in particular Dutch[22], French[23] and German[24] courts have been considering FRAND-related issues in national litigation based on on the circumstances of the disputes brought before them. Those cases show different approaches (not necessarily different results) with regard to FRAND determination concerning SEPs covering regional or global standards. It is difficult for competent courts in the Member States to handle SEP-related cases and make detailed and consistent FRAND determinations. This is in large part due to the lack of transparency and complexity of the issues that are central to such determinations, such as the essentiality of patents, comparable licences and compliance with FRAND requirements. While the initiative will neither interpret the CJEU case-law nor adopt methodologies for FRAND determination per se, it will establish mechanisms that promote the necessary transparency, increase certainty and reduce the potential for inconsistent rulings. This will be a significant improvement in the courts' abilities to handle SEP disputes.

- **Subsidiarity (for non-exclusive competence)**

Measures taken at national, regional or local level to increase transparency and facilitate licensing of SEPs may not be efficient for the following reasons. First, instead of an EU-wide solution for SEPs, there might be different national solutions for the SEPs on a specific standard. Second, under an EU-wide approach, it will not be necessary to conduct more than a essentiality check per patent family to find that patents are indeed truly essential to a standard. The check would be done based on a single EU-wide methodology. Third, non-centralised alternative dispute resolution processes may come to different results for the same SEP portfolio, opening the door to 'forum shopping' within the EU. An EU-wide approach can help avoid these problems.

- **Proportionality**

The initiative is limited to what is necessary to achieve transparency with regard to SEPs and pricing and provide stakeholders with tools to negotiated SEP licensing agreements. Action at EU level will be efficient and save costs for stakeholders, in particular SEP holders, and for Member States. For example, there could be one register instead of many registers, one essentiality check for the whole EU, one methodology for carrying out such checks, and a streamlined and transparent FRAND determination process. SEP holders and implementers will not have to repeatedly incur the same costs in each EU Member state that has chosen to introduce SEP specific rules.

- **Choice of the instrument**

EU-wide rules on transparency regarding SEPs and FRAND terms would have a harmonising effect within the EU which would facilitate the work of national courts and the future Unified Patent court. The instrument to implement this initiative should be a regulation. A

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22 Court of Appeal of The Hague, judgment of 2 July 2019, Philips v Wiko, Case number : C/09/511922/HA ZA 16-623; Hoge Raad, Judgment of 25 February 2022, Wiko v Philips, Nummer 19/04503, ECLI:NL:HR:2022:294; District Court The Hague, Judgment of 15 December 2021, Vestel v Access Advance, ECLI:NL:RBDHA:2021:14372.

23 Paris Court, order of the pre-trial judge of 6 February 2020, TCT v Philips, RG 19/02085 – Portalis 352J-W-B7D-CPCIX; TJ Paris, 3.3, judgment of 7 December 2021, Xiaomi v Philips and ETSI, RG 20/12558.

24 German Federal Court of Justice ('Bundesgerichtshof – BGH'), judgement of 5 May 2020, Sisvel v. Haier, KZR 36/17, and German Federal Court of Justice, judgment of 24 November 2020, FRAND-Einwand II, KZR 35/17; Order of 24 June 2021, Nokia Technologies v Daimler, C-182/21, EU:C:2021:575 (request for a preliminary ruling from the Landgericht Düsseldorf, removed from the Register).

regulation would be directly applicable, including by empowering an EU agency with the tasks of managing a register of SEPs, and establishing a common FRAND determination procedure that would ensure uniformity across the EU and provide greater legal certainty. These outcomes cannot be achieved by means of a Directive.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Ex-post evaluations/fitness checks of existing legislation**

Not applicable

- **Stakeholder consultations**

The Commission has conducted a series of webinars[25]. The statistics for the webinars can be summarised as follows: 16 hours of content; by over 60 speakers; over 450 interactions in the Q&A field; over 1 700 impressions on the events; over 800 people in the Commission SEP Teams group; and over 1 000 respondents to the Commission surveys in total.

The call for evidence was published on 14 February 2022 and was open until 9 May 2022. During that period 97 replies and 49 position papers were submitted.

The public consultation took place between 14 February 2022 and 9 May 2022. During that period 74 replies were submitted.

A targeted survey for start-ups and SMEs was published on 28 October 2022 and was closed on 20 November 2022. At the request of a number of stakeholders, the survey was re-opened on 25 November 2022 without a closing date to enable stakeholders keep on responding as the markets on the Internet of Things ('IoT') develop. By the end of 2022, the Commission had received 39 replies.

Discussion with Member States' representatives took place in within the Commission Expert Group on IP Policy and relevant Council working parties.

The positions of the main stakeholders such as SEP holders, implementers, their consultants and experts as well as their representative associations are largely known. For this reason, the public consultation addressed very specific SEP-related issues and sought views on concrete potential actions.

Around half of all respondents assessed the impact of the current SEP licensing framework on SMEs and start-ups as negative, a third thought there was no impact, and around 5 % deemed it positive.

Almost three quarters of respondents would request a licence in order not to infringe a SEP and 60 % to be able to plan production and costs. The main reasons for having/licencing SEP are securing a return on investment on R&D (70 % of answers), followed by use of SEP for defensive/bargaining purposes (60 %) and participation in standardisation process in the future (40 %).

Lack of transparency on the FRAND royalty rate, on SEP landscape (who owns SEPs) and divergent court rulings were named as the key problems by three quarters of all respondents, including all respondents in the groups of those with predominantly implementer-friendly views (implementers). For the group of those with predominantly SEP-holder-friendly views (SEP holders) the main problems were hold-out and anti-suit injunctions.

[25] See webpage https://ec.europa.eu/growth/content/webinar-series-standard-essential-patents_en

Respondents asked for more public information on SEPs as regards ‘patent and application number’ (88 % of all responses), ‘relevant standard, version, section of the standard’ (80 %), ‘contact details of SEP holder’ (80 %), ‘transfer of ownership’ (77 %), ‘licensing programmes’ (76 %) and ‘standard FRAND terms and conditions’ (72 %). Around 60 % of all respondents and 90 % of implementers supported third-party essentiality checks as long as independent experts do them. Only 24 % of SEP holders supported such a solution. A third of all respondents considered that essentiality checks should not have legal consequences.

Around two thirds of all respondents and around 80 % of implementers thought that essentiality assessment might help in assessing a product's SEP exposure and deciding whom to negotiate with, smoothen licensing negotiation and prevent over pricing. More than half of SEP holders disagreed with these impacts but agreed that checks might provide a reliable overview of the share of each SEP holders’ essential patents.

Around three quarters of respondents agreed that fair and reasonable terms and conditions might depend on functionalities of the standard implemented in a product. Around 70 % thought these terms should be independent of the level of licencing.

70 % of all respondents and 100 % of implementers argued that it is important to know the reasonable aggregate royalty rate for a product. Only 20 % of SEP holders shared that view.

Arbitration (53 % of all answers) was deemed more useful than mediation (35 %) for FRAND assessment, especially by SEP holders and academia/authorities/non-governmental organisations.

- **Collection and use of expertise**

The impact assessment relied primarily, but not excusively, on two external studies and the contribution of the SEP Expert Group:

'Baron, J., Arque-Castells, P., Leonard, A., Pohlmann, T., Sergheraert, E., Empirical Assessment of Potential Challenges in SEP Licensing, European Commission, DG GROW, 2023';

'Charles River Associates, Transparency, Predictability, and Efficiency of SSO-based Standardization and SEP Licensing, European Commission, DG GROW, 2016, https://ec.europa.eu/docsroom/documents/48794';

‘Group of Experts on Licensing and Valuation of Standard Essential Patents – Contribution to the Debate on SEPs’ (2021).

The Commission has conducted many studies, the most relevant of which are:

‘European Commission, Joint Research Centre, Bekkers, R., Henkel, J., Tur, E. M., et al., Pilot study for essentiality assessment of standard essential patents, Publications Office of the European Union, 2020';

‘Landscape study of potentially essential patents disclosed to ETSI’, JRC study (2020);

‘Licensing Terms of Standard Essential Patents: A Comprehensive Analysis of Cases’, JRC study (2017);

‘Patents and Standards: A modern framework for IPR-based standardisation’ (2014).

In addition, the Commission reviewed numerous papers and positions submitted by stakeholders, professional articles on the subject and studies conducted on behalf of other authorities. The Commission analysed initiatives on SEPs in non-EU countries. To prepare the impact assessment and the draft regulation, the Commission consulted with leading

experts, judges and academics. Finally, the Commission attended numerous webinars and conferences.

- **Impact assessment**

The Commission conducted an impact assessment and submitted it to the Regulatory Scrutiny Board in February 2023 and received a positive opinion on 17 March 2023 (REF to be added). The final impact assessment takes into account comments contained in that opinion.

In the impact assessment, the Commission considered the following problems: high licensing transaction costs and uncertainty about the SEP royalty burden. Due to lack of sufficient information, implementers cannot assess their SEP exposure far enough in advance to take into account the licensing costs when planning their product business. On the other hand, SEP holders complain about long and expensive negotiations, especially with large implementers.

More specifically, the following causes of these problems were identified. First, there is only limited information on who owns SEPs, and it is not certain that all patents for which licences are sought are really necessary (essential) to implement a standard. Second, there is very little information on SEP licence fees (FRAND royalty), so implementers with little or no expertise or resources find it impossible to assess the reasonableness of a SEP holder's royalty demand. Finally, licensing disputes can be time- and cost-intensive.

Consequently, the initiative aims at facilitating SEP licensing negotiations and lowering transaction costs for both SEP holders and implementers by (i) providing more clarity on who owns SEPs and which SEPs are truly essential; (ii) providing more clarity on FRAND royalty and other terms and conditions, including awareness raising with regard to licensing in the value chain; and (iii) facilitating SEP dispute resolution.

The following options were considered to achieve these objectives (the policy options are built incrementally, each adds new elements to the preceding one):

Option 1: Voluntary guidance. This would involve establishing non-binding guidance on SEP licensing. A competence centre on SEPs created within the European Union Intellectual Property Office (EUIPO) would provide free advice to SMEs on licensing negotiations (including trainings) and monitor the SEP market, conduct studies on SEP licensing and promote alternative dispute resolution.

Option 2: SEP register with essentiality checks. SEP holders seeking to license their SEPs for royalty and to enforce them in the EU would have to register the patents in the SEP register. To ensure the quality of the register, essentiality checks would be conducted by an independent evaluator using a methodology to be determined by the Commission at EU level and a system administered by the EUIPO. Sub-options are: to (i) check all registered patents; or (ii) check a small number of patents pre-selected by SEP holders and a random sample of patents registered by each SEP holder.

Option 3: SEP register with essentiality checks and conciliation (FRAND determination) procedure. Before launching a litigation, parties to SEP licensing dispute would have to go through a mandatory conciliation process. An independent conciliator would seek to help parties reach mutually acceptable licensing terms and conditions. At the end of the process, if the parties fail to reach agreement, the conciliator will issue a non-binding report with recommendations on the FRAND rate (with a confidential and a non-confidential part).

Option 4: Aggregate royalty for SEP. Processes would be established for determining an aggregate royalty (i.e. total maximum price) for using a standard before or shortly after its publication. SEP holders would be expected to agree on such royalty (potentially with the

help of an independent facilitator from the competence centre). Additionally, both implementers and SEP holders could request an expert opinion on the aggregate royalty, where all the interested parties would be able to present their views. Finally, an aggregate royalty could be determined during the conciliation if the parties so request. This aggregate royalty would equally not be binding and would be published in the SEP register.

Option 5: SEP clearing house. Establishment of a one-stop-shop for implementers to acquire SEP licences by depositing an aggregate royalty with the competence centre. SEP holders should inform the centre how to allocate the aggregate royalty among them, failing which they would not be able to collect their royalty payments. They should also sign licence agreements with any implementer who would make a deposit. Any royalties not collected by SEP holders within a year from the deposit would be returned to the implementers.

Option 4 (voluntary guidance, SEP register with essentiality checks, FRAND determination procedure and aggregate royalty determination for SEPs) is the preferred option. The option reduces information asymmetry between a SEP holder and an implementer by providing the latter with information who the relevant SEP holders are, how many SEPs they have registered in the register and what their essentiality rate is (derived from a representative random sample of all registered SEPs) and what the potential [or maximum] total cost of using a standardised technology (aggregate royalty) is. A pre-trial obligatory conciliation is likely to reduce SEP dispute settlement costs to about 1/8 as the conciliator will assist both parties in reaching an agreement. A competence centre will provide objective information, guidance and support to SMEs on SEPs and SEP licensing. Benefits and costs are presented in the table below.

Table 1: Average total approximated annual costs and benefits of the preferred option per affected party and location (EUR million).

		EU	**non-EU**	*Total*
SEP implementers	Costs	-0.77	-0.77	-1.5
	Benefits	12.89	13.03	25.9
	Net	*12.11*	*12.26**	*24.4*
SEP holders	Costs	-8.13	-46.04	-54.2
	Benefits	3.79	21.50	25.3
	Net	*-4.33*	*-24.54*	*-28.9*
Subtotal (net effect for implementers and holders)		*7.8*	*-12.3*	*-4.5*
European or national patent office benefit		29.0		29.0
Total net benefit		*36.8*	*-12.3*	*24.5*

***** concerns non-EU implementers with subsidiaries in the EU

Note: numbers rounded which may affect totals

- **Regulatory fitness and simplification**

This initiative is not part of the REFIT simplification effort as there are currently no EU rules on SEPs that could be simplified or made more efficient.

- **Fundamental rights**

The proposal should improve the conduct of business for both SEP holders and implementers, and ultimately other businesses downstream (Article 16 of the Charter).

The proposal respects the intellectual property rights of patent holders (Article 17(2) of the EU Charter of Fundamental Rights), although it includes a restriction on the ability to enforce a SEP that has not been registered within the prescribed time-limits and introduces a requirement to conduct conciliation (FRAND determination) prior to enforcing individual SEPs. Limitations on the exercise of IP rights are allowed under the EU Charter, provided that the proportionality principle is respected. According to settled case-law, fundamental rights can be restricted provided that those restrictions correspond to objectives of general interest pursued by the EU and do not constitute, with regard to the aim pursued, a disproportionate and intolerable interference which infringes the very essence of the rights guaranteed[26]. In that respect, the proposal is in the public interest in that it provides a uniform, open and predictable information and outcome on SEPs for the benefit of SEP holders, implementers and end users, at Union level. It aims at dissemination of technology for the mutual advantage of the SEP holders and implementers. Furthermore, the rules concerning the FRAND determination are time-limited and aimed at improving and streamlining the process but are not ultimately binding.[27]

The FRAND determination is also consistent with the right to an effective remedy and to access to justice (Article 47 of the EU Charter) as the implementer and the SEP holder fully retain that right. If the SEP is not registered, the exclusion of the right to effective enforcement is temporary, thus limited, and necessary, and meets objectives of general interest. As confirmed by the CJEU[28], a mandatory dispute resolution as a precondition to access to courts would be deemed to be compatible with the principle of effective judicial protection. The FRAND determination follows the conditions for mandatory dispute resolution outlined in the CJEU judgments, taking into account the particular characteristics of SEP licensing.

4. BUDGETARY IMPLICATIONS

This proposal would have no impact on the European Union. The SEP system introduced with the initiative will remain fully self-funded, using fees paid by EUIPO competence centre service users. EUIPO is going to finance set up costs (including IT costs) of the competence centre, the SEP register and other services. It is expected to recuperate these set up costs by fees charged when the system is fully operational.

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[26] Judgment of the Court of Justice of 13 December 1979, Hauer v. Land Rheinland-Pfalz, C-44/79, EU:C:1979:290, para. 32; judgment of the Court of Justice of 11 July 1989, Hermann Schräder HS Kraftfutter GmbH & Co. KG v. Hauptzollamt Gronau, C-256/87, EU:C:1999:332, para. 15, and judgment of the Court of Justice of 13 July 1989, Hubert Wachauf v. Bundesamt für Ernährung und Forstwirtschaft, C-5/88, ECLI:EU:C:1989:321, paras. 17 and 18.

[27] The conciliation procedure follows the conditions for mandatory recourse to alternative dispute settlement procedures as a condition for the admissibility of an action before the courts, as outlined in the judgment of the Court of Justice of 18 March 2010, Rosalba Alassini v Telecom Italia SpA (C-317/08), Filomena Califano v Wind SpA (C-318/08), Lucia Anna Giorgia Iacono v Telecom Italia SpA (C-319/08) and Multiservice Srl v Telecom Italia SpA (C-320/08), Joined cases C-317/08, C-318/08, C-319/08 and C-320/08, ECLI:EU:C:2010:146, taking into account the specificities of SEP licensing.

[28] see footnote above.

The EUIPO estimates that set-up cost of the competence centre and register including IT infrastructure will amount to around EUR 2.4 million and may involve work of up to 12 FTEs. The EUIPO running cost of the new system will require around EUR 2 million annually (excluding services of external experts such as essentiality experts or conciliators). The costs will be higher in the initial year(s) when registration of an estimated number of 72 000 patent families, and essentiality checks for an estimated number of 14 500 SEPs are expected (which are estimated to be the peak of all registrations and essentiality checks). In the subsequent years, the number of registrations and essentiality checks is expected to drop to 10% of the peak numbers. During the operational period, the competence centre would require on average around 30 FTEs in the peak year(s), and around 10 FTEs in the following years. The financial and budgetary impacts of this proposal are presented in the legislative financial statement annexed to this proposal. Detailed calculation of costs are presented in Annex 7.1 of the Impact Assessment.

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

The Commission will use the data collected by the competence centre (EUIPO) to monitor implementation of this proposal and the achievement of its objectives. The monitoring activities would take into account the required implementation period (including the time needed to enact the necessary new implementing legislation based on implementing powers to be conferred to the Commission) and the time needed for market participants to adapt to the new situation. The set of pertinent indicators referred to in Section 9 of the impact assessment would be considered for evaluating the changes.

A first evaluation will be scheduled for 8 years after entry into force of the Regulation (allowing for the fact that the Regulation will start to apply 24 months after entry into force). The implementing acts need to be adopted, and the competence centre needs to be set up organisationally during that time. Subsequent evaluations will be carried out every 5 years.

- **Detailed explanation of the specific provisions of the proposal**

Title I determines the subject matter and the scope of the proposal.

The proposal provides for enhanced transparency with regard to information necessary for SEP licensing; registration of SEPs; procedure for evaluating the essentiality of registered SEPs; and procedure for determination FRAND terms and conditions for a SEP licence.

The proposal applies to SEPs in force in one or more Member States. It concerns standards published by a standard development organisation (SDO) that calls on SEP holders to commit to licensing on fair, reasonable and non-discriminatory (FRAND) terms and conditions. It does not apply to SEPs that are subject to royalty-free intellectual property policy of the SDO that has published the standard. The proposal does not apply to claims of invalidity and infringement of SEPs unrelated to the scope of this Regulation.

Title II of the proposal creates a competence centre within EUIPO to administer databases, a register and the procedures for essentiality checks of SEPs and the FRAND determination. The competence centre will also provide training, support and general advice on SEPs to SMEs and raise awareness of SEP licensing.

Title III This Title includes provisions detailing the process of notifying standards and aggregate royalty, registration of SEPs and expert opinion on aggregate royalty. It also includes provisions concerning the information and data that the competence centre would include in the register and databases. The registration will be subject to a fee.

The SEP registration process is triggered when contributors or implementers notify the competence centre of a standard and/or aggregate rates for a standard and specific implementations of the standard. The competence centre publishes a notice inviting SEP holders to register. SEP holders have 6 months to register. To incentivise timely registration following the 6 months, SEP holders cannot enforce their SEPs until they register. A SEP holder that has not registered within the 6 months may also not seek royalties and damages prior to the registration. This is not only to encourage registration but also to ensure legal certainty for implementers.

The rules take account of the fact that certain SEPs may be granted by a patent office after the 6 month period and certain implementations of a standard may not be known at the time of publication of the standard. A SEP may be removed from the register only where the SEP has expired, has been invalided or found non-essential. The registration can be modified and should be updated by the SEP holder. Any stakeholder can signal that a registration is incorrect or incomplete and needs to be modified.

Contributors or implementers may request an expert opinion on the aggregate royalty, subject to a fee. The competence centre would then appoint a panel of three conciliators to deliver the expert opinion. Any stakeholder can participate in the process and express its views provided that it demonstrates its interest. The expert opinion should also consider potential impacts on the value chain in question. The expert opinion will not be binding but will serve to provide the industry with some guidance in respect of individual SEP licensing negotiations.

In addition to the data provided by the SEP holders in the register and/or the databases on individual SEPs, public licensing arrangements and contact details, the competence centre should collect data on case law worldwide, rules of third countries and public information on FRAND terms and conditions. It should also produce statistics and commission studies. The objective would be to have a one-stop shop for everything a stakeholder needs to know about SEPs and SEP licensing. Most of the information will be available free of charge to the public. Some specific detailed information, for example, on particular SEPs or on reports from FRAND determinations will be available only on registration and for a fee. SMEs will benefit from reduced fees.

Title IV of the proposal contains rules for the selection of candidate evaluators and conciliators to carry out tasks assigned to them in proceedings set out in the proposal. The evaluators or conciliators should not only have the requisite technical competence but should demonstrate that they are independent and no biased. The competence centre should establish a roster of candidates that satisfy all conditions. The competence centre should regularly review the rosters that a sufficient number of qualified candidates is maintained.

Title V of the proposal pertains to essentiality checks of SEPs. Determining whether a patent is essential to a standard is a very difficult technical task. Despite the best efforts of the SEP holders, there may be registered SEPs that are not actually essential to the standard for which they are registered. Essentiality checks are thus very important to ensure the quality of the register and also to prevent any potential abuse, because of a lack of checks on the registered data. Essentiality checks are also important for SEP holders or implementers, who may wish to submit some of their SEPs for such a check to demonstrate essentiality or non-essentiality during negotiations. The essentiality checks will be subject to a fee payable by the SEP holders whose SEPs are checked and by the implementers who request such checks. The lack of an essentiality check should not preclude licensing negotiations or any court or administrative procedure in relation to such SEPs.

Essentiality checks on claimed SEPs entered into the SEP register will be conducted by evaluators who have expertise in the relevant technical field and whose independence is

beyond doubt. Such checks will be made annually on a sampling basis and there will be only one essentiality check per patent family. The checks will be conducted based on methodology that ensures a fair and statistically valid selection capable of producing sufficiently accurate results about the percentage of truly essential patents among each SEP holder's registered SEPs.

If the during the check, the evaluator has reasons to believe that the claimed SEP may not be essential to the standard, she or he should inform the SEP holder through the competence centre of any such reasons and give the SEP holder time to submit its observations. Only after considering the response will the evaluator deliver its final reasoned opinion. The SEP holder would be able to request a peer evaluation before a negative opinion by the evaluator is issued. The results of the peer evaluation should serve to improve the essentiality check process and ensure consistency.

Title VI of the proposal establishes provisions for the determination of FRAND terms and conditions. The FRAND determination must be initiated by the SEP holder or implementer before initiating respective court proceedings in the EU. A FRAND determination may also be initiated by one of the parties voluntarily to resolve disputes related to FRAND terms and conditions.

Where the responding party does not reply to the request, the competence centre will either terminate the procedure or, upon request of the requesting party, continue with the FRAND determination. This may be necessary either to establish that an offer is FRAND or to determine the amount of the security.

If both parties engage in the process, or in case the proceedings are continued with one party only, a conciliator will be appointed. The parties or party, as applicable, will be requested to make submissions and proposals. They can also commit to comply with the outcome of the FRAND determination. The conciliator will assist them in an independent and impartial manner in their endeavour to reach a FRAND rate determination. The conciliator will be empowered to proactively seek information, consult all information available in the register and databases, including the confidential reports of other FRAND determinations and hear any experts, where necessary. The conciliator will make proposal(s) to the parties. The procedure should not last longer than 9 months. If, at the end of the procedure, the parties have not yet settled, the conciliator will make a final proposal, which the parties may or may not accept.

If the parties settle, the conciliator will terminate the procedure without a report. If the parties do not settle at the end of the procedure, the conciliator will terminate the procedure and issue a report on the determination of FRAND terms and conditions. The non-confidential part of that report will contain their last proposal and the methodology the conciliator applied for the determination, and will be available for consultation in the register/database(s).

If a party obstructs the FRAND determination or seeks resolution in other jurisdictions, the conciliator may propose that the other party either terminate or continue with the procedure. The complying party will decide how to proceed depending on its needs.

Title VII of the proposal contains provisions setting out the treatment of micro-enterprises and small and medium-sized enterprises taking into account their specific needs. The competence centre will offer training and provide support on SEP-related matters for micro-enterprises, small and medium-size enterprises free of charge. The costs will be borne by the EUIPO. When negotiating a SEP licence with micro, small and medium-sized enterprises, SEP holders will be required to consider offering them more favourable FRAND terms and conditions.

Title VIII of the proposal contains rules as regards the fees and charges for the services of the competence centre. Those fees should be reasonable and reflect the costs for the service rendered. The Commission will adopt implementing acts to determine the administrative fees, and the fees for expert opinions on aggregate royalty, evaluators and conciliators, the amounts to be charged and the payment method. Fees should be appropriate to the needs of micro, small and medium-sized enterprises.

Title IX of the proposal contains final provisions. The proposed regulation applies to standards published after its date of application. There may also be a need to cover certain important standards such as 4G on which many IoT applications run and for which SEP licencing is inefficient. Such standards shall be determined in a delegated act and may consequently be notified to the competence centre within a limited time-period after the date of application to trigger the registration process. This Title also includes the empowerment of the Commission to adopt delegated and implementing acts and the evaluation and review clause. Finally, the Title contains provisions to amend Regulation (EU) 2017/1001.

2023/0133 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on standard essential patents and amending Regulation (EU)2017/1001

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[29],

Having regard to the opinion of the Committee of the Regions[30],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) On 25 November 2020, the Commission published its intellectual property action plan[31], where it announced its goals of promoting transparency and predictability in licensing of standard essential patents (SEPs), including by improving the SEP licensing system, for the benefit of Union industry and consumers, and in particular small and medium-sized enterprises (SMEs)[32]. The action plan was supported by Council Conclusions of 18 June 2021[33] and by the European Parliament in its Resolution[34]

(2) This Regulation aims at improving the licensing of SEPs, by addressing the causes of inefficient licensing such as insufficient transparency with regard to SEPs, fair, reasonable and non-discriminatory (FRAND) terms and conditions and licensing in the value chain, and limited use of dispute resolution procedures for resolving FRAND disputes. All these together reduce the overall fairness and efficiency of the system and result in excess administrative and transactional costs. By improving the licensing of SEPs, the Regulation aims to incentivise participation by European firms in the standard development process and the broad implementation of such standardised

29 OJ C , , p. .

30 OJ C , , p. .

31 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Making the most of the EU's innovative potential An intellectual property action plan to support the EU's recovery and resilience of 25 November 2020, COM(2020) 760 final.

32 OJ L 124 of 20.05.2003, p. 36.

33 Council conclusions on intellectual property policy, as approved by the Council (Economic and Financial Affairs) at its meeting on 18 June 2021.

34 European Parliament resolution of 11 November 2021 on an intellectual property action plan to support the EU's recovery and resilience (2021/2007(INI)).

technologies, particularly in Internet of Things (IoT) industries. Therefore, this Regulation pursues objectives that are complementary to, but different from that of protecting undistorted competition, guaranteed by Articles 101 and 102 TFEU. This Regulation should also be without prejudice to national competition rules.

(3) SEPs are patents that protect technology that is incorporated in a standard. SEPs are 'essential' in the sense that implementation of the standard requires use of the inventions covered by SEPs. The success of a standard depends on its wide implementation and as such every stakeholder should be allowed to use a standard. To ensure wide implementation and accessibility of standards, standard development organisations demand the SEP holders that participate in standard development to commit to license those patents on FRAND terms and conditions to implementers that chose to use the standard. The FRAND commitment is a voluntary contractual commitment given by the SEP holder for the benefit of third parties, and it should be respected as such also by subsequent SEP holders. This Regulation should apply to patents that are essential to a standard that has been published by a standard development organisation, to which the SEP holder has made a commitment to license its SEPs on fair, reasonable and non-discriminatory (FRAND) terms and conditions and that is not subject to a royalty-free intellectual property policy, after the entry into force of this Regulation.

(4) There are well established commercial relationships and licensing practices for certain use cases of standards, such as the standards for wireless communications, with iterations over multiple generations leading to considerable mutual dependency and significant value visibly accruing to both SEP holders and implementers. There are other, typically more novel use cases – sometimes of the same standards or subsets thereof - with less mature markets, more diffuse and less consolidated implementer communities, for which unpredictability of royalty and other licensing conditions and the prospect of complex patent assessments and valuations and related litigation weigh more heavily on the incentives to deploy standardised technologies in innovative products. Therefore, in order to ensure a proportionate and well targeted response, certain procedures under this Regulation, namely the aggregate royalty determination and the compulsory FRAND determination prior to litigation, should not be applied to identified use cases of certain standards or parts thereof for which there is sufficient evidence that SEP licensing negotiations on FRAND terms do not give rise to significant difficulties or inefficiencies.

(5) Whereas transparency in SEP licensing should stimulate a balanced investment environment, along entire Single Market value chains, in particular for emerging technology use cases underpinning Union objectives of green, digital and resilient growth, the Regulation should also apply to standards or parts thereof, published before its entry into force where inefficiencies in the licensing of the relevant SEPs severely distort the functioning of the internal market. This is particularly relevant for market failures hindering investment in the Single Market, the roll-out of innovative technologies or the development of nascent technologies and emerging use cases. Therefore, taking into account those criteria, the Commission should determine by a delegated act the standards or parts thereof that have been published before the entry into force of this Regulation and the relevant use cases, for which SEPs can be registered.

(6) Because a FRAND commitment should be made for any SEP declared to any standard intended for repeated and continuous application, the meaning of standards should be

broader than in Regulation (EU) No 1025/2012 of the European Parliament and of the Council[35].

(7) Licensing on FRAND terms and conditions includes licensing royalty-free. Given that most issues arise with royalty-bearing licensing policies, this Regulation does not apply to royalty-free licensing.

(8) In view of the global character of SEP licensing, references to aggregate royalty and FRAND determination may refer to global aggregate royalties and global FRAND determinations, or as otherwise agreed by the notifying stakeholders or the parties to the proceedings.

(9) In the Union, standard setting and the application of competition law rules related to FRAND obligation to standard essential patents are guided by the Horizontal Guidelines[36] and the Court of Justice judgment of 16 July 2015 in case C-170/13, *Huawei Technologies Co. Ltd v ZTE Corp. and ZTE Deutschland GmbH*[37]. The Court of Justice recognised the right of a SEP holder to seek to enforce its patents in national courts subject to certain conditions that must be fulfilled to prevent an abuse of dominant position by the SEP holder when seeking an injunction. Since a patent confers on its holder the exclusive right to prevent any third party from using the invention without the holder's consent only in the jurisdiction for which it is issued, the patent disputes are governed by national patent laws and civil proceedings and/or enforcement laws harmonised by Directive 2004/48/EC of the European Parliament and of the Council[38].

(10) As there are specific procedures for assessing the validity and the infringement of patents, this Regulation should not affect such procedures.

(11) Any reference to a competent court of a Member State in this Regulation includes the Unified Patent Court where the conditions are met.

(12) To facilitate the implementation of this regulation, the European Union Intellectual Property Office (EUIPO) should perform the relevant tasks by means of a competence centre. The EUIPO has extensive experience with managing databases, electronic registers and alternative dispute settlement mechanisms, which are key aspects of the functions assigned under this Regulation. It is necessary to equip the competence centre with necessary human and financial resources to fulfil its tasks.

(13) The competence centre should set up and administer an electronic register and an electronic database containing detailed information on SEPs in force in one or more Member States, including essentiality check results, opinions, reports, available case-law from jurisdictions across the globe, rules relating to SEPs in third countries, and results of studies specific to SEPs. In order to raise awareness and facilitate SEP

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35 Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12.)

36 Communication from the Commission – Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements, OJ C 11, 14.01.2011, pp. 1 (currently under review)

37 Judgment of the Court of Justice of 16 July 2015, Huawei Technologies Co. Ltd v ZTE Corp. and ZTE Deutschland GmbH, C-170/13, ECLI:EU:C:2015:477

38 DIRECTIVE 2004/48/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 on the enforcement of intellectual property rights (OJ L 157, 30.4.2004, p. 45.)

licensing for SMEs, the competence centre should offer assistance to SMEs. The setting up and administering a system for essentiality checks and processes for aggregate royalty determination and FRAND determination by the competence centre should include actions improving the system and the processes on a continuous basis, including through the use of new technologies. In line with this objective, the competence centre should establish training procedures for evaluators of essentiality and conciliators for providing opinions on aggregate royalty as well as on FRAND determination and should encourage consistency in their practices.

(14) The competence centre should be the subject of Union rules on access to documents and data protection. Its tasks should be designed to increase transparency by making existing information relevant to SEPs available to all stakeholders in a centralised and systematic way. Therefore, a balance would have to be made between the free public access to basic information and the need to finance the functioning of the competence centre. In order to cover the maintenance costs a registration fee should be requested to access detailed information contained in the database, such as results of any essentiality checks and non-confidential FRAND determination reports.

(15) Knowledge of the potential total royalty for all SEPs covering a standard (aggregate royalty) applicable to the implementations of that standard is important for the assessment of the royalty amount for a product, which plays a significant role for the manufacturer's cost determinations. It also helps SEP holder to plan expected return on investment. The publication of the expected aggregate royalty and the standard licensing terms and conditions for a particular standard would facilitate SEP licensing and reduce the cost of SEP licensing. Thus, it is necessary to make public the information on total royalty rates (aggregate royalty) and the standard FRAND terms and conditions of licensing.

(16) SEP holders should have the opportunity to first inform the competence centre of the publication of the standard or the aggregate royalty which they have agreed upon among themselves. Except for those use cases of standards for which the Commission establishes that there are well established and broadly well-functioning licensing practices of SEPs, the competence centre may assist the parties in the relevant aggregate royalty determination. In this context, if there is no agreement on an aggregate royalty among SEP holders, certain SEP holders may request the competence centre to appoint a conciliator to assist the SEP holders willing to participate in the process in determining an aggregate royalty for the SEPs covering the relevant standard. In this case, the role of the conciliator would be to facilitate the decision-making by the participating SEP holders without making any recommendation for an aggregate royalty. Finally, it is important to ensure that there is a third independent party, an expert, that could recommend an aggregate royalty. Therefore, SEP holders and/or implementers should be able to request the competence centre for an expert opinion on an aggregate royalty. When such a request is made, the competence centre should appoint a panel of conciliators and administer a process in which all interested stakeholders are invited to participate. After receiving information from all of the participants, the panel should provide a non-binding expert opinion for an aggregate royalty. The expert opinion on the aggregate royalty should contain a non-confidential analysis of the expected impact of the aggregate royalty on the SEP holders and the stakeholders in the value chain. Important in this respect would be to consider factors such as, efficiency of SEP licensing, including insights from any customary rules or practices for licensing of intellectual property in the value chain

and cross-licensing, and impact on incentives to innovate of SEP holders and different stakeholders in the value chain.

(17) In line with the general principles and objectives of transparency, participation and access to European standardisation, the centralised register should make information regarding the number of SEPs applicable to a standard, the ownership of relevant SEPs, and the parts of the standard covered by the SEPs publicly available. The register and the database will contain information on relevant standards, products, processes, services and systems, which implement the standard, SEPs in force in the EU, standard SEP licensing FRAND terms and conditions or any licensing programmes, collective licensing programmes and essentiality. For SEP holders the register will create transparency with regard to the relevant SEPs, their share of all SEPs declared to the standard and the features of the standard covered by the patents. SEP holders will be in a better position to understand how their portfolios compare with other SEP holders' portfolios. This is important not only for negotiations with implementers but also for the purpose of cross-licensing with other SEP holders. For implementers, the register will provide a trusted source of information on the SEPs, including with regard to the SEP holders from whom the implementer may need to obtain a licence. Making such information available in the register will also help shorten the length of technical discussions during the first stage of the SEP licensing negotiations.

(18) Once a standard has been notified or an aggregate royalty is specified, whichever is made first, the competence centre will open the registration of SEPs by holders of SEPs in force in one or more Member States.

(19) In order to ensure transparency of about SEPs, it is appropriate to require from SEP holders to register their patents which are essential to the standard for which the registration is open. SEP holders should register their SEPs within 6 months following the opening of the registration by the competence centre or the grant of the relevant SEPs, whichever is first. In case of timely registration, SEPs holders should be able to collect royalties and claim damages for uses and infringements that happened before the registration.

(20) SEP holders may register after the indicated time limit. However, in that case, SEP holders should not be able to collect royalties and claim damages for the period of delay.

(21) Clauses in licensing agreement that set a royalty for a large number of patents – present or future – should not be affected by the invalidity, non-essentiality, or unenforceability of a small number of those patents when they do not affect the overall amount and enforceability of the royalty or other clauses in such agreements.

(22) SEP holders should ensure that their SEP registration(s) are updated. Updates should be registered within 6 months for relevant status changes, including ownership, invalidation findings or other applicable changes resulting from contractual commitments or public authorities' decisions. Failure to update the registration may lead to the suspension of the registration of the SEP from the register.

(23) A SEP holder may also request the modification of a SEP registration. An interested stakeholder may also request the modification of a SEP registration, if it can demonstrate that the registration is inaccurate based on a definitive decision by a public authority. A SEP can only be removed from the register at the request of the SEP holder, if the patent is expired, was invalidated or found non-essential by a final

decision or ruling of a competent court of a Member State or found non-essential under this Regulation.

(24) To further ensure the quality of the register and avoid over-registration, essentiality checks should also be conducted randomly by independent evaluators selected according to objective criteria to be determined by the Commission. Only one SEP from the same patent family should be checked for essentiality.

(25) These essentiality checks should be conducted on a sampling from SEP portfolios to ensure that the sample is capable of producing statistically valid results. The results of the sampled essentiality checks should determine the ratio of positively checked SEPs from all the SEPs registered by each SEP holder. The essentiality rate should be updated annually.

(26) SEP holders or implementers may also designate annually up to 100 registered SEPs for essentiality checks. If the pre-selected SEPs are confirmed essential, the SEP holders may use this information in negotiations and as evidence in courts, without prejudicing the right of an implementer to challenge the essentiality of a registered SEP in court. The selected SEPs would have no bearing on the sampling process as the sample should be selected from all registered SEPs of each SEP holder. If a preselected SEP and a SEP selected for the sample set are the same, only one essentiality check should be done. Essentiality checks should not be repeated on SEPs from the same patent family.

(27) Any assessment of essentiality of SEPs conducted by an independent entity prior to the entry into force of the Regulation, for example through patent pools, as well as essentiality determinations by judicial authorities should be indicated in the register. Those SEPs should not be re-checked for essentiality after the relevant evidence supporting the information in the register is provided to the competence centre.

(28) The evaluators should work independently in accordance with the rules of procedure and Code of Conduct to be determined by the Commission. The SEP holder would be able request a peer evaluation before the issuance of a reasoned opinion. Unless a SEP is the subject of a peer review, there would be no further review of the essentiality check results. The results of the peer evaluation should serve to improve the essentiality check process, to identify and remedy shortcomings and improve consistency.

(29) The competence centre would publish the results of the essentiality checks, whether positive or negative, in the register and the database. The results of the essentiality checks would not be legally binding. Thus, any subsequent disputes with regard to essentiality would have to be addressed in the relevant court. The results from the essentiality checks, whether requested by a SEP holder or based on a sample, may, however, be used for the purpose of demonstrating essentiality of those SEPs in negotiations, in patent pools and in court.

(30) It is necessary to ensure that the registration and ensuing obligations provided for in this Regulation are not circumvented by removing a SEP from the register. When an evaluator finds a claimed SEP non-essential, only the SEP holder can request its removal from the register and only after the annual sampling process has been completed and the proportion of true SEPs from the sample has been established and published.

(31) The purpose of the FRAND commitment is to facilitate adoption and use of the standard by making SEPs available to implementers on fair and reasonable terms and

to provide the SEP holder a fair and reasonable return for its innovation. Thus, the ultimate goal of enforcement actions by SEP holders or actions brought by implementers based on a SEP holder's refusal to license should be to conclude a FRAND licence agreement. The main objective of the Regulation in this regard is to facilitate the negotiations and out of court dispute resolution that can benefit both parties. Ensuring access to swift, fair and cost-efficient ways of resolving disputes on FRAND terms and conditions should benefit SEP holders and implementers alike. As such, a properly functioning out-of-court dispute resolution mechanism to determine FRAND terms (FRAND determination) may offer significant benefits for all parties. A party may request a FRAND determination in order to demonstrate that its offer is FRAND or to provide a security, when they engage in good faith.

(32) The FRAND determination should simplify and speed up negotiations concerning FRAND terms and reduce costs. The EUIPO should administer the procedure. The competence centre should create a roster of conciliators that satisfy established competence and independence criteria, as well as a repository of non-confidential reports (the confidential version of the reports will be accessible only by the parties and the conciliators). The conciliators should be neutral persons with extensive experience in dispute resolution and substantial understanding of the economics of licensing on FRAND terms and conditions.

(33) The FRAND determination would be a mandatory step before a SEP holder would be able to initiate patent infringement proceedings or an implementer could request a determination or assessment of FRAND terms and conditions concerning a SEP before a competent court of a Member State. However, the obligation to initiate FRAND determination before the relevant court proceedings should not be required for SEPs covering those use cases of standards for which the Commission establishes that there are no significant difficulties or inefficiencies in licensing on FRAND terms.

(34) Each party may choose whether it wishes to engage in the procedure and commit to comply with its outcome. Where a party does not reply to the FRAND determination request or does not commit to comply with the outcome of the FRAND determination, the other party should be able to request either the termination or the unilateral continuation of the FRAND determination. Such a party should not be exposed to litigation during the time of the FRAND determination. At the same time, the FRAND determination should be an effective procedure for the parties to reach agreement before litigation or to obtain a determination to be used in further proceedings. Therefore, the party or parties that commit to complying with the outcome of the FRAND determination and duly engage in the procedure should be able to benefit from its completion.

(35) The obligation to initiate FRAND determination should not be detrimental to the effective protection of the parties' rights. In that respect, the party that commits to comply with the outcome of the FRAND determination while the other party fails to do so should be entitled to initiate proceedings before the competent national court pending the FRAND determination. In addition, either party should be able to request a provisional injunctionof a financial nature before the competent court. In a situation where a FRAND commitment has been given by the relevant SEP holder, provisional injunctions of an adequate and proportionate financial nature should provide the necessary judicial protection to the SEP holder who has agreed to license its SEP on FRAND terms, while the implementer should be able to contest the level of FRAND royalties or raise a defence of lack of essentiality or of invalidity of the SEP. In those national systems that require the initiation of the proceedings on the merits of the case

as a condition to request the interim measures of a financial nature, it should be possible to initiate such proceedings, but the parties should request that the case be suspended during the FRAND determination. When determining what level of the provisional injunction of financial nature is to be deemed adequate in a given case, account should be taken, inter alia, of the economic capacity of the applicant and the potential effects for the effectiveness of the measures applied for, in particular for SMEs, also in order to prevent the abusive use of such measures. It should also be clarified that once the FRAND determination is terminated, the whole range of measures, including provisional, precautionary and corrective measures, should be available to parties.

(36) When the parties enter into the FRAND determination, they should select a conciliator for the FRAND determination from the roster. In case of disagreement, the competence centre would select the conciliator. The FRAND determination should be concluded within 9 months. This time would be necessary for a procedure that ensures that the rights of the parties are respected and at the same time is sufficiently swift to avoid delays in concluding licences. Parties may settle at any time during the process, which results in the termination of the FRAND determination.

(37) Upon appointment, the conciliation centre should refer the FRAND determination to the conciliator, who should examine whether the request contains the necessary information, and communicate the schedule of procedure to the parties or the party requesting the continuations of the FRAND determination.

(38) The conciliator should examine the parties' submissions and suggestions for the determination of FRAND terms and conditions, and consider the relevant negotiation steps, among other relevant circumstances. The conciliator, upon its own initiative or the request of a party, should be able to require the parties to submit evidence it deems necessary for the fulfilment of its task. It should also be able to examine publicly available information and the competence centre's register and reports of other FRAND determinations, as well as non-confidential documents and information produced by or submitted to the competence centre.

(39) If a party fails to engage in the FRAND determination after the conciliator has been appointed, the other party may request the termination or may request that the conciliator issues a recommendation for a FRAND determination on the basis of the information it was able to assess.

(40) If a party initiates a procedure in a jurisdiction outside the Union resulting in legally binding and enforceable decisions regarding the same standard that is subject to FRAND determination and its implementation, or including SEPs from the same patent family as SEPs subject to FRAND determination and involving one or more of the parties to the FRAND determination as a party; before or during of the FRAND determination by a party, the conciliator, or where he/she has not been appointed has not been established, the competence centre, should be able to terminate the procedure upon the request of the other party.

(41) At the conclusion of the procedure, the conciliator should make a proposal recommending FRAND terms and conditions. Either party should have the option to accept or reject the proposal. If the parties do not settle and/or do not accept its proposal, the conciliator should draft a report of the FRAND determination. The report would have a confidential and a non-confidential version. The non-confidential version of the report should contain the proposal for FRAND terms and conditions and the methodology used and should be provided to the competence centre for publication

in order to inform any subsequent FRAND determination between the parties and other stakeholders involved in similar negotiations. The report would thus have a dual purpose to encourage the parties to settle and to provide transparency as to the process and the recommended FRAND terms in cases of disagreement.

(42) The Regulation respects the intellectual property rights of patent owners (Article 17(2) of EU Charter of Fundamental Rights), although it includes a restriction on the ability to enforce a SEP that has not been registered within a certain time-limit and introduces a requirement to conduct a FRAND determination before enforcing individual SEPs. The limitation on the exercise of intellectual property rights is allowed under the EU Charter, provided that the proportionality principle is respected. According to settled case-law, fundamental rights can be restricted provided that those restrictions correspond to objectives of general interest pursued by the Union and do not constitute, with regard to the aim pursued, a disproportionate and intolerable interference which infringes the very essence of the rights guaranteed[39]. In that respect, this Regulation is in the public interest in that it provides a uniform, open and predictable information and outcome on SEPs for the benefit of SEP holder, implementers and end users, at Union level. It aims at dissemination of technology for the mutual advantage of the SEP holders and implementers. Furthermore, the rules concerning the FRAND determination are temporary thus limited and aimed at improving and streamlining the process but are not ultimately binding.[40]

(43) The FRAND determination is also consistent with the right to an effective remedy and to access to justice as laid down in Article 47 of the Charter of Fundamental Rights of the European Union as the implementer and the SEP holder fully retain that right. In case of failure to register within the prescribed time limit, the exclusion of the right to effective enforcement is limited and necessary and meets objectives of general interest. As confirmed by the CJEU[41], the provision of a mandatory dispute resolution as a precondition to access to competent courts of Member States is deemed to be compatible with the principle of effective judicial protection. The FRAND determination follows the conditions for mandatory dispute resolution outlined in the CJEU judgments, taking into account the particular characteristics of SEP licensing.

(44) When determining the aggregate royalties and making FRAND determinations the conciliators should take into account in particular any Union acquis and judgments of the Court of Justice pertaining to SEPs as well as guidance issued under this

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39 Judgment of the Court of Justice of 13 December 1979, Hauer v. Land Rheinland-Pfalz, C-44/79, EU:C:1979:290, para. 32; judgment of the Court of Justice of 11 July 1989, Hermann Schräder HS Kraftfutter GmbH & Co. KG v. Hauptzollamt Gronau, C-256/87, EU:C:1999:332, para. 15, and judgment of the Court of Justice of 13 July 1989, Hubert Wachauf v. Bundesamt für Ernährung und Forstwirtschaft, C-5/88, EU:C:1989:321, paras. 17 and 18.

40 The conciliation procedure follows the conditions for mandatory recourse to alternative dispute settlement procedures as a condition for the admissibility of an action before the courts, as outlined in the CJEU judgments; Joint Cases C- 317/08 to C- 320/08 Alassini and Others of 18 March 2010, and Case C- 75/16 Menini and Rampanelli v. Banco Popolare Società Cooperativa of 14 June 2017, taking into account the specificities of SEP licensing.

41 Judgment of the Court of Justice of 18 March 2010, Rosalba Alassini v Telecom Italia SpA (C-317/08), Filomena Califano v Wind SpA (C-318/08), Lucia Anna Giorgia Iacono v Telecom Italia SpA (C-319/08) and Multiservice Srl v Telecom Italia SpA (C-320/08), Joined cases C-317/08, C-318/08, C-319/08 and C-320/08, EU:C:2010:146, and judgement of the Court of Justice of 14 June 2017,Livio Menini and Maria Antonia Rampanelli v Banco Popolare – Società Cooperativa, C- 75/16, EU:C:2017:457

Regulation, the Horizontal Guidelines[42] and the Commission's 2017 Communication 'Setting out the EU approach to Standard Essential Patents'.[43]Furthermore, the conciliators should consider any expert opinion on the aggregate royalty or in the absence thereof, should request information from the parties before it makes its final proposals well as guidance issued under this Regulation, as well as guidance issued under this Regulation.

(45) SEP licensing may cause friction in the value chains that have so far not been exposed to SEPs. It is, therefore, important that the competence centre raises awareness concerning SEP licensing in the value chain through any of the tools at its disposal. Other factors would include the ability of upstream manufacturers to pass the cost of a SEP licence downstream and any potential impact of existing indemnification clauses within a value chain.

(46) SMEs may be involved in SEP licensing both as SEP holders and implementers. While there are currently a few SME SEP holders, the efficiencies produced with this Regulation are likely to facilitate the licensing of their SEP. Additional conditions are necessary to relieve the cost burden on such SMEs such as reduced administration fees and potentially reduced fees for essentiality checks and conciliation in addition to free support and trainings. The SEPs of micro and small enterprises should not be the subject of sampling for essentiality check, but they should be able to propose SEPs for essentiality checks if they wish to. SME implementers should likewise benefit from reduced access fees and free support and trainings. Finally, SEP holders should be encouraged to incentivise licensing by SMEs through low volume discounts or exemptions from FRAND royalties.

(47) In order to supplement certain non-essential elements of this Regulation, the power to adopt acts, in accordance with Article 290 of the Treaty on the Functioning of the European Union, should be delegated to the Commission in respect of the items to be entered in the register or in respect of determining the relevant existing standards or to identify use cases of standards or parts thereof for which the Commission establishes that there are no significant difficulties or inefficiencies in licensing on FRAND terms. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[44]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

(48) In order to ensure uniform conditions for the implementation of the relevant provisions of this Regulation, implementing powers should be conferred on the Commission to adopt the detailed requirements for the selection of evaluators and conciliators, as well as adopt the rules of procedure and Code of Conduct for evaluators and conciliators. The Commission should also adopt the technical rules for the selection of a sample of SEPs for essentiality checks and the methodology for the conduct of such essentiality

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42 Communication from the Commission – Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements, OJ C 11, 14.01.2011, pp. 1 (currently under review)

43 Communication on Setting out the EU approach to Standard Essential Patents, COM(2017)712 final, 29.11.2017.

44 OJ L 123, 12.5.2016, p. 1.

checks by evaluators and peer evaluators. The Commission should also determine any administrative fees for its services in relation to the tasks under this Regulation and fees for the services evaluators, experts and conciliators, derogations thereof and payment methods and adapt them as necessary. The Commission should also determine the standards or parts thereof that have been published before the entry into force of this Regulation, for which SEPs can be registered. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council.[45]

(49) Regulation (EU) 2017/1001 of the European Parliament and of the Council[46] should be amended to empower EUIPO to take on the tasks under this Regulation. The functions of the Executive Director should also be expanded to include the powers conferred on him under this Regulation. Furthermore, the EUIPO's arbitration and mediation centre should be empowered to set up processes such as the aggregate royalty determination and the FRAND determination.

(50) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 of the European Parliament and of the Council.[47]

(51) As EUIPO, the Commission and stakeholders should be given time to prepare for the implementation and application of this Regulation, its application should be deferred.

(52) Since the objectives of this Regulation to increase transparency with regard to SEP licensing and to provide an efficient mechanism to resolve disagreements on FRAND terms and conditions cannot be sufficiently achieved by the Member States because of multiplication of costs but can rather, by reason of efficiencies and scale, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

HAVE ADOPTED THIS REGULATION:

Title I
General Provisions

Article 1

Subject matter and scope

1. This Regulation establishes the following rules on patents essential to a standard ('SEPs'):

   (a) rules providing for enhanced transparency with regard to information necessary for SEP licensing;

   (b) rules on the registration of SEPs;

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45 Regulation (EU) No 182/2011 of the European Parliament and of the Council laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13.)

46 Regulation (EU) 2017/1001 of the European Parliament and of the Council of 14 June 2017 on the European Union trade mark (OJ L 154, 16.6.2017, p. 1.)

47 Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39.)

(c) a procedure to evaluate the essentiality of registered SEPs;

(d) a procedure for the amicable settlement of disputes related to fair, reasonable and non-discriminatory nature of terms and conditions ('FRAND determination');

(e) competences for the EUIPO for the fulfilment of the tasks set out in this Regulation.

2. This Regulation shall apply to patents that are essential to a standard that has been published by a standard development organisation, to which the SEP holder has made a commitment to license its SEPs on fair, reasonable and non-discriminatory (FRAND) terms and conditions and that is not subject to a royalty-free intellectual property policy,

(a) after the entry into force of this Regulation, with the exceptions provided in paragraph 3;

(b) before the entry into force of this Regulation, in accordance with Article 66.

3. Articles 17 and 18 and Article 34(1) shall not apply to SEPs to the extent that they are implemented for use cases identified by the Commission in accordance with paragraph 4.

4. Where there is sufficient evidence that, as regards identified use cases of certain standards or parts thereof, SEP licensing negotiations on FRAND terms do not give rise to significant difficulties or inefficiencies affecting the functioning of the internal market, the Commission shall, after an appropriate consultation process, by means of a delegated act pursuant to Article 67, establish a list of such use cases, standards or parts thereof, for the purposes of paragraph 3.

5. This Regulation shall apply to holders of SEP in force in one or more Member States.

6. This Regulation shall not apply to claims of invalidity or claims of infringement unrelated to the implementation of a standard notified under this Regulation.

7. This Regulation is without prejudice to the application of Articles 101 and 102 TFEU or to the application of corresponding national competition law rules.

Article 2

Definitions

For the purposes of this Regulation, the following definitions shall apply:

(1) 'standard essential patent' or 'SEP' means any patent that is essential to a standard;

(2) 'essential to a standard' means that the patent contains at least one claim for which it is not possible on technical grounds to make or use an implementation or method which complies with a standard, including options therein, without infringing the patent under the current state of the art and normal technical practice;

(3) ('standard' means a technical specification, adopted by a standard development organisation, for repeated or continuous application, with which compliance is not compulsory;

(4) ‘technical specification’ means a document that prescribes technical requirements to be fulfilled by a product, process, service or system as defined in Article 2 of Regulation (EU) No 1025/2012 of the European Parliament and of the Council[48];

(5) ‘standard development organisation’ means any standardising body that is not a private industrial association developing proprietary technical specifications, that develops technical or quality requirements or recommendations for products, production processes, services or methods;

(6) ‘SEP holder’ means an owner of a SEP or a person holding an exclusive licence for a SEP in one of more Member States;

(7) ‘implementer’ means a natural or legal person that implements, or intends to implement, a standard in a product, process, service or system;

(8) ‘FRAND terms and conditions’ means fair, reasonable and non-discriminatory terms and conditions of licensing SEPs;

(9) ‘FRAND determination’ means a structured procedure for the determination of the FRAND terms and conditions of a SEP licence;

(10) ‘aggregate royalty’ means the maximum amount of royalty for all patents essential to a standard;

(11) ‘patent pool’ means an entity created by an agreement between two or more SEP holders to license one or more of their patents to one another or to third parties;

(12) ‘peer evaluation’ means a process for the re-examination of the preliminary results of essentiality checks by evaluators other that those that carried out the original essentiality check;

(13) ‘claim chart’ means a presentation of correspondence between the elements (features) of one patent claim and at least one requirement of a standard or recommendation of a standard;

(14) ‘requirement of a standard’ means expression, in the content of a document, that conveys objectively verifiable criteria to be fulfilled and from which no deviation is permitted if conformance with the document is to be claimed;

(15) ‘recommendation of a standard’ means expression, in the content of a document, that conveys a suggested possible choice or course of action deemed to be particularly suitable without necessarily mentioning or excluding others;

(16) ‘patent family’ means a collection of patent documents that cover the same invention and whose members have the same priorities;

(17) ‘stakeholder’ means any person that can demonstrate a legitimate interest in SEPs, including a SEP holder, an implementer, an agent for a SEP holder or an implementer, or an association representing the interests of SEP holders and implementers;

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[48] Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12.).

(18) ´competence centre' means the EUIPO administrative units that fulfil the tasks entrusted to EUIPO under this Regulation.

Title II
Competence centre

Article 3

Tasks of the competence centre

1. The tasks under this Regulation shall be performed by a competence centre established within the EUIPO with the necessary human and financial resources.

2. The competence centre shall support transparency and FRAND determination in relation to SEPs and shall perform the following tasks:

   (a) set up and maintain an electronic register and an electronic database for SEPs;

   (b) set up and manage rosters of evaluators and conciliators;

   (c) set up and administer a system for assessment of the essentiality of SEPs;

   (d) set up and administer the process for the FRAND determination;

   (e) provide training to evaluators and conciliators;

   (f) administer a process for aggregate royalty determination;

   (g) enhance transparency and information sharing through:

      (i) publishing the results and reasoned opinions of the essentiality checks and non-confidential reports of the FRAND determinations;

      (ii) enabling access to case-law (including alternative dispute resolution) on SEPs, including from third country jurisdictions;

      (iii) compiling non-confidential information on FRAND determination methodologies and FRAND royalties;

      (iv) enabling access to SEP-related rules of third countries;

   (h) provide training, support and general advice on SEPs to SMEs;

   (i) conduct studies and any other necessary activities to support the objectives of this Regulation;

   (j) raise awareness about SEP licensing, including SEP licensing in the value chain.

3. Using the powers conferred by Article 157 of Regulation (EU) 2017/1001, the Executive Director of the EUIPO shall adopt the internal administrative instructions and shall publish the notices that are necessary for the fulfilment of all the tasks entrusted to the competence centre by this Regulation.

Title III
Information on SEP made available through the competence centre

Chapter 1
General Provisions

Article 4

Register of standard essential patents

1. A Union register for SEPs ('the register') is established.
2. The register shall be maintained in electronic format by the competence centre.
3. The register shall contain the following entries:
   (a) information on relevant standards;
   (b) registered SEPs identification, including the country of registration and patent number;
   (c) the standard version, the technical specification and the specific sections of the technical specification for which the patent is considered essential;
   (d) reference to the terms of the SEP holder's FRAND licensing commitment to the standard development organisation;
   (e) name, address and contact details of the SEP holder;
   (f) if the SEP holder is part of a group of companies, the name, address and contact details of the parent company;
   (g) name, address and contact details of the SEP holder's legal representatives in the Union, where relevant;
   (h) the existence of any public standard terms and conditions, including SEP holder's royalty and discount policies;
   (i) the existence of any public standard terms and conditions for SEP licensing to SMEs;
   (j) availability for licensing through patent pools, where applicable;
   (k) contact details for licensing, including licensing entity;
   (l) the date of registration of the SEP in the register and the registration number.
4. The register shall also contain the following entries, each accompanied by the date of recording of such entry:
   (a) changes in the contact details of entries referred to in paragraph (3), points (e), (f), (g) and (k);
   (b) the grant or transfer of a licence through patent pools, where applicable pursuant to Article 9;
   (c) information on whether an essentiality check or peer evaluation have been performed and reference to the result;

(d) information on whether the SEP is expired or invalidated by a final judgment of a competent court of a Member State;

(e) particulars regarding proceedings and decisions on SEPs pursuant to Article 10;

(f) date of publication of information pursuant to Article 19(1) in conjunction with Article 14(7), Article 15(4) and Article 18(11);

(g) the date of suspension of the SEP from the Register pursuant to Article 22;

(h) corrections of the SEP, pursuant to Article 23;

(i) the date of removal of the SEP from the register pursuant to Article 25 and the grounds for removal;

(j) the correction to or removal from the register of the item referred to in points (b), (e) and (f).

5. The Commission is empowered to adopt delegated acts in accordance with Article 67, amending paragraphs (3) and (4) to determine items other than those referred to in paragraphs (3) and (4) that are to be entered in the Register for the purposes of this Regulation.

6. The competence centre shall collect, organise, make public and store the items referred to in paragraphs (3) and (4), including any personal data for the purposes of this Regulation.

7. The competence centre shall keep the register easily accessible for public inspection. The data shall be considered to be of public interest and may be accessed by any third party free of charge.

Article 5

Electronic database

1. The competence centre shall establish and maintain an electronic database for SEPs.

2. The following information in the database shall be accessible to any third party subject to the registration with the competence centre:

(a) patent bibliographic data on the claimed SEP or SEP, including priority date, family members, grant date and expiration date;

(b) public standard terms and conditions, including SEP holder's royalty and discount policies pursuant to Article 7, first paragraph, point (b), if available;

(c) public standard terms and conditions for SEP licensing to SMEs pursuant to Article 62(1), if available;

(d) information regarding known products, processes, services or systems and implementations pursuant to Article 7, first paragraph, point (b);

(e) information pertaining to essentiality pursuant to Article 8;

(f) non-confidential information on FRAND determinations pursuant to Article 11;

(g) information on aggregate royalties pursuant to Articles 15, 16 and 17;

(h) expert opinions referred to in Article 18;

(i) non-confidential reports of the conciliators pursuant to Article 57;

(j) SEPs selected for essentiality checks pursuant to Article 29, the reasoned opinions or the final reasoned opinions pursuant to Article 33;

(k) the date and the grounds for removal of the SEP from the database pursuant to Article 25;

(l) information on SEP related rules in third countries pursuant to Article 12;

(m) case-law and reports pursuant to Article 13(3) and (5);

(n) awareness raising and training materials.

3. Access to the information pursuant to paragraph (2), points (f), (h), (i), (j) and (k) may be subject to the payment of a fee.

4. However, public authorities, including courts, shall have full access to the information in the database referred to in paragraph (2) free of charge subject to registration with the competence centre.

Article 6

Common provisions on the register and the database

1. When a party requests that data and documents of the database be kept confidential, that party shall provide a non-confidential version of the information submitted in confidence in sufficient detail to permit a reasonable understanding of the substance of the information submitted in confidence. The competence centre may disclose that non-confidential version.

2. The competence centre shall keep the files of any procedure relating to the registration of the SEP. The Executive Director of the EUIPO shall determine the form in which those files shall be kept and made available. The competence centre shall keep the files for 10 years after the removal of the registration of the SEP. Upon request, personal data may be removed from the register or the database after 18 months from the expiry of the SEP or removal of the SEP from the register.

3. The competence centre may correct any information contained in the register or the database pursuant to Article 23.

4. The SEP holder and its legal representative in the Union shall be notified of any change in the register or the database when that change concern a particular SEP.

5. Upon request, the competence centre shall issue registration certificates or certified copies of the data and documents in the register or the database. The registration certificates and certified copies may be subject to the payment of a fee.

6. The Commission shall determine the conditions of access to the database, including the fees for such access, or for registration certificates and certified copies from the database or the register, by means of an implementing act. The implementing act shall be adopted in accordance with the examination procedure referred to in Article 68(2).

Article 7

Identification of implementations of a standard and related SEP licensing terms and conditions

A SEP holder shall provide to the competence centre the following information:

(a) information as regards the products, processes, services or systems in which the subject-matter of the SEP may be incorporated or to which it is intended to be applied, for all existing or potential implementations of a standard, to the extent such information is known to the SEP holder.

(b) where available, its standard terms and conditions for SEP licensing, including its royalty and discount policies, within 7 months from the opening of the registration for the relevant standard and implementation by the competence centre.

Article 8

Information pertaining to essentiality

A SEP holder shall provide to the competence centre the following information to be included in the database and referenced in the register:

(a) a final decision on essentiality for a registered SEP made by a competent court of a Member State within 6 months from the publication of such decision.

(b) any essentiality check prior to [OJ: please insert the date = 24 months from entry into force of this regulation] by an independent evaluator in the context of a pool, identifying the SEP registration number, the identity of the patent pool and its administrator, and the evaluator.

Article 9

Information to be provided by patent pools

Patent pools shall publish on their websites at least the following information and inform the competence centre thereof:

(a) standards subject to collective licensing;

(b) the administrative entity's shareholders or ownership structure;

(c) process for evaluating SEPs;

(d) roster of evaluators having residence in the Union;

(e) list of evaluated SEPs and list of SEPs being licensed;

(f) illustrative cross-references to the standard;

(g) list of products, services and processes that may be licensed through the patent pool or the entity;

(h) royalties and discount policy per product category;

(i) standard licence agreement per product category;

(j) list of licensors in each product category;

(k) list of licensees for each product category.

Article 10

Information on decisions on SEPs

1. Competent courts of Member States shall notify the competence centre within 6 months from the adoption of a judgment concerning SEPs on:

   (a) injunctions;

   (b) infringement proceedings;

   (c) essentiality and validity;

   (d) abuse of dominance;

   (e) determination of FRAND terms and conditions.

2. Any person may inform the competence centre about any judicial proceeding or alternative dispute resolution proceeding concerning a SEP.

Article 11

Information on FRAND determinations

1. Persons involved in alternative dispute resolution proceedings concerning SEPs in force in a Member State shall disclose to the competence centre within 6 months from the termination of the procedure the standards and the implementations concerned, the methodology used for the calculation of FRAND terms and conditions, information on the name of the parties, and on specific licensing rates determined.

2. No confidential information shall be disclosed by the competence centre without the prior consent of the affected party.

Article 12

Information on SEP related rules in third countries

1. The competence centre shall collect and publish in the database information on any SEP related rules in any third country.

2. Any person may provide the competence centre with such information as well as information on updates, corrections and public consultations. The competence centre shall publish that information in the database.

Article 13

Enhancing transparency and information sharing

1. The competence centre shall store in the database all the data provided by stakeholders, as well as opinions and reports of evaluators and conciliators.

2. The collection, storage and processing of such data shall serve the purposes of:

   (a) administering the registrations of SEPs, essentiality checks and conciliation proceedings pursuant to this Regulation;

   (b) accessing the information necessary for conducting those proceedings more easily and efficiently;

   (c) communicating with the parties to the proceedings;

(d) producing reports and statistics enabling the competence centre to improve its operations and the functioning of the registration of SEPs and the proceedings under this Regulation.

3. The competence centre shall include in the database case-law from competent courts of Member States, from third country jurisdictions and alternative dispute resolution bodies.

4. The competence centre shall collect all information on FRAND terms and conditions, including any discounts, which have been made public by SEP holders, disclosed to it pursuant to Article 11 and included in the FRAND determination reports and shall make such disclosures accessible to public authorities in the Union, including competent courts of Member States, subject to a written request. Confidential documents shall be accompanied by a non-confidential version of the information submitted in confidence in sufficient detail to permit a reasonable understanding of the substance of the information submitted in confidence.

5. The competence centre shall publish in the database an annual report on methodologies for FRAND determinations based on information from court and arbitration decisions and statistical information on licences and licensed products from the FRAND determinations.

6. Upon a reasoned request by a stakeholder, any confidential information shall be redacted in a non-confidential format before the competence centre publishes or transmits such information.

Chapter 2
Notification of a standard and an aggregate royalty

Article 14

Notification of a standard to the competence centre

1. Holders of a patent in force in one or more Member States which is essential to a standard for which FRAND commitments have been made shall notify to the competence centre, where possible through the standard development organisation or through a joint notification, the following information:

(a) the commercial name of a standard;

(b) the list of relevant technical specifications that define the standard;

(c) the date of the publication of the latest technical specification;

(d) implementations of the standard known to the SEP holders making the notification.

2. Such notification shall be made within 30 days of the publication of the latest technical specification.

3. In the absence of the notification under paragraph (1), any holder of a SEP in force in one or more Member State shall notify individually, no later than 90 days from the publication of the latest technical specification, to the competence centre the information referred to in paragraph (1).

4. In the absence of notification under paragraph (1) or under paragraph (3) any implementer may notify, to the competence centre the information referred to in paragraph (1).

5. The competence centre shall also notify the relevant standard development organisation of the publication. In case of notification pursuant to paragraphs (3) and (4), it shall also notify, where possible, known SEP holders individually or request confirmation from the standard development organisation that it has duly notified the SEP holders.

6. The competence centre shall publish on the EUIPO website the notifications made pursuant to paragraphs (1), (3) and (4) for comments by stakeholders. Stakeholders may submit their comments to the competence centre within 30 days from the publication of the list.

7. After expiry of the time limit referred to in paragraph (6) the competence centre shall consider all comments received including all relevant technical specifications and implementations and publish the information pursuant to paragraph (1).

Article 15

Notification of an aggregate royalty to the competence centre

1. Holders of SEPs in force in one or more Member States for which FRAND commitments have been made may jointly notify the competence centre the aggregate royalty for the SEPs covering a standard.

2. The notification made in accordance with paragraph (1) shall contain the information on the following:

   (a) the commercial name of the standard;

   (b) the list of technical specifications that define the standard;

   (c) the names of the SEP holders making the notification referred to in paragraph (1);

   (d) the estimated percentage the SEP holders referred to in paragraph (1) represent from all SEP holders;

   (e) the estimated percentage of SEPs they own collectively from all SEPs for the standard;

   (f) the implementations known to the SEP holders referred to in point (c);

   (g) the global aggregate royalty, unless the notifying parties specify that the aggregate royalty is not global;

   (h) any period for which the aggregate royalty referred to in paragraph (1) is valid.

3. The notification referred to in paragraph (1) shall be made at the latest 120 days after:

   (a) the publication of a standard by the standard development organisation for implementations known to the SEP holders referred to in paragraph (2), point (c); or

   (b) a new implementation of the standard becomes known to them.

4. The competence centre shall publish in the database the information provided under paragraph (2).

Article 16

Revision of aggregate royalty

1. In case of revision of the aggregate royalty, the SEP holders shall notify the competence centre about the revised aggregate royalty and the reasons for the revision.

2. The competence centre shall publish in the database the initial aggregate royalty, the revised aggregate royalty and the reasons for the revision in the register.

Article 17

Process for facilitating agreements on aggregate royalty determinations

1. Holders of SEPs in force in one or more Member States representing at least 20 % of all SEPs of a standard may request the competence centre to appoint a conciliator from the roster of conciliators to mediate the discussions for a joint submission of an aggregate royalty.

2. Such a request shall be made no later than 90 days following the publication of the standard or no later than 120 days following the first sale of new implementation on the Union market for implementations not known at the time of publication of the standard.

3. The request shall contain the following information:

   (a) the commercial name of the standard;

   (b) the date of publication of the latest technical specification or the date of the first sale of new implementation on the Union market;

   (c) the implementations known to the SEP holders referred to in paragraph (1);

   (d) the names and contact details of the SEP holders supporting the request;

   (e) the estimated percentage of SEPs they own individually and collectively from all potential SEPs claimed for the standard.

4. The competence centre shall notify the SEP holders referred to in paragraph (3), point (d) and request them to express their interest in participating in the process and to provide their estimated percentage of SEPs from all SEPs for the standard.

5. The competence centre shall appoint a conciliator from the roster of conciliators and inform all SEP holders that expressed interest to participate in the process.

6. SEP holders that submit to the conciliator confidential information shall provide a non-confidential version of the information submitted in confidence in sufficient detail to permit a reasonable understanding of the substance of the information submitted in confidence.

7. Where the SEP holders fail to make a joint notification within 6 months from the appointment of the conciliator, the conciliator shall terminate the process.

8. If the contributors agree on a joint notification, the procedure set out in Article 15(1), (2) and (4) shall apply.

Article 18

Non-binding expert opinion on aggregate royalty

1. A SEP holder or an implementer may request the competence centre for a non-binding expert opinion on a global aggregate royalty.

2. The request referred to in paragraph (1) shall be made no later than 150 days after:

   (a) the publication of the relevant standard for known implementations; or

   (b) new implementations are first sold on the Union market.

3. That request shall include:

   (a) commercial name of the standard;

   (b) list of relevant technical specifications that define the standard;

   (c) list of relevant products, processes, services or systems or implementations;

   (d) list of known stakeholders and contact details.

4. The competence centre shall notify the relevant standard development organisation and all known stakeholders of the request. It shall publish the request on EUIPO's website and invite stakeholders to express interest in participating in the process within 30 days from the day when the request was published.

5. Any stakeholder may request to participate in the process after explaining the basis of its interest. SEP holders shall provide their estimated percentage of those SEPs of all SEPs for a standard. Implementers shall provide information on any relevant implementations of the standard, including any relevant market share in the Union.

6. If the requests for participation include SEP holders representing collectively at least an estimated 20% of all SEPs for the standard, and implementers holding collectively at least 10% relevant market share in the Union or at least 10 SMEs, the competence centre shall appoint a panel of three conciliators selected from the roster of conciliators with the appropriate background from the relevant field of technology.

7. Stakeholders that submit to the panel confidential information shall provide a non-confidential version of the information submitted in confidence in sufficient detail to permit a reasonable understanding of the substance of the information submitted in confidence.

8. Following the appointment, the panel shall request the participating SEP holders to, within one month:

   (a) propose an aggregate royalty, including the information referred to in Article 15(2), or

   (b) submit justification on the impossibility to propose an aggregate royalty due to technological, economic, or other considerations.

9. The panel shall duly consider the submissions provided for in paragraph 8 and decide:

   (a) to suspend the procedure for the expert opinion on aggregate royalty for an initial period of no longer than 6 months, which can be further extended on the basis of a duly justified request by one of the participating SEP holders, or

   (b) to provide the expert opinion.

10. The panel shall provide the expert opinion within 8 months of the end of the suspension period pursuant to paragraph 8(a) or of the decision referred to in paragraph 8(b). The opinion shall be supported by at least two of the three conciliators.

11. 1The expert opinion shall include a summary of the information provided in the request, the information referred to in Article 15(2), the names of the conciliators, the procedure, the reasons for the opinion on the aggregate royalty and the underlying methodology. The reasons for any divergent views shall be specified in an annex to the expert opinion.

12. The expert opinion shall include an analysis of the value chain concerned and the potential impact of the aggregate royalty on the innovation incentives of both SEP holders and stakeholders in the value chain where licensing is to take place.

13. The competence centre shall publish the expert opinion and notify the participants of that publication.

Chapter 3
Registration of SEPs

Article 19

Administration of the register of standard essential patents

1. The competence centre shall create an entry in the register for a standard for which FRAND commitments have been made within 60 days from the earliest of the following events:

   (a) publication by the competence centre of the standard and related information pursuant to Article 14(7);

   (b) publication by the competence centre of an aggregate royalty and related information pursuant to Article 15(4) and Article 18(11).

2. The competence centre shall publish a notice on the EUIPO website informing stakeholders that an entry in the register has been made and refer to the publications referred to in paragraph (1). The competence centre shall notify known SEP holders individually by electronic means and the relevant standard development organisation of the notice in this paragraph.

Article 20

Registration of standard essential patents

1. Upon request of a SEP holder the competence centre shall register any patent in force in one or more Member States and falling within the scope of this Regulation that is essential for a standard, for which the competence centre has published a notice pursuant to Article 19(2).

2. For a SEP to be included in the register, at least one patent claim shall correspond with at least one requirement or recommendation to the standard, identified by standard name, version (and/or release) and sub-clause.

3. The request for registration shall be made within 6 months from the publication of the notice pursuant to Article 19(2). In case the SEP is only granted by a national or European patent office after the publication of the notice pursuant to Article 19(2),

the request for registration shall be made within 6 months from the grant of the SEP by the relevant patent office.

4. The request shall include the information set out in Article 4(3) and Article 5(2), points (a), (b), (d) and (e).

5. A SEP holder shall update the information in the register and database to reflect relevant changes in relation to its registered SEP by notifying the competence centre within 6 months from the change occurring.

6. The request for registration will only be accepted following the payment of the registration fee by the SEP holder. The Commission shall determine the registration fee in the implementing act issued based on Art. 63(5). The registration fee shall include, in case of medium and large enterprises, the expected costs and fees of the essentiality check for SEPs selected pursuant to Article 29(1).

Article 21

Date of registration

1. The date of registration shall be the date on which the competence centre has received a registration request pursuant to Article 20(2), (4) and (5) .

2. The competence centre shall publish the registered SEPs in the register within 7 working days from the date of registration.

Article 22

Examination of the conditions of registration

1. A sample of SEP registrations shall be checked annually for completeness and correctness.

2. The EUIPO shall adopt a methodology for selecting a sample of SEP registrations for checks.

3. Where the registration does not contain the information in accordance with Articles 4 and 5 or contains incomplete or inaccurate information, the competence centre shall request the SEP holder to provide the complete and accurate information within the set time limit of no less than 2 months.

4. If the SEP holder fails to provide the correct and complete information, the registration shall be suspended from the register, until such time as the incompleteness or inaccuracy is remedied.

5. A SEP holder whose SEP has been suspended from the register pursuant to paragraph (4) and considers that the finding of the competence centre is incorrect may apply before the Boards of Appeal of the EUIPO for a decision on the matter. The application shall be made within 2 months from the suspension. Within 2 months from the application, the Boards of Appeal of the EUIPO shall either reject the application or request the competence centre to correct its finding and inform the requesting person.

6. Any completing or correcting information on a SEP pursuant to this article shall be made free of charge.

Article 23

Correction of an entry in the register or information in the database

1. A SEP holder may request a correction of its SEP registration or of the information contained in the database by filing an appropriate request to the competence centre, except as provided for in paragraph (2).

2. Any third party may request the competence centre to correct a SEP registration or information contained in the database. The request shall contain the following information:

   (a) the name and contact details of the requesting person;

   (b) the registration number of the registered SEP;

   (c) the reasons for the request;

   (d) evidence from an independent source supporting the request.

3. The competence centre shall notify the request to the SEP holder and invite the SEP holder to correct the entry in the register or the information submitted for the database, where relevant within a time limit no less than 2 months.

4. The competence centre shall notify the SEP holder and invite the SEP holder to correct the entry in the register or the information submitted for the database, where relevant within a time limit no less than 2 months, when the competence centre is informed by a competent court of a Member State pursuant to Article 10(1) or a patent office or any third party of:

   (a) the expiry of a registered SEP

   (b) the invalidation of a registered SEP by a competent authority; or

   (c) a final judgment that the registered SEP is not essential to the relevant standard.

5. If the SEP holder fails to correct the entry in the register or the information submitted for the database within the given time limit, the registration shall be suspended from the register, until such time as the incompleteness or inaccuracy is remedied.

6. A SEP holder whose SEP has been suspended from the register pursuant to paragraph (5) and considers that the finding of the competence centre is incorrect may apply before the Boards of Appeal of the EUIPO for a decision on the matter. The application shall be made within 2 months from the suspension. Within two months from the application, the Boards of Appeal of the EUIPO shall either reject the application or request the competence centre to correct its finding and inform the requesting person.

7. The treatment of requests for correction pursuant to This article by the competence centre shall be suspended from the selection of the SEP for essentiality check pursuant to Article 29 until the publication of the result of the essentiality check in the register and the database pursuant to Article 33(1).

8. The competence centre may correct any linguistic errors or errors of transcription and manifest oversights or technical errors attributable to it in the register and in the database of its own motion.

9. Any corrections pursuant to this article shall be made free of charge.

Article 24

Effects of absence of registration or suspension of registration of SEPs

1. A SEP that is not registered within the time-limit set out in Article 20(3) may not be enforced in relation to the implementation of the standard for which a registration is required in a competent court of a Member State, from the time-limit set out in Article 20(3) until its registration in the register.

2. A SEP holder that has not registered its SEPs within the time-limit set out in Article 20(3) shall not be entitled to receive royalties or seek damages for infringement of such SEPs in relation to the implementation of the standard for which registration is required, from the time-limit set out in Article 20(3) until its registration in the register.

3. Paragraphs (1) and (2) are without prejudice to provisions included in contracts setting a royalty for a broad portfolio of patents, present or future, stipulating that the invalidity, non-essentiality or unenforceability of a limited number thereof shall not affect the overall amount and enforceability of the royalty or other terms and conditions of the contract.

4. Paragraphs (1) and (2) apply also in case the registration of a SEP is suspended, during the suspension period pursuant to Article 22(4) or 23(5), except where the Boards of Appeal request the competence centre to correct its findings in accordance with Article 22(5) and 23(6).

5. A competent court of a Member State requested to decide on any issue related to a SEP in force in one or more Member States, shall verify whether the SEP is registered as part of the decision on admissibility of the action.

Article 25

Removing a SEP from the register and the database

1. A SEP holder may request the removal of its registered SEP from the register and the database, on the following grounds:

   (a) expiry of the patent;

   (b) invalidation of the patent by a competent authority;

   (c) final judgment of a competent court of a Member State that the registered patent is not essential to the relevant standard;

   (d) as a consequence of a negative result from the essentiality check pursuant to Article 31(5) and Article 33(1).

2. Such a request may be made at any time, except from the selection of the SEP for essentiality check pursuant to Article 29 until the publication of the result of the essentiality check in the register and database pursuant to Article 33(1).

3. The competence centre shall remove the SEP from the register and the database.

Title IV
Evaluators and Conciliators

Article 26

Evaluators and conciliators

1. An evaluator shall conduct essentiality checks.
2. A conciliator shall conduct the following tasks:
   (a) mediate among parties in establishing an aggregate royalty;
   (b) provide a non-binding opinion on an aggregate royalty;
   (c) serve in a FRAND determination.
3. The evaluators and conciliators shall adhere to a code of conduct.
4. The competence centre shall appoint [10] evaluators from the roster of evaluators as peer evaluators for a period of [three] years.
5. By [OJ: please insert the date = 18 months from entry into force of this regulation], the Commission shall by means of an implementing act adopted in accordance with the examination procedure referred to in , lay down the practical and operational arrangements concerning:
   (a) the requirements for evaluators or conciliators, including a Code of Conduct;
   (b) the procedures pursuant to Articles 17, 18, 31 and 32 and Title VI.

Article 27

The selection procedure

1. The competence centre shall conduct a procedure of selecting candidates based on the requirements established in the implementing act referred to in Article 26(5).
2. The competence centre shall establish a roster of suitable candidates for evaluators or conciliators. There may be different rosters of evaluators and conciliators depending on the technical area of their specialisation or expertise.
3. Where the competence centre has not yet established roster of candidates evaluators or conciliators at the moment of the first registrations or FRAND determination, the competence centre shall invite ad hoc renowned experts who satisfy the requirements set out in the implementing act referred to in Article 26(5).
4. The competence centre shall regularly review the rosters that a sufficient number of qualified candidates is maintained.

Title V
Essentiality checks of standard essential patents

Article 28

General requirement for essentiality checks

1. The competence centre shall administer a system of essentiality checks, ensuring that they are conducted in an objective and impartial manner and that confidentiality of the information obtained is safeguarded

2. The essentiality check shall be conducted by an evaluator selected pursuant to Article 27. Evaluators shall conduct essentiality checks of registered SEPs for the standard for which they are registered.

3. Essentiality checks shall not be done on more than one SEP from the respective patent family.

4. The lack of an essentiality check or an ongoing essentiality check shall not preclude licensing negotiations or any court or administrative procedure in relation to a registered SEP.

5. The evaluator shall summarise the result of the essentiality check and the reasons for it in a reasoned opinion, or, in case of peer evaluation, in a final reasoned opinion, which shall not be legally binding.

6. The result of the essentiality check conducted and the reasoned opinion of the evaluator or the final reasoned opinion of the peer evaluator may be used as evidence before stakeholders, patent pools, public authorities, courts or arbitrators.

Article 29

Administration of essentiality checks

1. The competence centre shall select annually a sample of registered SEPs from different patent families from each SEP holder and with regard to each specific standard in the register for essentiality checks. Registered SEPs of micro and small enterprises shall be excluded from the annual sampling process. The checks shall be conducted based on a methodology that ensures the establishment of a fair and statistically valid selection that can produce sufficiently accurate results about the essentiality rate in all registered SEPs of a SEP holder with regard to each specific standard in the register. By [OJ: please insert the date = 18 months from entry into force of this regulation] the Commission shall, by means of an implementing act, determine the detailed methodology. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 68(2).

2. The competence centre shall notify the SEP holders about the SEPs selected for essentiality checks. Within the time limit established by the competence centre, the SEP holders may submit within the same time period a claim chart with a maximum amount of five correspondences between the SEP and the relevant standard, any additional technical information that may facilitate the essentiality check and translations of the patent requested by the competence centre.

3. The competence centre shall publish the list of SEPs selected for essentiality check.

4. If a SEP selected for essentiality check was already the subject of a previous or ongoing essentiality check pursuant to This title or of an essentiality decision or check referred to in Article 8, no additional essentiality check shall be done. The result from the previous essentiality check or decision shall be used for the determination of the percentage of sampled per SEP holder and per specific registered standard that has passed successfully the essentiality check.

5. Each SEP holder may voluntarily propose annually up to 100 registered SEPs from different patent families to be checked for essentiality with regard to each specific standard for which SEP registration was made.

6. Any implementer may voluntarily propose annually up to 100 registered SEPs from different patent families to be checked for essentiality with regard to each specific standard for which SEP registrations have been made.

7. The competence centre shall allocate the SEPs for essentiality check to evaluators based on the roster of evaluators established pursuant to Article 27 and shall provide access to the evaluator access to the complete documentation provided by the SEP holder.

8. The competence centre shall ensure that the identity of the evaluator remain undisclosed to the SEP holders during the examination of the essentiality pursuant to Article 31 or during the peer evaluation pursuant to Article 32. All the communication between the SEP holder and the evaluator shall pass through the competence centre.

9. In case of failure to respect formal requirements pursuant to Article 28, other procedural requirements or the code of conduct, the competence centre may, at the request of any stakeholder submitted within one month from the publication of the reasoned opinion or final reasoned opinion or on its own initiative, review the examination and decide to:

   (a) maintain, or

   (b) revoke

   the results of examination of the essentiality of a registered SEP or of the peer evaluation.

10. Where the competence centre revokes the results pursuant to paragraph 9(b), the competence centre shall appoint a new evaluator or peer evaluator to conduct a new examination of the essentiality check pursuant to Article 31 or new peer evaluation pursuant to Article 32.

11. The party that requests the review of the examination of the essentiality check or peer evaluation and re-appointment of the evaluator and considers that the finding of the competence centre is incorrect may apply before the Boards of Appeal of the EUIPO for a decision on the matter. The application shall be made within 2 months from the finding of the competence centre. The Boards of Appeal of the EUIPO shall either reject the application or request the competence centre to appoint a new evaluator and inform the requesting person and, where relevant, the SEP holder

Article 30

Observations by stakeholders

1. Within 90 days following the publication of the list of registered SEPs selected for sampling, any stakeholder may submit to the competence centre written observations concerning the essentiality of the selected SEPs.

2. The observations referred to in paragraph (1) shall be communicated to the SEP holder who may comment on them within the time limit established by the competence centre.

3. The competence centre shall provide the observations and the responses by the SEP holder to the evaluator following the expiry of the set time limits.

Article 31

Examination of the essentiality of a registered SEP

1. The examination of essentiality shall be conducted following procedure that ensures sufficient time, rigorousness and high-quality.
2. The evaluator may invite the SEP holder concerned to file observations, within a period to be fixed by the evaluator.
3. Where an evaluator has reasons to believe that the SEP may not be essential to the standard, the competence centre shall inform the SEP holder of any such reasons and specify a period within which the SEP holder may submit its observations, or submit an amended claim chart.
4. The evaluator shall duly consider any information provided by the SEP holder.
5. The evaluator shall issue his reasoned opinion to the competence centre within 6 months from its appointment. The reasoned opinion shall include the name of the SEP holder and of the evaluator, the SEP subject to the essentiality check, the relevant standard, a summary of the examination procedure, the result of the essentiality check and the reasons on which that result is based.
6. The competence centre shall notify the reasoned opinion to the SEP holder.

Article 32

Peer evaluation

1. Where the competence centre has informed the SEP holder pursuant to Article 31(3), the SEP holder may request peer evaluation before the expiry of the period to submit its observations pursuant to Article 31(3).
2. If the SEP holder requests a peer evaluation, the competence centre shall appoint a peer evaluator.
3. The peer evaluator shall duly consider all the information submitted by the SEP holder, the reasons of the initial evaluator why the SEP may not be essential to the standard and any amended claim chart or additional observations provided by the SEP holder.
4. In case the peer evaluation confirmed the preliminary conclusions of the evaluator that the evaluated SEP may not be essential to the standard for which it was registered, the peer evaluator shall inform the competence centre and provide the reasons for this opinion. The competence centre shall inform the SEP holder and invite the SEP holder to submit its observations.
5. The peer evaluator shall duly consider the observations of the SEP holder and issue a final reasoned opinion to the competence centre within 3 months from its appointment. The final reasoned opinion shall include the name of the SEP holder, of the evaluator and of the peer evaluator, the SEP subject to the essentiality check, the relevant standard, a summary of the examination and peer evaluation procedure, the preliminary conclusion of the evaluator, the result of the peer evaluation and the reasons on which that result is based.

6. The competence centre shall notify the final reasoned opinion to the SEP holder.

7. The results of the peer evaluation shall serve to improve the essentiality check process and ensure consistency.

Article 33

Publication of the results of the essentiality checks

1. The competence centre shall enter the result of the essentiality check or of the peer evaluation in the register and the reasoned opinion and final reasoned opinion in the database. The result of the essentiality check under this Regulation shall be valid for all SEPs from the same patent family.

2. The competence centre shall publish in the register the percentage of sampled SEPs per SEP holder and per specific registered standard that passed successfully the essentiality test.

3. Where the publication of the results contains an error attributable to the competence centre, the competence centre shall of its own motion or at the request of the SEP holder registrant correct the error and publish the correction.

Title VI
FRAND determination

Article 34

Initiation of the FRAND determination

1. The FRAND determination in respect of a standard and implementation for which an entry in the register has been created, shall be initiated by any of the following persons:

   (a) SEP holder, prior to any initiation of a SEP infringement claim before a competent court of a Member State;

   (b) an implementer of a SEP prior to any request for the determination or assessment of FRAND terms and conditions of a SEP licence before a competent court of a Member State.

2. The party requesting the FRAND determination shall be referred to as the 'requesting party', any party responding to the request as the 'responding party', and both shall be referred to as the 'parties' for the purposes of FRAND determination.

3. The FRAND determination may be initiated by a party or entered into by the parties to resolve disputes related to FRAND terms and conditions voluntarily.

4. The obligation to initiate FRAND determination pursuant to paragraph 1 prior to the court proceedings is without prejudice to the possibility for either party to request, pending the FRAND determination, the competent court of a Member State to issue a provisional injunction of a financial nature against the alleged infringer. The provisional injunction shall exclude the seizure of property of the alleged infringer and the seizure or delivery up of the products suspected of infringing a SEP. Where national law provides that the provisional injunction of a financial nature can only be requested where a case is pending on the merits, either party may bring a case on the merits before the competent court of a Member State for that purpose. However, the parties shall request the competent court of a Member State to suspend the

proceedings on the merits for the duration of the FRAND determination. In deciding whether to grant the provisional injunction, the competent court of a Member States shall consider that a procedure for FRAND determination is ongoing.

5. Once the FRAND determination is terminated, the whole range of measures, including provisional, precautionary and corrective measures, shall be available to parties.

Article 35

Rules of procedure

The FRAND determination shall be governed by Article 34 to Article 58, as further implemented pursuant to Article 26(5).

Article 36

Content of the request to initiate a FRAND determination

1. The FRAND determination shall be initiated by a written request to the competence centre that shall contain the following information:

   (a) the name and contact information of the requesting party;

   (b) the name and address of the responding party;

   (c) the registration numbers of the relevant SEPs in the register;

   (d) the commercial name of the standard and the name of the standard developing organisation.

   (e) a summary of the licensing negotiations to date, if applicable;

   (f) references to any other FRAND determination, if applicable.

2. Where the request to initiate a FRAND determination is made by a SEP holder, in addition to the information listed in paragraph (1), it shall contain the following information:

   (a) claim charts mapping patent claims to the standard of selected registered SEPs;

   (b) proof of essentiality checks, if available.

3. The request to initiate a FRAND determination may include a proposal for a FRAND determination.

Article 37

Duration of the FRAND determination

1. Unless otherwise agreed by the parties, the period from the date of the submission of the request to continue the FRAND determination in accordance with Article 38(5)(b) or Article 38(3)(c) or Article 38(4)(a), second sentence, or Article 38(4)(c), as applicable, until the date of the termination of the procedure shall not exceed 9 months.

2. The period for the time barring of claims before a competent court of a Member State shall be suspended for the duration of the FRAND determination.

Article 38

Notification of the FRAND determination request and response

1. The competence centre shall notify the request to the responding party within 7 days and shall inform the requesting party thereof.

2. The responding party shall notify the competence centre within 15 days from the receipt of the notification of the request for FRAND determination from the competence centre in accordance with paragraph (1). The response shall indicate whether the responding party agrees to the FRAND determination and whether it commits to comply with its outcome.

3. Where the responding party does not reply within the time limit laid down in paragraph (2) or informs the competence centre of its decision not to participate in the FRAND determination, or not to commit to comply with the outcome, the following shall apply:

   (a) the competence centre shall notify the requesting party thereof and invite it to indicate within seven days whether it requests the continuation of the FRAND determination and whether it commits to comply with the outcome of the FRAND determination;

   (b) where the requesting party requests the continuation of the FRAND determination and commits to its outcome, the FRAND determination shall continue, but Article 34(1) shall not apply to the court proceedings for the requesting party in relation to the same subject matter.

   (c) where the requesting party fails to request, within the time limit referred to in subparagraph (a), the continuation of the FRAND determination, the competence centre shall terminate the FRAND determination.

4. Where the responding party agrees to the FRAND determination and commits to comply with its outcome pursuant to paragraph (2), including where such commitment is contingent upon the commitment of the requesting party to comply with the outcome of the FRAND determination, the following shall apply:

   (a) the competence centre shall notify the requesting party thereof and request to inform the competence centre within seven days whether it also commits to comply with the outcome of the FRAND determination. In case of acceptance of the commitment by the requesting party, the FRAND determination shall continue and the outcome shall be binding for both parties;

   (b) where the requesting party does not reply within the time limit referred to in subparagraph (a) or informs the competence centre of its decision not to commit to comply with outcome of the FRAND determination, the competence centre shall notify the responding party and invite it to indicate within seven days whether it requests the continuation of the FRAND determination.

   (c) where the responding party requests the continuation of the FRAND determination, the FRAND determination shall continue, but Article 34(1) shall not apply to the court proceedings for by the responding party in relation to the same subject matter;

   (d) where the responding party fails to request, within the time-limit referred to in subparagraph (b), the continuation of the FRAND determination, the competence centre shall terminate the FRAND determination.

5. Where either party commits to comply with the outcome of the FRAND determination, while the other party fails to do so within the applicable time limits, the competence centre shall adopt a notice of commitment to the FRAND determination and notify the parties within 5 days from the expiry of the time-limit to provide the commitment. The notice of commitment shall include the names of the parties, the subject-matter of the FRAND determination, a summary of the procedure and information on the commitment provided or on the failure to provide commitment for each party.

6. The FRAND determination shall concern a global SEP licence, unless otherwise specified by the parties in case both parties agree to the FRAND determination or by the party that requested the continuation of the FRAND determination. SMEs that are parties to the FRAND determination may request to limit the territorial scope of the FRAND determination.

Article 39

Selection of conciliators

1. Following the reply to the FRAND determination by the responding party in accordance with Article 38(2), or the request to continue in accordance with Article 38(5), the competence centre shall propose at least 3 candidates for the FRAND determination from the roster of conciliators referred to Article 27(2). The parties or party shall select one of the proposed candidates as a conciliator for the FRAND determination.

2. If the parties do not agree on a conciliator, the competence centre shall select one candidate from the roster of conciliators referred to in Article 27(2).

Article 40

1. The selected candidate shall communicate to the competence centre the acceptance to take up the task of a conciliator for the FRAND determination, which shall notify the communication of acceptance to the parties.

2. The day following the notification of the acceptance to the parties, the conciliator is appointed, and the competence centre shall refer the case to him/her.

Article 41

Preparation of the proceedings

If during the FRAND determination a conciliator is unable to participate, withdraws or needs to be replaced because he or she does not comply with the requirements as provided for in Article 26, the procedure provided for in Article 39 shall apply. The time period referred to in Article 37 shall be extended for the time necessary for the appointment of the new conciliator for the FRAND determination.

Article 42

Preparation of the proceedings

1. After the case is referred to the conciliator in accordance with Article 40(2), he/she shall examine whether the request contains the information required under Article 36 in accordance with the Rules of procedure.

2. He/she shall communicate to the parties or the party requesting the continuation of the FRAND determination the conduct as well as the schedule of procedure.

Article 43

Written procedure

The conciliator shall invite each party to file written submissions setting out its arguments concerning the determination of the applicable FRAND terms and conditions, including supporting documentation and evidence, and set appropriate time limits.

Article 44

Objection to the FRAND determination

1. A party may submit an objection stating that the conciliator is unable to make a FRAND determination on legal grounds, such as a previous binding FRAND determination or agreement between the parties, no later than in the first written submission. The other party shall be given opportunity to submit its observations.
2. The conciliator shall decide on the objection and either reject it as unfounded before considering the merits of the case or join it to the examination of the merits of the FRAND determination. If the conciliator overrules the objection or joins it to the examination of the merits of the determination of FRAND terms and conditions, it shall resume consideration of the determination of FRAND terms and conditions.
3. If the conciliator decides that the objection is founded, it shall terminate the FRAND determination and shall draw up a report stating the reasons of the decision.

Article 45

Conduct of the FRAND determination

1. The conciliator shall assist the parties in an independent and impartial manner in their endeavour to reach a determination of FRAND terms and conditions.
2. The conciliator may invite the parties or the party requesting the continuation of the FRAND determination to meet with him/her or may communicate with him/her orally or in writing.
3. The parties or the party requesting the continuation of the FRAND determination shall cooperate in good faith with the conciliator and, in particular, shall attend the meetings, comply with his/her requests to submit all relevant documents, information and explanations as well as use the means at their disposal to enable the conciliator to hear witnesses and experts whom the conciliator might call.
4. The responding party may join the FRAND determination at any moment before its termination.
5. At any stage of the procedure upon request by both parties, or the party requesting the continuation of the FRAND determination, as applicable, the conciliator shall terminate the FRAND determination.

Article 46

Failure of a party to engage

1. If a party:

   (a) fails to comply with any request of the conciliator, Rules of procedure or schedule of procedure referred to in Article 42(2),

   (b) withdraws its commitment to comply with the outcome of the FRAND determination as set out in Art. 38, or

   (c) in any other way fails to comply with a requirement relating to the FRAND determination,

   the conciliator shall inform both parties thereof.

2. Having received the notification of the conciliator, the complying party may ask the conciliator to take one of the following actions:

   (a) make a proposal for a FRAND determination in accordance with Article 55 based on the information available to it, attaching such weight as it considers fit to any evidence submitted to it,

   (b) terminate the procedure.

3. If the party requesting the continuation of the FRAND determination fails to comply with any request of the conciliator or in any other way fails to comply with a requirement relating to the FRAND determination, the conciliator shall terminate the procedure.

Article 47

Parallel proceedings in a third country

1. For the purposes of this article a parallel proceeding means a proceeding that satisfies the following conditions:

   (a) any procedure before a court, tribunal, an administrative or state authority of a third country taking legally binding and enforceable decisions on patent assertion, injunction, infringement, abuse of a dominant market position or a determination of FRAND terms and conditions;

   (b) concerning a licensing dispute regarding the same standard and implementation and a patent which in substance has the same claims as the SEPs that is subject to the FRAND determination;

   (c) involving one or more of the parties to the FRAND determination as a party.

2. Where a parallel proceeding has been initiated before or during the FRAND determination by a party, the conciliator, or where he/she has not been appointed, the competence centre, shall terminate the FRAND determination upon the request of any other party.

Article 48

Evidence

1. Without prejudice to the protection of confidentiality in accordance with Article 54(3) at any time during the FRAND determination, at the request of a party or on its own motion, the conciliator may request the production of documents or other evidence.

2. The conciliator may examine publicly available information and the competence centre's register and confidential and non-confidential reports of other FRAND determinations, as well as non-confidential documents and information produced by or submitted to the competence centre.

Article 49

Witnesses and experts

The conciliator may hear witnesses and experts requested by either party provided that the evidence is necessary for the FRAND determination and that there is time to consider such evidence.

Article 50

Proposal for a determination of FRAND terms and conditions

1. At any time during the FRAND determination, the conciliator or a party on its own motion or by invitation of the conciliator may submit proposals for a determination of FRAND terms and conditions
2. If the requesting party has submitted a written proposal for FRAND terms and conditions in its written submission, the responding party shall be given opportunity to comment on it and/or submit a written counter-proposal in its reply.
3. When submitting suggestions for FRAND terms and conditions, the conciliator shall take into account the impact of the determination FRAND terms and conditions on the value chain and on the incentives to innovation of both the SEP holder and the stakeholders in the relevant value chain. To that end, the conciliator may rely on the expert opinion referred to in Article 18 or, in case of absence of such an opinion request additional information and hear experts or stakeholders.

Article 51

Recommendation of a determination of FRAND terms and conditions by the conciliator

The conciliator shall notify the parties a written recommendation of a determination of FRAND terms and conditions at the latest 5 months before the time limit referred to in Article 37.

Article 52

Submission of reasoned proposals for determination of FRAND terms and conditions by the parties

Following the notification of the written recommendation of FRAND terms and conditions by the conciliator, either party shall submit a detailed and reasoned proposal for a determination of FRAND terms and conditions. If a party has already submitted a proposal for the determination of FRAND terms and conditions, revised versions shall be submitted, if necessary, taking into account the recommendation of the conciliator.

Article 53

Oral procedure

If the conciliator considers it necessary or if a party so requests, an oral hearing shall be held within 20 days after the submission of reasoned proposals for determination of FRAND terms and conditions.

Article 54

Disclosure of information

1. When the conciliator receives information for the purposes of FRAND determination from a party, it shall disclose it to the other party so that the other party has the opportunity to present any explanation.

2. A party may request the conciliator that specific information in a submitted document is kept confidential.

3. When a party requests the information in a document it had submitted to be kept confidential, the conciliator shall not disclose that information to the other party. The party invoking confidentiality shall also provide a non-confidential version of the information submitted in confidence in sufficient detail to permit a reasonable understanding of the substance of the information submitted in confidence. This non-confidential version shall be disclosed to the other party.

Article 55

Reasoned proposal for a determination of FRAND terms and conditions by the conciliator

1. At the latest 45 days before the end of the time limit referred to in Article 37, the conciliator shall submit a reasoned proposal for a determination of FRAND terms and conditions to the parties or, as applicable, the party requesting the continuation of the FRAND determination.

2. Either party may submit observations to the proposal and suggest amendments to the proposal by the conciliator, who may reformulate its proposal to take into account the observations submitted by the parties and shall inform the parties or the party requesting the continuation of the FRAND determination, as applicable, of such reformulation.

Article 56

Termination of the FRAND determination and notice of termination

1. In addition to the termination of the FRAND determination for reasons provided for Article 38(4), Article 44(3), Article 45(5), Article 46(2), point (b), Article 46(3) and Article 47(2), the FRAND determination shall be terminated in any of the following ways:

   (a) a settlement agreement is signed by the parties;

   (b) a written declaration is signed by the parties accepting the reasoned proposal for a determination of FRAND terms and conditions by the conciliator referred to in Article 55;

   (c) a written declaration is made by a party not to accept the reasoned proposal of a determination of FRAND terms and conditions by the conciliator referred to in Article 55;

(d) a party has not submitted a reply to the reasoned proposal of a determination of FRAND terms and conditions by the conciliator referred to in Article 55.

2. In case of termination of the FRAND determination, the competence centre shall adopt a notice of termination of the FRAND determination and notify the parties within 5 days from termination. The notice of termination shall include the names of the parties and the conciliator, the subject-matter of the FRAND determination, a summary of the procedure and the reasons for its termination.

3. The notice of termination notified to the SEP owner shall be considered to constitute a document within the meaning of Article 6(3) point (c) of Regulation (EU) No 608/2013 with regard to any request for a customs action against goods suspected to infringing its SEP.

4. A competent court of a Member State, asked to decide on determination of FRAND terms and conditions, including in abuse of dominance cases among private parties, or SEP infringement claim concerning a SEP in force in one or more Member States subject to the FRAND determination shall not proceed with the examination of the merits of that claim, unless it has been served with a notice of termination of the FRAND determination, or, in the cases foreseen in Article 38(3)(b) and Article 38(4)(c), with a notice of commitment pursuant to Article 38(5).

5. In the cases foreseen in Article 38(3)(b) and in Article 38(4)(c), Article 34(5) shall apply mutatis mutandis in the proceedings before a competent court of a Member State.

Article 57

Report

1. The conciliator shall provide the parties with a written report following the termination of the FRAND determination in cases listed in Article 56(1), point (c) and Article 56(1), point (d).

2. The report shall include the following:

(a) the names of the parties;

(b) a confidential assessment of the FRAND determination;

(c) confidential summary of the main issues of disagreement;

(d) a non-confidential methodology and the assessment of the determination of FRAND terms and conditions by the conciliator.

3. The confidential report shall be available only to the parties and to the competence centre. The competence centre shall publish the non-confidential report in the database.

4. Either party to the FRAND determination may file the report in any proceedings before a competent court of a Member State against the other party to the FRAND determination, notwithstanding any procedural bar.

Article 58

Confidentiality

1. Except the methodology and the assessment of the FRAND determination by the conciliator referred to in Article 57(2), point (d), the competence centre shall keep confidential the determination of FRAND terms and conditions, any proposals for determination of FRAND terms and conditions submitted during the procedure and any documentary or other evidence disclosed during the FRAND determination which is not publicly available, unless otherwise provided by the parties.

2. Notwithstanding paragraph (1), the competence centre may include information concerning the FRAND determination in any aggregate statistical data that it publishes concerning its activities, provided that such information does not allow identification the parties or the particular circumstances of the dispute to be identified.

Title VII
Procedural rules

Article 59

Communications to and notifications from the competence centre

1. The communication to and notifications from the competence centre shall be conducted in principle by electronic means.

2. The Executive Director of the EUIPO shall determine to what extent and under which technical conditions communications and notifications referred to in paragraph (1) are to be submitted electronically.

Article 60

Time limits

1. Time limits shall be laid down in terms of full years, months, weeks or days. Calculation shall start on the day following the day on which the relevant event occurred.

2. The Executive Director of the EUIPO shall determine, before the commencement of each calendar year, the days on which the EUIPO is not open for receipt of documents or on which ordinary post is not delivered in the locality in which the EUIPO is located.

3. The Executive Director of the EUIPO shall determine the duration of the period of interruption in the case of a general interruption in the delivery of post in the Member State where the EUIPO is located or, in the case of an actual interruption of the EUIPO's connection to admitted electronic means of communication.

4. In cases of exceptional occurrences making the communication between the parties to the proceedings and the competence centre very cumbersome, the Executive Director of the EUIPO may extend all time limits that would otherwise expire on or after the date of commencement of such an occurrence, as determined by the Executive Director in relation to the following subjects:

   (a) parties to the proceedings having their residence or registered office in the region concerned;

   (b) representatives or assistants with a place of business in the region concerned, appointed by the parties.

5. When determining the length of extension referred to in the second subparagraph, the Executive Director of the EUIPO shall take into account the end date of the exceptional occurrence. If the occurrence referred to in the second subparagraph affects the seat of the EUIPO, the determination of the Executive Director of the EUIPO shall specify that it applies in respect of all parties to the proceedings.

Title VIII
Micro, Small and Medium-size Enterprises

Article 61

Training, advice and support

1. The competence centre shall offer training and support on SEP related matters for micro, small and medium-size enterprises free of charge.

2. The competence centre may commission studies, if it considers it necessary, to assist micro, small and medium-size enterprises on SEP related matters.

3. The costs of the services referred to in paragraph (1) and paragraph (2) shall be borne by the EUIPO.

Article 62

FRAND terms for micro, small and medium-sized enterprises

1. When negotiating a SEP licence with micro, small and medium-sized enterprises, SEP holders shall consider offering to them FRAND terms and conditions that are more favourable than the FRAND terms and conditions they offer to enterprises that are not micro, small and medium-sized for the same standard and implementations.

2. If a SEP holder offers more favourable FRAND terms and conditions to micro, small and medium-sized enterprises, or concludes a SEP licence that includes more favourable terms and conditions, pursuant to paragraph (1), such FRAND terms and conditions shall not be considered in a FRAND determination, unless the FRAND determination is conducted solely with regard to FRAND terms and conditions for another micro, small or medium-sized enterprise.

3. SEP holders shall also consider discounts or royalty-free licensing for low sales volumes irrespective of the size of the implementer taking the licence. Such discounts or royalty-free licensing shall be fair, reasonable and non-discriminatory and shall be available in the electronic database as set out in Article 5(2), point (b).

Title IX
Fees and Charges

Article 63

Fees and charges

1. The competence centre may charge administrative fees for the services it renders under this Regulation.

2. Fees may be charged at least in respect of the following matters:

(a) for the conciliators facilitating agreements on aggregate royalty determinations in accordance with Article 17;

(b) for the expert opinion on aggregate royalty in accordance with Article 18;

(c) for the essentiality check carried out by the evaluator in accordance with Article 31 and by the peer evaluator in accordance with Article 32;

(d) for the conciliators for the FRAND determination in accordance with Title VI.

3. Where the competence centre charges fees in accordance with paragraph 2, the fees shall be borne as follows:

(a) the fees referred to in paragraph (2), point (a) by the SEP holders that participated in the process based on their estimated percentage of SEPs from all SEPs for the standard;

(b) the fees referred to in paragraph (2), point (b) equally by the parties that participated in the procedure of the expert opinion on aggregate royalty, unless they agree otherwise, or the panel suggests a different apportionment based on the size of the parties determined on the basis of their turnover;

(c) the fees referred to in paragraph (2), point (c) by the SEP holder that requested an essentiality check pursuant to Article 29(5) or peer evaluation pursuant to Article 32(1) and the implementer that requested an essentiality check pursuant to Article 29(6);

(d) the fees referred to in paragraph (2), point (d) equally by the parties, unless they agree otherwise, or the conciliator suggests a different apportionment based on the level of participation of the parties in the FRAND determination.

4. The level of the fees shall be reasonable and shall correspond to the costs of the services. It shall take into account the situation of micro, small and medium-sized enterprises.

5. By [OJ: please insert the date = 18 months from entry into force of this Regulation], the Commission shall adopt an implementing act determining the amounts of the fees referred to in Article 63, the arrangement concerning the payment methods related to the rules set out in paragraph (3) and paragraph (4) of this Article. The implementing act shall be adopted in accordance with the examination procedure referred to in Article 68(2).

Article 64

Payment of fees

1. Fees shall be paid to the EUIPO. All payments shall be made in euro. The Executive Director of the EUIPO may establish which specific payment methods may be used.

2. If the amounts requested are not paid in full within 10 days after the date of the request, the competence centre may notify the defaulting party and give it the opportunity to make the required payment within [5] days. It shall submit a copy of the request to the other party, in case of an aggregate royalty or FRAND determination.

3. The date on which the payment shall be considered to have been made to the EUIPO shall be the date on which the amount of the payment or of the transfer is actually entered in a bank account held by EUIPO.

4. If any part of the required payment remains outstanding after the deadline in paragraph (2), the competence centre may suspend access to the database of the defaulting party, until payment is made.

Article 65

Financial provisions

1. The expenses incurred by the EUIPO or the evaluators or conciliators selected by the EUIPO pursuant to Articles 26 and 27 in carrying out the tasks conferred to it in accordance with this Regulation shall be covered by the administrative fees to be paid to the EUIPO by the users of the services of the competence centre.

2. Regarding costs incurred by the EUIPO for activities entrusted to it by this Regulation which are not covered by the fees under this Regulation, the EUIPO shall finance those activities from its own budgetary means.

Title X
Final Provisions

Article 66

Opening registration for an existing standard

1. Until [OJ: please insert the date = 28 months from the entry into force of this regulation] holders of SEPs essential to a standard published before the entry into force of this Regulation ('existing standards'), for which FRAND commitments have been made, may notify the competence centre pursuant to Articles 14, 15 and 17 of any of the existing standards or parts thereof that will be determined in the delegated act in accordance with paragraph (4). The procedures, notification and publication requirements set out in this Regulation apply *mutatis mutandis*.

2. Until [OJ: please insert the date = 28 months from entry into force of this regulation] implementers of a standard, standard published before the entry into force of this Regulation, for which FRAND commitments have been made may notify pursuant to Article 14(4) the competence centre of any of the existing standards or parts thereof, that will be determined in the delegated act in accordance with paragraph (4). The procedures, notification and publication requirements set out in this Regulation apply *mutatis mutandis*.

3. Until [OJ: please insert the date = 30 months from entry into force of this regulation] a SEP holder or an implementer may request an expert opinion pursuant to Article 18 regarding SEPs essential to an existing standard or parts thereof, that will be determined in the delegated act in accordance with paragraph (4). The requirements and procedures set out in Article 18 apply *mutatis mutandis.*

4. Where the functioning of the internal market is severely distorted due to inefficiencies in the licensing of SEPs, the Commission shall, after an appropriate consultation process, by means of a delegated act pursuant to Article 67, determine which of the existing standards, parts thereof or relevant use cases can be notified in accordance with paragraph (1) or paragraph (2), or for which an expert opinion can be requested in accordance with paragraph (3). The delegated act shall also determine which procedures, notification and publication requirements set out in this Regulation apply to those existing standards. The delegated act shall be adopted

within [OJ: please insert the date = 18 months from entry into force of this regulation].

5. This article shall apply without prejudice to any acts concluded and rights acquired by [OJ: please insert the date = 28 months from entry into force of this regulation].

Article 67

Exercise of delegation of power

1. The power to adopt the delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt a delegated act referred to in Articles 1(4), 4(5) and 66(4) shall be conferred on the Commission for an indeterminate period of time from the date of entry into force of this Regulation.

3. The delegation of power referred to in Articles 1(4), 4(5) and 66(4) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Articles 1(4), 4(5) and 66(4) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of 2 months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 2 months at the initiative of the European Parliament or of the Council.

Article 68

Committee procedure

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Article 69

Commission guidance

The Commission may issue guidance under this Regulation on matters covered by its scope, excluding matters related to the interpretation of Article 101 and Article 102 TFEU.

Article 70

Evaluation

1. By [OJ: please insert the date = 5 years from entry into force of this regulation] the Commission shall evaluate the effectiveness and efficiency of the SEP registration and the essentiality check system.

2. By [OJ: please insert the date = 8 years from entry into force of this regulation], and every five years thereafter, the Commission shall evaluate the implementation of this Regulation. The evaluation shall assess the operation of this Regulation, in particular the impact, effectiveness and efficiency of the competence centre and its working methods.

3. When preparing the evaluation reports referred to in paragraphs (1) and (2), the Commission shall consult the EUIPO and stakeholders.

4. The Commission shall submit the evaluation reports referred to in paragraphs (1) and (2) together with its conclusions drawn based on those reports to the European Parliament, to the Council, to the European Economic and Social Committee and to the Management Board of the EUIPO.

Article 71

Amendments to Regulation (EU) 2017/1001

Regulation (EU) 2017/1001 is amended as follows:

1. Article 151(1) is amended as follows:

   (a) the following point is inserted:

   ‘(ba) administration, promotion and support of the tasks conferred on it, performed by a competence centre, under Regulation (EU) No … of the European Parliament and of the Council+* ;

   * Regulation (EU) .../... of the European Parliament and of the Council of ... on standard essential patents (OJ ...).’;

   (b) paragraph 3 is replaced by the following:

   ‘3. The Office may provide alternative dispute resolution services, including mediation, conciliation, arbitration, determination of royalties and FRAND determination.’;

2. in Article 157(4), the following point is added:

   ’(p) exercising the powers conferred on him or her under Regulation (EU) …++.’;

3. Article 170 is amended as follows:

   (a) the title is replaced by the following:

   ‘Alternative Dispute Resolution Centre’;

   (b) paragraphs 1 and 2 are replaced by the following

   ‘1. For the purposes of Article 151(3), the Office may establish an Alternative Dispute Resolution Centre (‘the Centre’).

   2. Any natural or legal person may use the services of the Centre for settling disputes relating to intellectual property rights’;

(c) paragraph 15 is replaced by the following:

‘15. The Office may cooperate with other recognised national or international bodies providing alternative dispute resolution services.’;

(d) the following paragraph is added:

‘16. Articles 18, 19 and Articles 34 to 58 of Regulation …++ shall apply to the Centre in all proceedings relating to standard essential patents.’.

[+ OJ: Please insert in the text the number of this Regulation and insert the number, date and OJ reference of this Regulation in the footnote.]

[++ OJ: Please insert in the text the number of this Regulation.]

Article 72

Entry into force and application

1. This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

2. It shall apply from … [OP: please insert the date = 24 months after the date of entry into force of this Regulation].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

LEGISLATIVE FINANCIAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

1.2. Policy area(s) concerned

1.3. The proposal/initiative relates to:

1.4. Objective(s)

1.4.1. General objective(s)

1.4.2. Specific objective(s)

1.4.3. Expected result(s) and impact

1.4.4. Indicators of performance

1.5. Grounds for the proposal/initiative

1.5.1. Requirement(s) to be met in the short or long term including a detailed timeline for roll-out of the implementation of the initiative

1.5.2. Added value of Union involvement (it may result from different factors, e.g. coordination gains, legal certainty, greater effectiveness or complementarities). For the purposes of this point 'added value of Union involvement' is the value resulting from Union intervention, which is additional to the value that would have been otherwise created by Member States alone.

1.5.3. Lessons learned from similar experiences in the past

1.5.4. Compatibility with the Multiannual Financial Framework and possible synergies with other appropriate instruments

1.5.5. Assessment of the different available financing options, including scope for redeployment

1.6. Duration and financial impact of the proposal/initiative

1.7. Method(s) of budget implementation planned

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

2.2. Management and control system(s)

2.2.1. Justification of the management mode(s), the funding implementation mechanism(s), the payment modalities and the control strategy proposed

2.2.2. Information concerning the risks identified and the internal control system(s) set up to mitigate them

2.2.3. Estimation and justification of the cost-effectiveness of the controls (ratio of "control costs ÷ value of the related funds managed"), and assessment of the expected levels of risk of error (at payment & at closure)

2.3. Measures to prevent fraud and irregularities

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

Regulation of the European Parliament and of the Council on Standard Essential Patents and amending Regulation (EU) 2017/1001

1.2. Policy area(s) concerned

Internal market

1.3. The proposal/initiative relates to:

☒ **a new action**

☐ **a new action following a pilot project/preparatory action**[49]

☐ **the extension of an existing action**

☐ **a merger or redirection of one or more actions towards another/a new action**

1.4. Objective(s)

1.4.1. General objective(s)

This initiative aims at: (i) ensuring that end users, including small businesses and EU consumers benefit from products based on the latest standardised technologies at reasonable prices; (ii) making the EU an attractive place for innovation and standards development (including for global participants); and (iii) ensuring that both EU SEP holders and implementers innovate in the EU, make and sell products in the EU and are competitive on global markets.

1.4.2. Specific objective(s)

Specific objective No

• Provide more clarity on who owns SEP and which SEPs are truly essential.

• Provide clarity on FRAND royalty and other terms and conditions

• Facilitate SEP dispute resolution.

1.4.3. Expected result(s) and impact

Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.

Increase transparency of SEP licensing, lowering transaction cost and facilitating SEP dispute resolution for both SEP holders and implementers.

1.4.4. Indicators of performance

Specify the indicators for monitoring progress and achievements.

Success indicators are defined in the impact assessment chapter 9Specify the indicators for monitoring progress and achievements.Each indicator should be accompanied by targets and baseline.

Table 1: Monitoring indicators

Research question	Indicators
Specific Objective 1. Provide information on SEPs ownership and essentiality	

[49] As referred to in Article 58(2)(a) or (b) of the Financial Regulation.

Has access to information on SEPs improved?	- Number of standards with SEPs registered in the database - Number of SEP holders registered - Number of essentiality checks conducted (overall, per SEP holder, per standard) - Is database up to date (when SEP is registered, is information updated) - Number of times database is used (access rate) and how it is used (e.g. new private services built on these data) - Perception of quality of register and essentiality checks - Results of peer evaluations (number of confirmed essentiality checks) - Cost/quality of the central system in comparison to available private solutions
Specific Objective 2. Provide clarity on FRAND royalty	
Has information on FRAND price, terms and conditions improved?	- Number of studies done by Competence Centre - Number of SMEs receiving assistance - Perception of quality of studies, assistance - Number of standards, and their applications - Number of aggregate royalties announced, or expert opinions provided - Perception of the aggregate royalty rate setting process/and rate itself by implementers and holders; use in court cases/judgements - Frequency of changes of the aggregate royalty - Cost/quality of the Competence Centre services in comparison to available private solutions
Specific Objective 3. Facilitate dispute resolution	
How the new systems changed dispute resolution	- Usage of conciliation (number of cases per year, duration, quality assessment by courts, usage in court proceedings and in judgments; usage in support of applications for customs' action) - Change in SEP litigation cost/duration due to conciliation - Usefulness of guidelines (perception by stakeholders, usage in court cases,)
Sources of information: Competence Centre database; Feedback/Surveys of new system (Competence Centre/register/conciliation/guidelines) users such as e.g. SEP holders and implementers, judges, essentiality checkers; Court cases/judgements/injunctions analysis; dedicated evaluation studies; public consultations; desk research	
General objectives	
Impact on SEP holders	- Number of SEP holders based in the EU - Number of SEPs registered by SEP holders based in the EU - Length of licence negotiations, number of licensors - Contribution of EU firms in standard development activities - Localisation of production/R&D of such products/services (EU/third countries)
Impact on SEP implementers	- Cost of SEP licence for EU firms, effort of obtaining a license - Percentage of SEPs covered through licensing. - Competitiveness of EU firms making SEP implementing products/services in the EU and third countries. - Localisation of production/R&D of such products/services (EU/third countries) - Contribution of EU firms in standard development activities
Impact on EU customers	- Time of introduction of new products/services using latest standards in the EU in comparison to other countries, price of such products
Sources of information: Surveys, official statistics (e.g. Eurostat's "Enterprises using IoT", isoc_eb_iot), dedicated evaluation studies; public consultations; desk research.	

1.5. Grounds for the proposal/initiative

1.5.1. Requirement(s) to be met in the short or long term including a detailed timeline for roll-out of the implementation of the initiative

Creation of the Competence Centre within the European Union Intellectual Property Office (EUIPO), including setting up of a SEP register, necessary IT tools as well as preparatory activities for the remaining components of the initiative (e.g. definition of all processes, preparation of all the procedures, setting up quality controls, compiling a list of SEP examiners, creating a roster of conciliators, training of SEP examiners and conciliators, gathering information SEP related policies and case law summaries, setting up SME assistance hub, preparation of training materials, etc.) is

expected to take up to two years. The system is expected to be fully operational afterwards.

1.5.2. Added value of Union involvement (it may result from different factors, e.g. coordination gains, legal certainty, greater effectiveness or complementarities). For the purposes of this point 'added value of Union involvement' is the value resulting from Union intervention, which is additional to the value that would have been otherwise created by Member States alone.

Action at EU level is expected to save costs for stakeholders, both SEP holders and implementers, and for Member States. For instance, there would be one register, one essentiality check per patent family, one common methodology for the conduct of such checks, and a streamlined and transparent conciliation (FRAND determination) process. SEP holders and implementers would not have to incur the same costs in each EU Member State which would be the case with national solutions, especially in a situation where most standards are regional or global.

1.5.3. Lessons learned from similar experiences in the past

EUIPO will build on its experience with managing registers for other IP titles, as well as its experience with assistance to SMEs and alternative dispute resolution services.

1.5.4. Compatibility with the Multiannual Financial Framework and possible synergies with other appropriate instruments

N/A

1.5.5. Assessment of the different available financing options, including scope for redeployment

This initiative will be fully self-financed by the EUIPO (through fees).

1.6. Duration and financial impact of the proposal/initiative

☐ **limited duration**

– ☐ in effect from [DD/MM]YYYY to [DD/MM]YYYY

– ☐ Financial impact from YYYY to YYYY for commitment appropriations and from YYYY to YYYY for payment appropriations.

☒ **unlimited duration**

– Implementation period expected to take up to two years, followed by full-scale operation.

1.7. Method(s) of budget implementation planned[50]

☐ **Direct management** by the Commission

– ☐ by its departments, including by its staff in the Union delegations;

– ☐ by the executive agencies

☐ **Shared management** with the Member States

☒ **Indirect management** by entrusting budget implementation tasks to:

– ☐ third countries or the bodies they have designated;

– ☐ international organisations and their agencies (to be specified);

– ☐ the EIB and the European Investment Fund;

– ☒ bodies referred to in Articles 70 and 71 of the Financial Regulation;

– ☐ public law bodies;

– ☐ bodies governed by private law with a public service mission to the extent that they are provided with adequate financial guarantees;

– ☐ bodies governed by the private law of a Member State that are entrusted with the implementation of a public-private partnership and that are provided with adequate financial guarantees;

– ☐ bodies or persons entrusted with the implementation of specific actions in the CFSP pursuant to Title V of the TEU, and identified in the relevant basic act.

– *If more than one management mode is indicated, please provide details in the 'Comments' section.*

Comments

No EU budget involved, fully financed by the EUIPO from fees.

[50] Details of budget implementation methods and references to the Financial Regulation may be found on the BUDGpedia site: https://myintracomm.ec.europa.eu/corp/budget/financial-rules/budget-implementation/Pages/implementation-methods.aspx

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

Specify frequency and conditions.

Rules of EUIPO will apply. The regulation will be evaluated every five years in accordance with Art 71 of the draft regulation.

2.2. Management and control system(s)

2.2.1. Justification of the management mode(s), the funding implementation mechanism(s), the payment modalities and the control strategy proposed

Rules of EUIPO will apply.

2.2.2. Information concerning the risks identified and the internal control system(s) set up to mitigate them

Rules of EUIPO will apply.

2.2.3. Estimation and justification of the cost-effectiveness of the controls (ratio of "control costs ÷ value of the related funds managed"), and assessment of the expected levels of risk of error (at payment & at closure)

Rules of EUIPO will apply.

2.3. Measures to prevent fraud and irregularities

Specify existing or envisaged prevention and protection measures, e.g. from the Anti-Fraud Strategy.

Rules of EUIPO will apply.

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

- Existing budget lines N/A

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number	Diff./Non-diff.[51]	from EFTA countries [52]	from candidate countries and potential candidates [53]	fromother third countries	other assigned revenue
	N/A	Diff./Non-diff.	YES/NO	YES/NO	YES/NO	YES/NO

- New budget lines requested N/A

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number	Diff./Non-diff.	from EFTA countries	from candidate countries and potential candidates	from other third countries	other assigned revenue
	N/A		YES/NO	YES/NO	YES/NO	YES/NO

[51] Diff. = Differentiated appropriations / Non-diff. = Non-differentiated appropriations.

[52] EFTA: European Free Trade Association.

[53] Candidate countries and, where applicable, potential candidates from the Western Balkans.

3.2. Estimated financial impact of the proposal on appropriations

3.2.1. Summary of estimated impact on operational appropriations

– ☒ The proposal/initiative does not require the use of operational appropriations

– ☐ The proposal/initiative requires the use of operational appropriations, as explained below:

EUR million (to three decimal places)

Heading of multiannual financial framework	Number	

DG: <…….>			Year **N**[54]	Year **N+1**	Year **N+2**	Year **N+3**	Enter as many years as necessary to show the duration of the impact (see point 1.6)			**TOTAL**
• Operational appropriations										
Budget line[55]	Commitments	(1a)								
	Payments	(2a)								
Budget line	Commitments	(1b)								
	Payments	(2b)								
Appropriations of an administrative nature financed from the envelope of specific programmes[56]										
Budget line		(3)								
TOTAL appropriations for DG <…….>	Commitments	=1a+1b +3								
	Payments	=2a+2b +3								

54 Year N is the year in which implementation of the proposal/initiative starts. Please replace "N" by the expected first year of implementation (for instance: 2021). The same for the following years.

55 According to the official budget nomenclature.

56 Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

• TOTAL operational appropriations	Commitments	(4)									
	Payments	(5)									
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)									
TOTAL appropriations under HEADING <….> of the multiannual financial framework	Commitments	=4+ 6									
	Payments	=5+ 6									

If more than one operational heading is affected by the proposal / initiative, repeat the section above:

• TOTAL operational appropriations (all operational headings)	Commitments	(4)									
	Payments	(5)									
TOTAL appropriations of an administrative nature financed from the envelope for specific programmes (all operational headings)		(6)									
TOTAL appropriations under HEADINGS 1 to 6 of the multiannual financial framework (Reference amount)	Commitments	=4+ 6									
	Payments	=5+ 6									

Heading of multiannual financial framework	**7**	‘Administrative expenditure’

This section should be filled in using the 'budget data of an administrative nature' to be firstly introduced in the Annex to the Legislative Financial Statement (Annex 5 to the Commission decision on the internal rules for the implementation of the Commission section of the general budget of the European Union), which is uploaded to DECIDE for interservice consultation purposes.

EUR million (to three decimal places)

	Year **N**	Year **N+1**	Year **N+2**	Year **N+3**	Enter as many years as necessary to show the duration of the impact (see point 1.6)	**TOTAL**

DG: <…….>									
• Human resources									
• Other administrative expenditure									
TOTAL DG <…….>	Appropriations								

TOTAL appropriations under HEADING 7 of the multiannual financial framework	(Total commitments = Total payments)								

EUR million (to three decimal places)

		Year **N**[57]	Year **N+1**	Year **N+2**	Year **N+3**	Enter as many years as necessary to show the duration of the impact (see point 1.6)			**TOTAL**
TOTAL appropriations under HEADINGS 1 to 7 of the multiannual financial framework	Commitments								
	Payments								

3.2.2. Estimated output funded with operational appropriations

Commitment appropriations in EUR million (to three decimal places)

Indicate objectives and outputs			Year **N**	Year **N+1**	Year **N+2**	Year **N+3**	Enter as many years as necessary to show the duration of the impact (see point 1.6)	**TOTAL**
	OUTPUTS							

[57] Year N is the year in which implementation of the proposal/initiative starts. Please replace "N" by the expected first year of implementation (for instance: 2021). The same for the following years.

⇩	Type[58]	Average cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	Total No	Total cost
SPECIFIC OBJECTIVE No 1[59]…																				
- Output																				
- Output																				
- Output																				
Subtotal for specific objective No 1																				
SPECIFIC OBJECTIVE No 2 ...																				
- Output																				
Subtotal for specific objective No 2																				
TOTALS																				

[58] Outputs are products and services to be supplied (e.g.: number of student exchanges financed, number of km of roads built, etc.).

[59] As described in point 1.4.2. 'Specific objective(s)…'

3.2.3. Summary of estimated impact on administrative appropriations

– ☒ The proposal/initiative does not require the use of appropriations of an administrative nature

– ☐ The proposal/initiative requires the use of appropriations of an administrative nature, as explained below:

EUR million (to three decimal places)

	Year N [60]	Year N+1	Year N+2	Year N+3	Enter as many years as necessary to show the duration of the impact (see point 1.6)			TOTAL
HEADING 7 of the multiannual financial framework								
Human resources								
Other administrative expenditure								
Subtotal HEADING 7 of the multiannual financial framework								
Outside HEADING 7[61] of the multiannual financial framework								
Human resources								
Other expenditure of an administrative nature								
Subtotal outside HEADING 7 of the multiannual financial framework								
TOTAL								

The appropriations required for human resources and other expenditure of an administrative nature will be met by appropriations from the DG that are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

60 Year N is the year in which implementation of the proposal/initiative starts. Please replace "N" by the expected first year of implementation (for instance: 2021). The same for the following years.

61 Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

3.2.3.1. Estimated requirements of human resources

– ☐ The proposal/initiative does not require the use of human resources.

– ☒ The proposal/initiative requires the use of human resources, as explained below:

The table below presents an indicative number of FTEs that the EUIPO may need to use in order to implement the proposal.

	2024* (implementation period)	2025 (implementation period)	2026 (operational period)	2027 and subsequent (operational period)
EUIPO AD/AST staff	6	6	6	6
EUIPO contractual staff	6	6	24	4
total	12	12	30	10

*real date will depend on the adoption of the proposal by co-legislators

The high number of FTEs in the year three (first year of the system's operation) is due to the expected registration of up to 72 000 patent families, while in the subsequent years the number of the registrations is expected to drop to around 10% of the initial registrations. The actual take-up of the new system is, however, uncertain – these are our estimations based on the impact assessment. It should be noted that the staff resources in the table above also include four FTEs in each year for operational activities, such as the operation of the Competence Centre, which will have the role of a back-office for FRAND determination processes (conciliations) and aggregate royalty processes.

Additionally, during the operational period EUIPO will outsource services such as essentiality checks and conciliations to external experts. We estimate that in the year three, around 82 FTEs of experts in the essentiality assessment will be necessary, going down to around eight FTEs of experts from the year four onwards. We also estimate that service of around two FTEs of conciliators will be required annually.

The table below presents an indicative cost of FTEs that EUIPO may need to use in order to implement the proposal.

EUR million (to three decimal places) in constant prices

	2024* (implementation period)	2025 (implementation period)	2026 (operational period)	2027 and subsequent (operational period)
EUIPO AD/AST staff	0.790		0.790	0.790
EUIPO contractual staff	0.810		3.120	0.520
Total	1.590		3.900	1.310

*real date will depend on the adoption of the proposal by co-legislators

Additionally, one-off IT expenditures are estimated at EUR 0.815 million, and annual IT maintenance expenditures at EUR 0.163 million.

An estimate for the remuneration of the outsourced experts is presented below.

EUR million (to three decimal places) in constant prices

	2024*-2025 (implementation period)	2026 (operational period)	2027 and subsequent (operational period)

External experts		74.025	9.067

Detailed calculations and forecasts are presented in the impact assessment, annex A7.1.

Estimate to be expressed in full time equivalent units

		Year **N**	Year **N+1**	Year **N+2**	Year **N+3**	Enter as many years as necessary to show the duration of the impact (see point 1.6)		
• Establishment plan posts (officials and temporary staff)								
20 01 02 01 (Headquarters and Commission's Representation Offices)								
20 01 02 03 (Delegations)								
01 01 01 01 (Indirect research)								
01 01 01 11 (Direct research)								
Other budget lines (specify)								
• External staff (in Full Time Equivalent unit: FTE)[62]								
20 02 01 (AC, END, INT from the 'global envelope')								
20 02 03 (AC, AL, END, INT and JPD in the delegations)								
XX 01 xx **yy zz** [63]	- at Headquarters							
	- in Delegations							
01 01 01 02 (AC, END, INT - Indirect research)								
01 01 01 12 (AC, END, INT - Direct research)								
Other budget lines (specify)								
TOTAL								

XX is the policy area or budget title concerned.

The human resources required will be met by staff from the DG who are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

Description of tasks to be carried out:

Officials and temporary staff	
External staff	

62 AC= Contract Staff; AL = Local Staff; END= Seconded National Expert; INT = agency staff; JPD= Junior Professionals in Delegations.

63 Sub-ceiling for external staff covered by operational appropriations (former 'BA' lines).

3.2.4. Compatibility with the current multiannual financial framework

N/A, the proposal is managed by EUIPO and finance by fees

The proposal/initiative:

– ☐ can be fully financed through redeployment within the relevant heading of the Multiannual Financial Framework (MFF).

Explain what reprogramming is required, specifying the budget lines concerned and the corresponding amounts. Please provide an excel table in the case of major reprogramming.

– ☐ requires use of the unallocated margin under the relevant heading of the MFF and/or use of the special instruments as defined in the MFF Regulation.

Explain what is required, specifying the headings and budget lines concerned, the corresponding amounts, and the instruments proposed to be used.

– ☐ requires a revision of the MFF.

Explain what is required, specifying the headings and budget lines concerned and the corresponding amounts.

3.2.5. Third-party contributions

The proposal/initiative:

– ☐ does not provide for co-financing by third parties

– ☒ provides for the co-financing by third parties estimated below:

EUIPO will collect fees in order to cover all its costs as well as the remuneration of the external experts. The table below presents the estimated value of fees collected by the EUIPO.[64]

EUR million (to three decimal places) in constant prices

	2024*-2025 (implementation period)	2026 (operation period)	2027 and subsequent (operation period)
		78.329	10.782

3.3. Estimated impact on revenue

– ☒ The proposal/initiative has no financial impact on revenue.

– ☐ The proposal/initiative has the following financial impact:

  – ☐ on own resources

  – ☐ on other revenue

  – please indicate, if the revenue is assigned to expenditure lines ☐

[64] Fees also cover the IT maintenance cost and a share of one-off costs (expected to be recovered during ten years).

Council of the European Union

Brussels, 2 May 2023
(OR. en)

8901/23
ADD 1

Interinstitutional File:
2023/0129(COD)

PI 58
PHARM 69
COMPET 387
MI 355
IND 209
IA 91
CODEC 751

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	27 April 2023
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2023) 224 final
Subject:	ANNEX to the proposal for a Regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) 816/2006

Delegations will find attached document COM(2023) 224 final.

Encl.: COM(2023) 224 final

EUROPEAN
COMMISSION

Brussels, 27.4.2023
COM(2023) 224 final

ANNEX

ANNEX

to the

proposal for a Regulation of the European Parliament and of the Council

on compulsory licensing for crisis management and amending Regulation (EC) 816/2006

{SEC(2023) 173 final} - {SWD(2023) 120 final} - {SWD(2023) 121 final} -
{SWD(2023) 122 final}

ANNEX - Crisis or emergency modes referred to in Article 4 and competent advisory bodies as referred to in Article 6(2) are listed below:

Union crisis or emergency mechanism	Crisis mode or emergency mode	Competent Advisory Body
1. Regulation XXX/XX of the European Parliament and of the Council establishing a Single Market Emergency Instrument and repealing Council Regulation (EC) 2679/98 [COM(2022) 459]	**Single Market emergency mode** activated by means of a Council implementing act [Article 14 of Regulation XXX/XX] [COM(2022) 459]	**Advisory Group** [Article 4 of Regulation XXX/XX] [COM(2022) 459]
2. Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU	**Public health emergency at Union level** formally recognized by means of a Commission implementing act [Article 23 of Regulation (EU) 2022/2371]	**Health Security Committee** [Article 4 of Regulation (EU) 2022/2371]
3. Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at	**Emergency framework** activated by the adoption of a Council Regulation [Article 3 of Regulation (EU) 2022/2372]	**The Health Crisis Board** [Article 5 of Regulation (EU) 2022/2372]

Union level		
4. Regulation XXX/XX establishing a framework of measures for strengthening Europe's semiconductor ecosystem [COM(2022) 46]	**Crisis stage** activated by a Commission implementing act [Article 18 of Regulation XXX/XXX] [COM(2022) 46]	**European Semiconductor Board** [Article 23 of Regulation XXX/XXX] [COM(2022) 46]
5. Regulation (EU) 2017/1938 of the European Parliament and of the Council of 25 October 2017 concerning measures to safeguard the security of gas supply and repealing Regulation (EU) No 994/2010	**Union emergency** declared by the Commission [Article 12 of Regulation (EU) 2017/1938]	**Gas Coordination Group** [Article 4 of Regulation (EU) 2017/1938]

Council of the European Union

Brussels, 2 May 2023
(OR. en)

8901/23

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Delegations will find attached document COM(2023) 224 final.

Encl.: COM(2023) 224 final

EUROPEAN
COMMISSION

Brussels, 27.4.2023
COM(2023) 224 final

2023/0129 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on compulsory licensing for crisis management and amending Regulation (EC) 816/2006

(Text with EEA relevance)

{SEC(2023) 173 final} - {SWD(2023) 120 final} - {SWD(2023) 121 final} -
{SWD(2023) 122 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

Intangible assets such as inventions, trade secrets and know-how are the cornerstone of the EU economy and competitiveness. Patent rights, in particular, play a key role in supporting EU innovation and creating the right environment for investment. For European innovation to flourish, a solid, predictable, and flexible legal framework for intellectual property rights, including patents, needs to be created. The Unitary Patent system helps further improve and harmonise the EU legal framework on patents. Beyond this, the Commission action plan on intellectual property rights has identified several areas of patent law that need to be further improved and harmonised. One of these areas is compulsory licensing. The COVID-19 crisis highlighted that an appropriate balance between patent rights and other rights and interests is a staple of the patent system. During the COVID-19 crisis, the conflicting interests were access to health products and preserving innovation incentives that are key to developing new health products, such as vaccines and therapeutics. The pandemic added another element to the discussion: the role intellectual property rights could and should play in a crisis. In other words, the question became: how we can preserve the balance and incentives for innovation while ensuring swift access to critical products and technologies in crises, even in the absence of voluntary agreements. Patent law already provides a solution: compulsory licensing.

A compulsory licence is the possibility for a government to allow a third party to use a patent without the authorisation of the rights-holder, subject to certain conditions. Compulsory licensing can therefore complement current EU efforts to improve its resilience to crises. In the aftermath of the COVID-19 crisis, the EU has tabled several EU crises instruments, such as the Proposal for a Regulation establishing a Single Market Emergency Instrument (SMEI) or Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level. These instruments provide the EU with a means of ensuring access to products needed to tackle a crisis in the Internal Market. The instruments focus on voluntary approaches. As evidenced by the COVID-19 crisis, voluntary agreements remain the most efficient tool to enable rapid manufacturing of patent-protected products, including in crises. However, there may be cases where such voluntary agreements are not available or appropriate. In such circumstances, compulsory licensing can provide a solution to allow the rapid manufacturing of products needed to tackle a crisis. However, to guarantee that such products can freely circulate within the Internal Market and reach all those in need, the compulsory licensing shall be granted at EU level.

Compulsory licensing has a dual role, as it can incentivise the conclusion of voluntary agreements and also enable the manufacturing of products needed to tackle a crisis in the absence of (appropriate) voluntary agreements. However, for compulsory licensing to fulfil this role, an efficient compulsory licensing scheme needs to be built in the EU, able to rely on the Single Market, complementing EU crisis instruments and in line with the EU's international obligations.

The Agreement on Trade-Related Aspects of Intellectual Property Rights ('TRIPS Agreement') sets the international legal framework on compulsory licensing. Article 31 of the TRIPS Agreement provides the framework for compulsory licensing in relation to the domestic market, while Article 31bis of the TRIPS Agreement provides the rules for

compulsory licensing for the manufacturing and export of pharmaceutical products to countries with public health problems.

There is currently no EU-wide harmonisation of compulsory licensing for the domestic market, including as regards European patents with a unitary effect. Instead, there is a patchwork of different national rules and procedures on compulsory licensing. National rules have insufficient territorial reach, since products manufactured under a compulsory licence in one Member State either cannot be supplied to another Member State, or can only be supplied in limited quantities. National procedures are also different from each other, and decision-making is not coordinated at EU level. This limits the ability to rely on the Internal Market to guarantee supplies across all the Union territory.

Against this background, this initiative aims to provide the Internal Market with an efficient compulsory licensing scheme for crisis management. The initiative has therefore two main objectives. First, it aims to enable the EU to rely on compulsory licensing in the context of the EU crisis instruments. Second, it introduces an efficient compulsory licensing scheme, with appropriate features, to allow a swift and appropriate response to crises, with a functioning Internal Market, guaranteeing the supply and the free movement of crisis-critical products subject to compulsory licencing in the internal market.

- **Consistency with existing policy provisions in the policy area**

In its intellectual property action plan, the Commission underlined 'the need to ensure that effective systems for issuing compulsory licences are in place'. The 2023 Commission work programme announced the establishment of clear rules for the compulsory licensing of patents. In the Council conclusions of 18 June 2021, the Council confirmed that the EU stood ready to discuss the flexibilities of compulsory licensing for the domestic market and for export purposes to third countries. It also confirmed the need to explore possible intellectual property tools and options to better coordinate the management of cross-border crises. In its resolution of November 2021, the European Parliament called on the Commission 'to analyse and explore possible options for ensuring effectiveness and better coordination of compulsory licensing in the EU'.

The TRIPS Agreement provides the international legal framework for compulsory licensing. This initiative is strictly in line with the boundaries of the TRIPS Agreement. Although the Unitary Patent system aims to further harmonise EU law on patents, it leaves the issue of compulsory licensing to national legislation. There are currently three other pieces of EU legislation that contain provisions on compulsory licensing:

- Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights: Article 29 of this Regulation provides for the possibility for the Community Plant Variety Office to grant a compulsory licence on a community plant variety right, on application by a Member State, by the Commission or by an organisation set up at EU level;
- Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions: Article 12 of this Directive provides for the possibility to apply for a compulsory licence, where a plant breeder cannot use a plant variety without infringing a patent or where the holder of a patent concerning a biotechnological invention cannot exploit it without infringing a prior plant variety right;
- Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of

pharmaceutical products for export to countries with public health problems: This Regulation sets out a procedure to grant compulsory licences in relation to patents and supplementary protection certificates concerning the manufacture and sale of pharmaceutical products, when such products are intended for export to eligible importing countries that need these products to address public health problems.

The first two EU acts cited above are not impacted by this proposal. The proposal would amend Regulation (EC) No 816/2006 in order to add the possibility, in the context of a cross-border manufacturing process, to rely on a compulsory licence granted by the Commission and applicable in the territory of the Union.

Member States have implemented different compulsory licensing schemes in national legislation, only applicable to their national territory. The proposal leaves these national compulsory licensing systems untouched. The Union compulsory licensing system introduced by this proposal does not aim at addressing purely national crises. The proposal instead aims to address crises that have a cross-border dimension within the EU, which do not fall within the scope of national compulsory licensing schemes.

This proposal is part of the EU patent package, which also provides for the introduction of a system for Unitary Supplementary Protection Certificates and an initiative on standard essential patents. The proposal complements the Unitary Patent system, which is a major step towards the completion of the Single Market for patents. Against this backdrop of increasing completion of the Single Market for patents, the initiative on compulsory licensing is therefore at the crossroads between the different EU crisis instruments and the international obligations and discussions on IP rights and compulsory licensing.

- **Consistency with other Union policies**

The Commission has recently tabled proposals to improve the EU's resilience to crises and better guarantee well-functioning supply chains in the Single Market. In that respect, reference can be made to the following key EU legislations:

- Proposal for a Regulation establishing a Single Market emergency instrument ('SMEI');
- Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU ('SCBTH');
- Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level ('Emergency Framework Regulation');
- Proposal for a Regulation of the European Parliament and of the Council establishing a framework of measures for strengthening Europe's semiconductor ecosystem ('Chips Act').

These pieces of legislations can either qualify as crisis instruments or as containing a crisis mechanism, setting up emergency mechanisms to ensure the supply of and access to critical products in the Single Market. None of these EU crisis instruments explicitly includes the use of compulsory licensing to address a crisis. This proposal makes compulsory licencing one of the tools available to respond to a crisis within the respective emergency frameworks, by closely linking compulsory licencing to EU crisis instruments.

The reform of the pharmaceutical legislation also provides for the suspension of regulatory data and market protection where a compulsory licence has been granted for a patent relating

to a medicinal product in order to address a public health emergency (see Article 80 para. 4 of Directive (EU) XXX/XX [COM(2023)192]). This increases the effectiveness of a compulsory licence, as rules on regulatory data and market protection can impede the authorisation of generic medicinal products.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

• Legal basis

The proposal is based on Articles 114 and 207 of the Treaty on the Functioning of the EU ('TFEU'). Article 114 TFEU empowers the European Parliament and the Council to adopt measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States, which have as their object the establishment and functioning of the internal market. Article 207 TFEU confers on the EU competence in the field of common commercial policy, including as regards IP rights which is relevant, since the proposal has an impact on Regulation (EC) No 816/2006, relating to the compulsory licensing of medicines for export purposes to third countries.

• Subsidiarity (for non-exclusive competence)

Action at EU level is justified to ensure the smooth functioning of the Single Market in crises. Currently, Member States can only act nationally, meaning that they can grant a compulsory licence for their own territory only. This can be sufficient for purely national crises, where both the crisis and the manufacturing capacities are in the same Member State. However, this will not be sufficient when a crisis has a cross-border dimension – this is considered highly probable due to the prevalence of cross-border supply chains. The inability of Member States to properly address a crisis with a cross-border dimension originates in the territoriality of national compulsory licensing schemes and the divergent, sometimes sub-optimal, compulsory licensing schemes in place to tackle a crisis. The proposed EU action will act on these specific points by creating a Union compulsory licence with a streamlined procedure. Without action at EU level, Member States would remain vulnerable to crises that have a cross-border dimension. Introducing an EU compulsory licensing scheme will help build a more resilient EU by providing an additional collective tool that supports other crisis instruments such as SMEI or the Emergency Framework Regulation.

• Proportionality

The adoption of a Regulation establishing a Union compulsory licensing scheme for crisis management does not go beyond what is necessary to achieve the identified objectives. It is limited to the aspects that Member States cannot achieve satisfactory on their own and where the EU can act more effectively, efficiently and with greater added value. The initiative's objective is to build a Union compulsory licensing scheme able to tackle crises with a cross-border dimension, in addition to the existing compulsory licensing national schemes for grounds other than crises. The proposal is therefore limited to what is necessary to tackle crisis with a cross-border dimension, only when such action cannot be implemented at national level or when such implementation would be inefficient.

• Choice of the instrument

The chosen instrument is a Regulation establishing a compulsory licencing system for crisis management at EU level with its own triggers, procedure and conditions. It leaves national compulsory licencing schemes in the Member States untouched but ensures coherence with other crisis and emergency instruments at EU level and is fully compliant with the international requirements for compulsory licencing laid down in the TRIPS Agreement.

Alternative regulatory methods such as a Directive harmonising national compulsory licencing schemes of the Member States are not considered appropriate.

First, a Directive would only create a certain degree of harmonisation. While the harmonisation of key aspects of compulsory licencing could help improve and clarify the features of national schemes, Member States' competent authorities would remain in charge of determining whether a crisis exists and whether to grant a compulsory licence. Hence, there would be a risk that the Directive would not be implemented and applied in a uniform manner due to existing differences in national law proceedings and judicial traditions.

Second, a Directive would only improve the situation of cross-border supply of products to a limited extent, as both the compulsory licence granted in the manufacturing country and those granted in the importing country would be based on harmonised rules. However, the lack of exhaustion of the patent right would still require several compulsory licences in all manufacturing and importing Member States.

Other measures like the adoption of recommendations aiming to bring about more uniformity of national laws would neither satisfactorily address the fragmentation of compulsory licensing in the EU nor the insufficient territorial reach of a national compulsory licence and coherence with existing and upcoming EU crisis instruments at EU level.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Stakeholder consultations**

The Commission conducted a call for evidence between 1 April and 29 April 2022, to gather views, opinions and evidence from public and private sector stakeholders. 57 stakeholders submitted feedback.

The European Commission also held an open public consultation between 7 July 2022 and 29 September 2022. This public consultation aimed to collect views from all stakeholders on how to build the most efficient compulsory licensing scheme in the EU and to ensure that it is fit to tackle EU-wide and global crises. This consultation was available on the Commission's better regulation portal and open to everybody. The public consultation received 74 replies. The results of the public consultation show that a large majority of respondents consider that public authorities should be entitled to allow production of critical products through a compulsory licence. Respondents are usually more in favour of a coordinating role for European institutions than a decision-making role. This can be explained by the fact that businesses and industry representatives expressed low levels of support for a decision-making role, and they were the dominant group of respondents to the consultation. Stakeholders generally consider the option of granting a compulsory licence at EU level, as proposed in this initiative, more positively in relation to the EU's ability to tackle crises than the granting of a compulsory licence at national level. There is a clear difference between among stakeholder views on this, with low support from industry representatives: a majority of companies and business associations consider that the impact would be negative. In contrast, no respondent in any other category considers the impact to be negative. A large majority considers it positive.

- **Collection and use of expertise**

In March 2022, the Commission launched the 'Compulsory licensing of intellectual property rights' study [CEIPI(2023)]. The study's objective was to assist the Commission in identifying potential problems as regards compulsory licensing in the EU and identifying and assessing policy options to improve coherence and effectiveness in the field. To this end, the study aimed to collect data through desk research, case studies, interviews with stakeholders

as well as organising two workshops. The study was conducted by the Centre for International Intellectual Property Studies (CEIPI), the Université de Strasbourg (UNISTRA), the Impact Licensing Initiative (ILI) and Ecorys Nederland BV (ECORYS).

During the study, Member State experts were asked to complete a questionnaire**.** The questions focused on the national experiences with compulsory licensing, the scope of application of compulsory licences and procedural aspects. In addition, a series of 25 semi-structured interviews of national experts, academia, policy representatives and industry experts were conducted. These interviews focused on gathering 'non-published' data on national procedures and legal requirements of compulsory licensing.

Two workshops were held:

- A first workshop on 'information collection on specific compulsory licence cases with exchange of views and experiences in the field of IPRs' was held in Brussels on 28/29 April 2022;
- A second workshop on 'policy options for compulsory licensing in Europe in case of a crisis' was held in Brussels on 9/10 June 2022.

A total of 24 participants attended both workshops, representing patent attorneys from multiple Member States, policy officials and representatives from different industries.

- **Impact assessment**

An impact assessment was carried out for the initiative, which received a positive opinion with reservations from the Regulatory Scrutiny Board on 3 February 2023. The impact assessment considered four policy options, in addition to the policy option consisting of no policy change:

- Option 1: Recommendation on compulsory licensing for crisis management. This would identify good national practices on compulsory licensing for crisis management and good coordination practices, with a view to increasing their uptake in Member States. This option was deemed insufficient, as it would not have a sufficient harmonising effect nor an appropriate territorial reach. In addition, it would not fully embed compulsory licensing in the EU crisis instruments.
- Option 2: Harmonisation of national laws on compulsory licensing for crisis management. The legislative initiative would harmonise national laws on the grounds, scope, procedure, and conditions for granting a compulsory licence for crisis management. The compulsory licence would remain within the remit of Member States and have predominantly a national effect. Although this option would further harmonise national compulsory licensing schemes, the territorial reach and coherence with EU crisis instruments of this option were still considered suboptimal.
- Option 3: Harmonisation and EU level binding measure to grant a compulsory licence for crisis management. The compulsory licence could be triggered: (i) by an EU-level decision activating a crisis mode or declaring an emergency under an existing EU crisis instrument (e.g. activation of the emergency mode under SMEI); or (ii) upon a request made to the Commission by more than one Member State in case of a cross-border crisis. The Commission, assisted by the relevant advisory body, would adopt an activation measure requiring one or several Member States to issue a compulsory licence. Option 3 would lead to several national compulsory licences, each applying to the territory of several EU countries or the whole EU. This option provided an appropriate territorial reach and ensured good coherence with EU crisis instruments. In addition, it would provide increased harmonisation compared to

Option 2. However, this harmonisation, and resulting coherence and efficiency of the Union compulsory licence, was limited compared to the optimal solution provided under Option 4.

- Option 4: Union compulsory licence to complement existing EU crisis instruments. The triggers would be the same as under Option 3. However, the Commission, assisted by the relevant advisory body, would adopt an activation measure granting a compulsory licence. This option would lead to the issuance, by the Commission, of one compulsory licence, with its own procedure and conditions and applicable to the territory of several EU countries or the whole EU.

According to the impact assessment, Option 4 would be the most effective and efficient to achieve the initiative's objectives. This preferred option would create a single procedure to grant a Union compulsory licence with the necessary features to tackle a crisis. The Commission activation measure would ensure that conditions are the same across the EU and would avoid national discrepancies that are likely to slow down or prevent an efficient compulsory licensing scheme to tackle cross-border crises. This single compulsory licence would apply in all relevant territories, covering cross-border situations. This would be the case for both the EU market and for export purposes. Coherence with EU crisis instruments would be ensured by the possibility to use their trigger and by reference to the (advisory) bodies set-up by the EU crisis instruments to discuss a Union compulsory licence. The proposed procedure would also cover crises with a cross-border dimension in the EU but which do not reach the activation threshold for an EU crisis instrument (e.g. a crisis spreading across several Member States). In the option described in the impact assessment, the procedure could be also initiated by the Member State(s) affected. However, following internal discussions within the Commission, the Member State right to initiate the procedure was not included in the legislative proposal. (as a result, the proposal partially deviates from Option 4 discussed in the impact assessment). Maintaining only the EU crisis instrument route was judged to be more coherent with the remaining EU crisis preparedness policy tools and more appropriate in terms of the exceptional nature of the proposed tool. The likely impacts of this change would be an even simpler procedure of initiation and more confidence among patent holders that the instrument would only be activated in case of major EU-wide crises. The latter would also limit potential detrimental effects of the proposal on competitiveness. No additional costs would be created by the change.

Under the preferred option, patent owners would see a reduction in costs and legal uncertainty, as negotiations would be limited to participation in one EU-level procedure. Potential licensees would benefit from the centralised procedure and the wide territorial scope of the licence that can bring economies of scale. Better sharing of information would also allow a reduction of costs for Member States as it could help identify best practices. On enforcement costs, Member States would benefit from the centralised procedure, as costs linked to the negotiations with the patent owners and the manufacturers would be incurred solely at EU level. EU residents would greatly benefit from this option as it would improve the EU's ability to issue an effective and efficient compulsory licence for the whole EU, including where there are cross-border supply chain disruptions. Third countries would also benefit from this option as this would provide the possibility of a compulsory licence covering a cross-border supply chain.

Improved EU readiness to tackle a major crisis would bring positive social impacts, as it would help limit various disruptions to everyday societal processes by curbing the crisis or eliminating it altogether. Although societal disruption can be caused by a crisis in any area (e.g. threats to the environment, national security, etc.), the recent COVID-19 pandemic provided multiple examples of disruptions that could have been avoided with a more effective

resilience tool. With regard to the environmental impact, the initiative's positive impacts could be decisive in increasing access to products and technologies that can tackle environmental crises. Since no environmental legislation is affected by this proposal and its principal objective is to streamline and harmonise compulsory licensing procedures in cross-border crises**,** no significant harm to the environment is expected under any of the options analysed.

- **Regulatory fitness and simplification**

The proposal creates a compulsory licencing system centralised at EU level. In crises a compulsory licence covering the whole EU can be granted by filing a single application and using a single procedure under unitary procedural rules and conditions. This means that one procedure can achieve what would otherwise only be achievable with the help of several national compulsory licencing procedures before different competent authorities of the Member States. If an unforeseen future crisis occurs, the compulsory licencing system established by the proposal would lower the costs of participation in compulsory licencing negotiations incurred by patent holders, manufacturers and Member States.

- **Fundamental rights**

The initiative would provide an additional tool to face crises. Through the improved supply of critical products and services, the most fundamental needs and rights of people in the EU (such as safety and health) would be more swiftly and efficiently catered for in a crisis setting.

This initiative impacts the right to intellectual property of patent and utility models owners (Article 17(2) of the EU Charter of fundamental rights – the 'Charter'), as compulsory licensing partially deprives patent owners of control over their rights. Intellectual property rights are not absolute rights, and limitations on the exercise of these rights are allowed under the Charter, provided that the proportionality principle is respected. In that respect, the proposal provides that compulsory licensing would remain an exceptional mechanism, with a scope limited to cross-border crises. In addition, compulsory licences would always be granted on a non-exclusive basis and subject to a definite duration. Finally, patent owners would be able to share their views on granting a compulsory licence and the conditions surrounding it. An important aspect of the conditions relates to patent owners being able to receive fair compensation for the limitation of their right. The proposal provides that patent owners would always be entitled to receive appropriate remuneration in respect of each compulsory licence granted under this initiative. This initiative may have a positive impact on other fundamental rights, as it would provide an additional tool to face crises, including health-related (right to health care – Article 35 of the Charter) or environmental crises (right to environmental protection – Article 37 of the Charter).

4. BUDGETARY IMPLICATIONS

If an unforeseen future crisis occurs, the proposed initiative would lower the costs incurred by patent holders, manufacturers and Member States of participating in compulsory licensing negotiations. These costs could be lower by roughly 75% to 80% for firms, compared to the *status quo* scenario (see impact assessment). For Member States, if national compulsory licensing negotiations were replaced by EU-level negotiations, the administrative costs are expected to stay unchanged or fall, as the same effort would be shared among several countries. The exact monetary value of cost savings for stakeholders is not possible to provide due to the rarity of such events and because the type and scale of any such future crisis are unknown. As the new instrument would only be used during major crisis affecting the EU, as a measure of last resort, its expected frequency of use is very low.

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

The proposed legislation includes a provision requiring an evaluation report no later than 3 years after the activation of a Union compulsory licence procedure. The preferred option requires Member States to inform the European Commission when they are considering granting and when they have granted a compulsory licence for crisis management, as well as providing information on the compulsory licence (i.e. transparency over the subject matter of the compulsory licence, the manufacturer, the conditions, etc.). Since recourse to compulsory licensing is expected to be rare, the overall number of compulsory licences issued on the basis of the proposed instrument is expected to be low. This means that monitoring of the basic descriptive indicators is not expected to require additional systems for data collection and monitoring (the collection and processing of information can be done manually).

- **Detailed explanation of the specific provisions of the proposal**

Article 1 specifies the subject matter of the proposal. It specifies that this proposal lays down the procedure and conditions for granting a Union compulsory licence to address a crisis in the EU.

Article 2 provides for the scope of the Union compulsory licence. To ensure the Union compulsory licence functions effectively during crises, the scope of the compulsory licence covers patents, published patent applications, supplementary protection certificates and utility models.

Article 3 provides definitions of key elements of this proposal. The definitions are based on existing definitions.

Article 4 provides the legal basis for the Commission to grant a Union compulsory licence for the whole EU. Under this provision, the Commission is entitled to grant a Union compulsory licence when a crisis mode or emergency mode is activated or declared at EU level. This aims to complement EU crisis mechanisms by allowing compulsory licensing to be used as part of such mechanisms.

Article 5 lays down the general conditions to be taken into account by the Commission when granting a Union compulsory licence.

Article 6 sets out rules for the consultation of an advisory body that is meant to provide the Commission with a non-binding opinion when considering a Union compulsory licence.

Article 7 sets out the procedure for granting a Union compulsory licence. The article states that the Union compulsory licence is granted by means of an implementing act. It also provides for sufficient participation by the rights-holder in order to guarantee their right to be informed and to provide comments. Further, it sets out the Commission's obligation to identify relevant rights-holders with regards to the compulsory licence.

Article 8 lays down rules on the specifications of the Union compulsory licence. The article further specifies the aspects the Commission should consider in its decision and the details that need to be specified.

Article 9 obliges the licensee to pay appropriate remuneration to the rights-holder and lays down criteria for the Commission to determine such remuneration.

Article 10 provides for specific conditions of the Union compulsory licence, to be fulfilled by the licensee. The article includes conditions limiting the use of the invention covered by the Union compulsory licence.

Article 11 provides for an export ban on products manufactured under a Union compulsory licence. These products cannot be exported outside the European Union.

Article 12 details the control measures undertaken by custom services, including as regards the export ban.

Article 13 establishes the principle of good faith in the relationship between rights-holder and licensee.

Article 14 entitles the Commission to modify, complement with additional measures or terminate the compulsory licence under certain conditions.

Article 15 entitles the Commission to issue fines if any of the parties to the compulsory licence do not comply with their obligations under this Regulation.

Article 16 entitles the Commission to issue periodic penalty payments if any of the parties to the compulsory licence do not comply with their obligations under this Regulation.

Article 17 provides for the rules as regards the limitation period for the imposition of fines and periodic penalty payments.

Article 18 provides for the rules as regards limitation period for the enforcement of fines and periodic penalty payments

Article 19 provides for the rules as regards the right for the rights-holder and the licensee to be heard and to access to the file in relation with the imposition of fines and periodic penalty payments.

Article 20 requires that the Commission publish the decisions on the imposition of fines and periodic penalty payments.

Article 21 provides that the Court of Justice of the European Union is entitled to review decisions by which the Commission has imposed fines or periodic penalty payments.

Article 22 requires Member States to notify the Commission if a national compulsory licence has been granted in order to address a crisis situation.

Article 23 amends existing Regulation (EC) No 816/2006 by Article 18a and Article 18b. Article 18a lays down rules on the grant of a Union compulsory licence for purposes of exporting medical products to third countries with public health problems. The article states that the Union compulsory licence is granted by means of an implementing act. Article 18b establishes a reference to the comitology committee as well as the reference to Regulation (EU) No 182/2011.

Article 24 establishes a committee for comitology procedure as well as the reference to the respective provisions in Regulation (EU) No 182/2011.

Article 25 requires the Commission to carry out a review where a Union compulsory licence has been granted due to a cross-border crisis in the EU.

Article 26 sets out the date when the regulation enters into force.

2023/0129 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on compulsory licensing for crisis management and amending Regulation (EC) 816/2006

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114 and 207 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[1],

Having regard to the opinion of the Committee of the Regions[2],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Crises require the setting-up of exceptional, swift, and adequate measures able to provide means to address the consequences of the crisis. In this context, the use of patented products or processes could prove indispensable to address the consequences of a crisis. Voluntary licensing agreements usually suffice to licence the patent rights on these products and allow their supply in the Union territory. Voluntary agreements are the most adequate, quick, and efficient solution to allow the use of patented products, including in crises. Nevertheless, voluntary agreements may not always be available or only under inadequate conditions such as lengthy delivery times. In such cases, compulsory licensing can provide a solution to allow access to patented products, in particular products necessary to tackle the consequences of a crisis.

(2) In the context of the Union crisis or emergency mechanisms, the Union should therefore have the possibility to rely on compulsory licensing. The activation of a crisis or an emergency mode or the declaration of a crisis or a state of emergency addresses obstacles to free movement of goods, services, and persons in crises and shortages of crisis-relevant goods and services. In cases where access to crisis-relevant products and processes protected by a patent cannot be achieved through voluntary cooperation, compulsory licensing can help in lifting any patent-related barriers and thus ensure the supply of products or services needed to confront an ongoing crisis or emergency. It is therefore important that, in the context of said crisis mechanisms, the Union can rely on an efficient and effective compulsory licensing scheme at Union level, which is uniformly applicable within the Union. This would guarantee a functioning internal market, ensuring the supply and the free movement of crisis-critical products subject to compulsory licencing in the internal market.

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1 OJ C , , p. .

2 OJ C , , p. .

(3) The possibility of using compulsory licences in situations of national emergency or other circumstances of extreme urgency is explicitly envisaged under the Agreement on Trade-Related Aspects of Intellectual Property Rights ('TRIPS Agreement')[3].

(4) All Member States have implemented compulsory licensing frameworks for patents in their national law. National laws usually allow compulsory licensing on the ground of public interest or in the event of an emergency. However, divergences exist across Member States, as regards the grounds, conditions, and procedures under which a compulsory licence can be granted. This results in a fragmented, suboptimal, and uncoordinated system preventing the Union from effectively relying on compulsory licensing when addressing a cross-border crisis.

(5) National compulsory licensing systems only operate within the national territory. They are designed to meet the needs of the population of the issuing Member State and to satisfy the public interest of that Member State. This limited territorial reach of a national compulsory licensing system is reinforced by the fact that there is no exhaustion of the patent right regarding products manufactured under a compulsory licence. Consequently, compulsory licensing schemes do not provide an adequate solution for cross-border manufacturing processes, and therefore there is no functioning internal market for product manufactured under a compulsory licence. Apart from the fact that the issuance of multiple national compulsory licences is a high hurdle for cross-border supply within the single market, it also bears the risk of contradicting and incoherent decisions among Member States. Consequently, the current compulsory licensing framework appears inadequate to address the realities of the internal market and its inherent cross-border supply chains. This suboptimal compulsory licensing framework prevents the Union from relying on an additional instrument when facing crises, in particular when voluntary agreements are unavailable or inadequate. At a time where the Union and its Member States are striving to improve their resilience to crises, it is necessary to provide for an optimal compulsory licensing system for crisis management that takes the full advantage of the internal market and allows Member States to support one another in crises.

(6) Therefore, it is necessary to establish a compulsory licence for crisis or emergency management at Union level. Under this system, the Commission should be empowered to grant a compulsory licence that is valid throughout the Union and that allows the manufacturing and distribution of products necessary to address a crisis or emergency in the Union ('Union compulsory licence').

(7) In recent years, the European Union has adopted several crisis mechanisms to improve its resilience to crises or emergencies affecting the Union. The recent mechanisms include the Single Market Emergency Instrument (SMEI) established under Regulation (EU) No XXX/XX [COM(2022) 459] and Regulation (EU) No 2022/2371 under which the Commission may recognise a public health emergency at Union level. In the event of a public health emergency at Union level a framework of measures for ensuring the supply of crisis-relevant medical countermeasures might be activated under Regulation (EU) No 2022/2372. Furthermore, in case of a significant shortage of semiconductors due to serious disruptions in their supply, the Commission may activate a crisis stage by means of implementing acts under Regulation (EU) No XXX/XX (Chips Act) [COM(2022) 46].

(8) These mechanisms provide for the activation of an emergency or crisis mode and aim at providing the means to address Union emergencies. By allowing the Commission to

[3] OJ L 336, 23.12.1994, p. 214

grant a compulsory licence when a crisis or emergency mode has been activated by a Union legal act, the necessary synergy between the existing crisis mechanisms and a Union wide compulsory licencing scheme is achieved. In such a case, the determination of the existence of a crisis or emergency depends solely on the Union legal act underlying the crisis mechanism and the crisis definition included therein. For the sake of legal certainty, the crisis mechanisms that qualify as Union emergency or extreme urgency measures and that can trigger a Union compulsory licence should be listed in an Annex to this Regulation.

(9) To ensure optimal efficiency of the Union compulsory licence as a tool to address crises, it should be made available in respect of a granted patent or utility model, of a published patent application or a supplementary protection certificate. The Union compulsory licence should equally apply to a national patents, European patents and European patents with unitary effect.

(10) Utility model systems protect new technical inventions that do not fulfil the patentability requirements through the granting of an exclusive right to prevent others, for a limited period of time, from commercially exploiting the protected inventions without consent of the right holders. The definition of utility models varies from one country to another, and not all Member States provide for utility model systems. In general, utility models are suited for protecting inventions that make small improvements to, or adaptations of, existing products, or that have a short commercial life. However, similarly to patents, utility models can protect inventions that could prove necessary to address a crisis and should therefore be included in the scope of the Union compulsory licence.

(11) A Union compulsory licence for a patent should extend to the supplementary protection certificate where such protection is granted when the patent expires during the duration period of that compulsory licence. This would allow a compulsory licence on a patent to produce its effect should the crisis-relevant products no longer be protected by a patent while being protected through a supplementary protection certificate after the expiration of the patent. It should also apply to a supplementary protection certificate in isolation where the licence is granted after the expiry of the patent.

(12) The Union compulsory licence should also apply to published patent applications for national patents and for European patents. As the grant of a patent after the publishing of the patent application can take years, targeting only inventions protected by a granted patent could prevent an effective and timely crisis response. In crises, solutions can derive from the latest state-of-the-art technology. Moreover, certain national patent legislations, as well as the European Patent Convention, provide for protection of patent applicants with regard to unconsented use of their inventions and the corresponding possibility for such applicants to licence the use of their patent application rights. In order to ensure that a Union compulsory licence on a published patent application continues to keep its effects once the patent is granted, the Union compulsory licence for published patent applications should extend to the patent once granted to the extent that the crisis-relevant product still falls within the scope of the patent claims.

(13) It should be clarified that this Regulation is without prejudice to Union law on copyright and related rights, including Directives 96/9[4], 2009/24[5]

[4] Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases (OJ L 77, 27.3.1996, p. 20)

Directives 2001/29/EC[6], 2004/48/EC[7] and (EU) 2019/790[8] of the European Parliament and of the Council, which establish specific rules and procedures that should remain unaffected.

(14) When a compulsory licence has been granted, regulatory data protection may, if still in force, prevent the effective use of the compulsory licence as it impedes the authorisation of generic medicinal products. This would result in serious negative consequences for Union compulsory licences granted to tackle a crisis, as this could hamper access to the medicinal products needed to address the crisis. For this reason, Union pharmaceutical legislation (cf. Art. 80 para. 4 of Directive (EU) No XXX/XX [COM(2023)192]) provides for the suspension of data exclusivity and market protection when a compulsory licence has been issued to tackle a public health emergency. Such suspension is allowed only in relation to the compulsory licence granted and its beneficiary and must comply with the objectives, the territorial scope, the duration, and the subject-matter of the granted compulsory licence. The suspension means that the data exclusivity and market protection produce no effect in relation to the licensee of the compulsory licence while that licence is in effect. When the compulsory licence ends, the data exclusivity and market protection resume their effect. The suspension should not result in an extension of the original duration of the regulatory data protection.

(15) In order to ensure as much coherence as possible with existing crisis mechanisms and with other Union legislation, the definition of a 'crisis-relevant product' should be based on the definition adopted in the Single Market Emergency Instrument (SMEI) but should be more general in order to cover products related to different kinds of crises or emergencies.

(16) A Union compulsory licence authorises the use of a protected invention without the consent of the rights-holder. Therefore, it must only be granted exceptionally and under conditions that take into account the interests of the rights-holder. This includes a clear determination of the scope, duration and territorial coverage of the licence. In the context of a Union level crisis mechanism, the crisis mode or emergency mode is activated or declared for a limited period of time. Where a Union compulsory licence is granted within such framework, the duration of the licence shall not extend beyond the duration of the activated or declared crisis or emergency mode. In order to ensure that the compulsory licence fulfils its objective as well as its conditions, the use of the invention should only be authorised to a qualified person able to manufacture the crisis-relevant product and to pay a reasonable remuneration to the rights-holder.

(17) When considering the granting of a Union compulsory licence, the Commission should, in order to be able to take a well-informed decision, be assisted by an advisory body. The consultation of the advisory body should arise early in the discussions on the need to issue a compulsory licence under the relevant instrument. Discussions on

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5 Directive 2009/24/EC of the European Parliament and of the Council of 23 April 2009 on the legal protection of computer programs (OJ L 111, 5.5.2009, p. 16)

6 Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the information society (OJ L 167, 22.6.2001, p. 10).

7 Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (OJ L 157, 30.4.2004, p. 45).

8 Directive (EU) 2019/790 of the European Parliament and of the Council of 17 April 2019 on copyright and related rights in the Digital Single Market and amending Directives 96/9/EC and 2001/29/EC (OJ L 130, 17.5.2019, p. 92).

whether there is a need for a Union compulsory licence will often start already in the context of the work of the advisory body involved in the context of the relevant Union crisis or emergency mechanisms. In such case, there is no need for the Commission to convene the advisory body but rather to swiftly indicate that that body also has the competence to assess the need for compulsory licensing at Union level, and the conditions thereof. Clarification as regards the competence of the advisory body should be given early in the process, as soon as concrete consideration of using compulsory licensing at Union level is expressed by the Commission.

(18) The participation of an advisory body aims at guaranteeing a comprehensive, thorough, and concrete assessment of the situation, taking into consideration the individual merits of each situation. It is therefore important that the advisory body has the right composition, expertise, and procedures to support the Commission when deciding on whether to grant a Union compulsory licence and under what conditions. Union crisis mechanisms usually include the setting-up of an advisory body ensuring coordination of action of the Commission and relevant bodies and agencies, the Council and the Member States. In this respect, an advisory group is set up under SMEI. Regulation (EU) No 2022/2371 provides for a Health Crisis Board and under Regulation (EU) No XXX/XX (Chips Act) [COM/2022) 46], the Commission relies on the Semiconductor Board. Those advisory bodies have the right composition, expertise, and procedures to address the crises and emergencies for which they have been set-up. When compulsory licensing is being discussed in the context of such crisis instrument, relying on the advisory body set-up for the specific instrument allows the Commission to be adequately advised and avoid duplication of advisory bodies, leading to incoherences between processes. The competent advisory bodies shall be listed, together with the corresponding crisis mechanisms, in an Annex to this Regulation. In case the Union crisis mechanism does not provide for an advisory body, the Commission should set up an ad hoc advisory body for the granting of the Union (the 'ad hoc advisory body').

(19) The role of the advisory body is to advise the Commission when discussions arise on the need to rely on compulsory licensing at Union level. It should provide the Commission with a non-binding opinion. Its main tasks include assisting of the Commission in the determination of the necessity to rely on compulsory licensing at Union level, and in the determination of the conditions for such licensing. When the advisory body is already set up, its existing rules of procedure should apply. As regards ad hoc advisory bodies, they should be composed of one representative of each Member State in order to provide the Commission with information and input concerning the situation on the national level, including information on manufacturing capacities, potential licensees and, if applicable, proposals for voluntary solutions. In addition, the advisory body should have the function of collecting and analysing relevant data, as well as ensuring coherence and cooperation with other crisis relevant bodies at Union and national level in order to ensure an adequate, coordinated and coherent crisis reply at Union level.

(20) The Commission should grant the Union compulsory licence in the light of the non-binding opinion of the advisory body. Persons, in particular the licensee and the rights-holder, whose interests may be affected by the Union compulsory licence should be given the opportunity to submit their comments. These elements should enable the Commission to consider the individual merits of the situation and determine, on that basis, the adequate conditions of the licence, including an adequate remuneration to be paid by the licensee to the rights-holder. To avoid overproduction of products

manufactured under a Union compulsory licence, the Commission should also consider any existing compulsory licences at national level.

(21) The Commission should guarantee that the rights-holder has the right to be heard before the adoption of the Union compulsory licence. Therefore, the Commission should inform the concerned rights-holder, where possible individually, without undue delay that a Union compulsory licence might be granted. The involvement of the rights-holder should be possible once there are ongoing advanced discussions in the relevant advisory body as regards the granting of a Union compulsory licence.

(22) When informed of advanced discussions as regards the granting of a Union compulsory licence, the rights-holder should have the possibility to propose a voluntary agreement, should the circumstances of the Union crisis or emergency, including the urgency of the situation, allow it. The rights-holder should also be given the opportunity to comment on the need for a Union compulsory licence and on the conditions of the licence, including remuneration, should it be granted. To this end, the rights-holder should be allowed to provide the Commission with written or oral comments and any information the rights-holder considers useful to allow the Commission to make a fair, comprehensive, and thorough assessment of the situation. The Commission should allow the rights-holder a reasonable period of time to provide comments and information, considering the situation of the rights-holder and the urgency of the situation. The comments of the rights-holder should, where relevant, be transmitted by the Commission to the competent advisory body. In order for confidential information to be shared with the Commission, the Commission shall ensure a safe environment for the sharing of this information and should take measures to preserve the confidentiality of the documents provided by the rights-holder in the context of that procedure. Once a Union compulsory licence has been granted, the Commission should notify the rights-holder as soon as reasonably practicable.

(23) The initiation of the compulsory licensing procedure should be publicised, by means of a notice published in the Official Journal of the European Union. This notice should include information on the discussions about the granting of a Union compulsory licence in the context of a Union crisis or emergency mechanism. This notice should also help the Commission in identifying the intellectual property rights concerned, the rights-holders concerned as well as potential licensees.

(24) The Commission should, assisted by the advisory body, make its best efforts to identify in its decision the patent, patent application, supplementary protection certificate and utility model related to the crisis-relevant products, and the rights-holders of those intellectual property rights. In certain circumstances, the identification of intellectual property rights and of their respective rights-holders may require lengthy and complex investigations. In such cases, a complete identification of all intellectual property rights and of their rights-holders may seriously undermine the efficient use of the Union compulsory licence to swiftly tackle the crisis or the emergency. Therefore, where the identification of all those intellectual property rights or rights-holders would significantly delay the granting of the Union compulsory licence, the Commission should be able to initially only indicate in the licence the non-proprietary name of the product for which it is sought. The Commission should nevertheless identify all applicable and relevant intellectual property rights and their rights-holder as soon as possible and amend the implementing act accordingly. The amended implementing act should also identify any necessary safeguards and remuneration to be paid to each identified rights-holder.

(25) Where the rights-holder or not all the rights-holders could be identified in a reasonable period of time, the Commission should exceptionally be entitled to grant the Union compulsory licence by referring only to the non-proprietary name of the crisis-relevant product where it is absolutely necessary considering the urgency of the situation. Nevertheless, after the granting of the Union compulsory licence, the Commission should identify, notify and consult the concerned rights-holders as quickly as possible, including by relying on publication measures and on national Intellectual Property Offices.

(26) The Union compulsory licence should also include information allowing the identification of the crisis-relevant product for which it is granted, as well as details on the licensee to whom the Union compulsory licence is granted, including details about the description, name or brand of the product; the commodity codes under which the crisis-relevant products are classified, as defined in Council Regulation (EEC) No 2658/87; details on the licensees (and, where applicable, the manufacturers) to whom the compulsory licence is granted, including their name, trade name or registered trade mark, their contact details, their unique identification number in the country where they are established and, where available, their Economic Operators Registration and Identification (EORI) number. Where required under Union legislation, other information should be included, such as a type, reference, model, batch or serial number, or unique identifier of a product passport.

(27) The licensee should pay an adequate remuneration to the rights-holder as determined by the Commission. The amount of the remuneration should be determined considering the economic value of the exploitation authorised under the licence to the licensee and to the Member States concerned by the crisis, any public support received by the rights-holder to develop the invention, the degree to which development costs have been amortized as well as humanitarian circumstances relating to the granting of the Union compulsory licence. In addition, the Commission should consider the comments made by the rights-holder and the assessment made by the advisory body with regard to the amount of the remuneration. In any case, the remuneration should not exceed 4 % of the total gross revenue generated by the licensee through the acts under the Union compulsory licence. This percentage is the same as the one provided for under Regulation 816/2006. In the event of a compulsory licence granted on the basis of a published patent application that ultimately does not lead to the granting of a patent, the rights-holder would have no ground to receive remuneration under the compulsory licence, as the subject matter for the receipt of the remuneration has not materialised. In such circumstances, the rights-holder should refund the remuneration it received under the compulsory licence.

(28) It is imperative that products manufactured under a Union compulsory licence reach only the internal market. The Union compulsory licence should therefore impose clear conditions upon the licensee as regards the activities authorised under the licence, including the territorial reach of those activities. The rights-holder should be able to challenge actions and uses of the rights concerned by the Union compulsory licence that do not comply with the conditions of the licence, as infringement of its intellectual property rights in accordance with Directive 2004/48/EC of the European Parliament and of the Council[9]. In order to facilitate monitoring of the distribution of products manufactured under a Union compulsory licence, including controls by customs authorities, the licensee should ensure that such products have special characteristics

[9] Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (OJ L 157 30.4.2004, p. 45).

that make them easily identifiable and distinguishable from the products marketed by the rights-holder.

(29) A Union compulsory licence in the context of a Union crisis or emergency mechanism should only be granted to supply the internal market with crisis-relevant products. Therefore, it should be prohibited to export products manufactured under a Union compulsory licence.

(30) Customs authorities should ensure, through a risk analysis approach, that products manufactured under a Union compulsory license are not exported. To identify such products, the main source of information to feed such customs risk-analysis should be the Union compulsory license itself. Information on each implementing act granting or modifying a Union compulsory license should thus be entered in the Electronic Customs Risk Management System (CRMS) referred to in Article 36 of Commission Implementing Regulation (EU) 2015/2447[10]. When customs authorities identify a product that is suspected not to comply with the export prohibition, they should suspend the export of that product and notify the Commission immediately. The Commission should reach a conclusion on the compliance with the export prohibition within 10 working days, but should have the possibility of requiring the customs authorities to maintain the suspension where necessary. To help its assessment the Commission may consult the relevant rights-holder. Where the Commission concludes that a product does not comply with the export prohibition, customs authorities should refuse its export.

(31) The legal validity of the implementing act granting the Union compulsory license, or any subsequent implementing act, should be subject to judicial review.

(32) The relation between the rights-holder and the licensee should be governed by the principle of good faith. The rights-holder and licensee should work towards the success of the Union compulsory licence and collaborate, where necessary, to ensure that the Union compulsory licence effectively and efficiently fulfils its objective. The Commission may act as an enabler in achieving the good-faith cooperation between the rights-holder and the licensee, taking into account interests of all parties. In that respect, the Commission should also be entitled to take additional measures in line with Union law to ensure that the compulsory licence meets its objective and ensure that necessary crisis-relevant goods can be made available in the Union. Such additional measures may include requesting further information which is deemed indispensable to achieve the objective of the compulsory licence. These measures should always include adequate safeguards to ensure the protection of the legitimate interests of all parties.

(33) In order to respond appropriately to the crisis situations, the Commission should be authorised to review the conditions of the Union compulsory licence and adapt them to changed circumstances. This should include the modification of the compulsory licence to indicate the complete list of rights and rights-holders covered by the compulsory licence, where this complete identification had not be done initially. This should also include the termination of the licence if the circumstances which led to it cease to exist and are unlikely to recur. When deciding on the revision of the Union compulsory licence, the Commission may decide to consult the competent advisory body for that purpose. If the Commission intends to change essential components of

[10] Commission Implementing Regulation (EU) 2015/2447 of 24 November 2015 laying down detailed rules for implementing certain provisions of Regulation (EU) No 952/2013 of the European Parliament and of the Council laying down the Union Customs Code (OJ L 343, 29.12.2015, p. 558).

the Union compulsory licence, such as its duration or remuneration or if the change itself could be the subject of a separate compulsory licence, it should be required to consult the advisory body.

(34) To prevent and stop any misuse of the Union compulsory licence, specific safeguards should be in place to allow the Commission to take action. In addition to the possibility to terminate the Union compulsory licence, the Commission should be authorised to impose fines and periodic penalty payments on the rights-holder and the licensee in order to enforce the obligations under this Regulation. The penalties should be effective, proportionate and dissuasive.

(35) Compliance with the relevant obligations imposed under this Regulation should be enforceable by means of fines and periodic penalty payments. To that end, appropriate levels of fines and periodic penalty payments should be laid down and the imposition of fines and periodic penalty payments should be subject to appropriate limitation periods in accordance with the principles of proportionality and *ne bis in idem*. All decisions taken by the Commission under this Regulation are subject to review by the Court of Justice of the European Union in accordance with the TFEU. The Court of Justice of the European Union should have unlimited jurisdiction in respect of fines and penalty payments in accordance with Article 261 TFEU.

(36) When a national compulsory licence has been granted for the purpose of addressing a crisis, the Member State or its competent authority should be required to notify the Commission of the granting of the licence, and of the specific conditions attached to it, since it allows the Commission to get an overview of national compulsory licences in the Member States and to take those compulsory licences into account when considering a Union compulsory licence, and in particular when setting the conditions for such licence.

(37) The possibility of a compulsory licence at Union level should not only be available for the supply of the Union market but also under certain conditions for export purposes concerning countries with public health problems, already regulated by Regulation (EC) No 816/2006 of the European Parliament and of the Council[11]. Under that Regulation, the granting of such compulsory licences is decided and performed nationally by the competent authorities of the Member States that have received a corresponding application from a person that intends to manufacture and sell pharmaceutical products covered by a patent or a supplementary protection for export to eligible third countries. Regulation (EC) No 816/2006 only allows compulsory licensing covering the manufacturing of products across several Member States through national procedures. In the context of a cross-border manufacturing process different national compulsory licences would be needed. This can lead to a burdensome and lengthy process as this would require the launch of different national procedures with possibly different scope and conditions. In order to achieve the synergies and efficient process as for the Union crisis mechanisms, a Union compulsory licence should also be available, in the context of Regulation (EC) No 816/2006. This will facilitate manufacturing of the relevant products across several Member States and provide Union-level solution in order to avoid a situation where several compulsory licences for the same product in more than one Member States would be required for licensees to manufacture and export the products as planned.

[11] Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems (OJ L 157, 9.6.2006, p. 1).

Any person considering to apply for a compulsory licence under, for the purposes and within the scope of Regulation (EC) No 816/2006 should have the possibility to request, with a single application, a compulsory licence under that Regulation that is valid throughout the Union, if that person, when relying on national compulsory licencing schemes of the Member States, would otherwise need to apply for multiple compulsory licences for the same crisis-relevant product in more than one Member State in order to realise its intended activities of manufacture and sale for export under Regulation (EC) No 816/2006. Therefore, Regulation (EC) No 816/2006 should be amended accordingly.

(38) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the granting, complementing, modification or termination of a Union compulsory license, the determination of the remuneration to be paid to the rights-holder, the procedural rules for the ad hoc advisory body and the characteristics allowing the identification of products produced under a Union compulsory licence. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[12]. The advisory procedure should be used for the adoption of implementing acts granting, complementing, modifying or terminating a Union compulsory licence, and implementing acts determining the remuneration. The choice of the advisory procedure is justified given that those implementing acts would be adopted in the context of a procedure with considerable participation of the Member States through the consultation of the advisory body. The examination procedure should be used for the adoption of implementing acts establishing procedural rules for the ad hoc advisory body and implementing acts establishing the characteristics allowing the identification of products produced under a Union compulsory licence.

(39) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the granting, modification or termination of a Union compulsory licence or the determination of the remuneration, imperative grounds of urgency so require.

(40) Union compulsory licensing for crisis management is a tool that is only used in exceptional circumstances. The evaluation should therefore be conducted only where a Union compulsory licence has been granted by the Commission. The evaluation report should be submitted by the last day of the third year following the granting of the Union compulsory licence, to allow an adequate and substantiated assessment of this Regulation.

(41) Since a period of time is required to ensure that the framework for the proper functioning of the system for Union compulsory licencing is in place, the application of this Regulation should be deferred.

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[12] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

HAVE ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation has the objective to ensure that in crises the Union has access to crisis-relevant products. To this end, this Regulation lays down rules on the procedure and conditions for the granting of a Union compulsory licence of intellectual property rights that are necessary for the supply of crisis-relevant products to the Member States in the context of a Union crisis or emergency mechanism.

Article 2

Scope

1. This Regulation establishes Union compulsory licensing of the following intellectual property rights in force in one or more Member States:
   (a) patents, including published patent applications;
   (b) utility models; or
   (c) supplementary protection certificates;
2. This Regulation is without prejudice to the rules laid down by other Union legal acts regulating copyright and related rights, including Directive 2001/29, Directive 2009/24 and the *sui generis* rights granted by Directive 96/9/EC on the legal protection of databases.

Article 3

Definitions

For the purposes of this Regulation, the following definitions shall apply:

(a) 'crisis-relevant products' means products or processes that are indispensable for responding to a crisis or emergency or for addressing the impacts of a crisis or emergency in the Union;

(b) 'relevant activities' means the acts of making, using, offering for sale, selling or importing.

(c) 'rights-holder' means a holder of any of the intellectual property rights referred to in Article 2(1);

(d) 'protected invention' means any invention protected by any of the intellectual property rights referred to in Article 2(1);

(e) 'Union compulsory licence' means a compulsory licence granted by the Commission to exploit a protected invention of crisis-relevant products for any of the relevant activities in the Union;

(f) 'customs authorities' means customs authorities as defined in Article 5, point (1), of Regulation (EU) No 952/2013 of the European Parliament and of the Council[13];

Article 4

Union compulsory licence

The Commission may grant a Union compulsory licence where a crisis mode or an emergency mode listed in the Annex to this Regulation has been activated or declared in accordance with one of the Union acts listed in that Annex.

Article 5

General conditions of a Union compulsory licence

1. The Union compulsory licence shall

   (a) be non-exclusive and non-assignable, except with that part of the enterprise or goodwill which enjoys such compulsory licence;

   (b) have a scope and duration that is limited to the purpose for which the compulsory licence is granted and limited to the scope and duration of the crisis or emergency mode in the framework of which it is granted;

   (c) be strictly limited to the relevant activities of crisis-relevant products in the Union;

   (d) only be granted against payment of an adequate remuneration to the rights-holder;

   (e) be limited to the territory of the Union;

   (f) only be granted to a person deemed to be in a position to exploit the protected invention in a manner that permits the proper carry out of the relevant activities of the crisis-relevant products and in accordance with the obligations referred to in Article 10.

2. A Union compulsory licence for an invention protected by a published patent application shall cover a patent granted based on that application, provided that the granting of that patent takes place while the Union compulsory licence is valid.

3. A Union compulsory licence for an invention protected by a patent shall cover a supplementary protection certificate issued with reference to that patent, provided that the transition from patent protection to protection conferred by a supplementary protection certificate takes place while the Union compulsory licence is valid.

Article 6

Advisory body

1. When the Commission considers the granting of a Union compulsory licence, it shall without undue delay consult an advisory body.

[13] Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (OJ L 269, 10.10.2013, p. 1).

2. The advisory body referred to in paragraph 1 shall be the advisory body competent for the Union crisis or emergency mechanism as listed in Annex I to this Regulation (the 'competent advisory body'). For the purposes of the present Regulation, the competent advisory body shall assist and advise the Commission as regards the following tasks:

   (a) the gathering of crisis-relevant information, market intelligence and the analysis of those data;

   (b) the analysis of the crisis-relevant information gathered by Member States or the Commission and aggregated data received by other crisis-relevant bodies at Union and international level;

   (c) the facilitation of exchanges and sharing of information with other relevant bodies and other crisis-relevant bodies at Union and national level, as well as at international level, where appropriate;

   (d) the identification of the rights protecting the crisis-relevant product;

   (e) the establishment of whether there is a need to grant a Union compulsory licence;

   (f) the identification and consultation of the representatives of right holders or their representatives as well as potential licensees and consulting other economic operators, and the industry;

   (g) the establishment, if relevant, of whether the criteria for termination or modification of the Union compulsory licence set out in Article 15 have been fulfilled.

3. The advisory body shall cooperate and coordinate closely, where appropriate, with other relevant crisis-related bodies and with intellectual property offices at Union and national level.

4. For the purpose of the present Regulation, the Commission:

   (a) shall ensure participation and invite representatives of other crisis-relevant bodies at Union level as observers to the relevant meetings of the advisory body in order to ensure coherence with the measures implemented through other Union mechanisms; and

   (b) may invite representatives of the European Parliament, representatives of economic operators, right holders, potential licensees, stakeholder organisations, social partners and experts to attend meetings of the advisory body as observers.

5. In the absence of any existing competent advisory body, the tasks referred to in paragraph 2 shall be performed by an ad hoc advisory body set up by the Commission (the 'ad hoc advisory body'). The Commission shall chair the ad hoc advisory body and ensure its secretariat. Each Member State shall have the right to be represented in the ad hoc advisory body.

6. The Commission shall adopt an implementing act laying down the rules of procedure for the ad hoc advisory body referred to in paragraph 5. The rules of procedure shall specify that the ad hoc advisory body shall not be set up for a period exceeding the duration of the crisis or emergency. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 24 (3).

Article 7

Procedure for granting a Union compulsory licence

1. The competent or, where relevant ad hoc, advisory body referred to in Article 6 shall provide the Commission with an opinion without undue delay. That opinion shall be issued in accordance with the rules of procedure of the advisory body and shall contain an assessment of the need for a Union compulsory licence and the conditions for such licence. The opinion shall take account of the following:

   (a) the nature of the crisis or emergency;

   (b) the scope of the crisis or emergency and how it is expected to evolve;

   (c) the shortage of crisis-relevant products and the existence of other means than a Union compulsory licence that could adequately and swiftly remedy such shortage.

2. The opinion of the advisory body shall not be binding on the Commission. The Commission may set a time limit for the advisory body to submit its opinion. The time limit shall be reasonable and appropriate to the circumstances of the situation, taking particular account of the urgency of the matter.

3. Before the granting of a Union compulsory licence, the Commission shall give the rights-holder and the licensee an opportunity to comment on the following:

   (a) the possibility to reach a voluntary licensing agreement with manufacturers on intellectual property rights for the purpose of manufacturing, using and distributing the crisis-relevant products;

   (b) the need to grant the Union compulsory licence;

   (c) the conditions under which the Commission intends to grant the Union compulsory licence, including the amount of the remuneration.

4. The Commission shall notify the rights-holder and the licensee as soon as possible of the fact that a Union compulsory licence may be granted. Wherever the identification of the rights-holders is possible and does not cause significant delay, the Commission shall notify them individually.

5. When the Commission considers the granting of a Union compulsory licence, it shall without undue delay publish a notice to inform the public about the initiation of the procedure under this article. This notice shall also include, where already available and relevant, information on the subject of the compulsory licence and an invitation to submit comments in accordance with paragraph 3. The notice shall be published in the Official Journal of the European Union.

6. When assessing whether a Union compulsory licence is to be granted, the Commission shall consider the following:

   (a) the opinion referred to in paragraph 2;

   (b) the rights and interests of the rights-holder and the licensee;

   (c) existing national compulsory licences reported to the Commission in accordance with Article 22.

7. Where the Commission finds that the requirements for a Union compulsory licence are met, the Commission shall grant it by means of an implementing act. The

implementing act shall be adopted in accordance with the advisory procedure referred to in Article 24(2). On duly justified imperative grounds of urgency relating to the impacts of the crisis, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 24(4). In case of procedure under Article 24(4), the implementing act shall remain in force for a period not exceeding 12 months.

8. When adopting the implementing act, the Commission shall ensure the protection of confidential information. While respecting the confidentiality of the information, the Commission shall ensure that any information relied on for the purpose of its decision is disclosed to an extent that allows to understand the facts and considerations that led up to the adoption of the implementing act.

Article 8

Content of the Union compulsory licence

1. The Union compulsory licence shall specify the following:

(a) the patent, patent application, supplementary protection certificate or utility model for which the licence is granted or, where the identification of those rights would significantly delay the granting of the licence, the non-proprietary name of the products which are to be manufactured under the licence;

(b) the right-holder, provided they can be identified with reasonable efforts having regard to the circumstances, including the urgency of the situation;

(c) the licensee, in particular the following information:

(1) name, trade name and registered trade mark;

(2) contact details;

(3) unique identification number in the country where the licensee is established;

(4) where available, the Economic Operators Registration and Identification (EORI) number;

(d) the duration for which the Union compulsory licence is granted;

(e) the remuneration to be paid to the rights-holder determined in accordance with Article 9;

(f) the non-proprietary name of the crisis-relevant product which is to be manufactured under the Union compulsory licence and its commodity code (CN code) under which the crisis-relevant product is classified, as defined in Council Regulation (EEC) No 2658/87;

(g) the details referred to in Article 10(1)(c), (d) and (e) allowing the identification of the crisis-relevant product manufactured under the Union compulsory licence and, where applicable, any other specific requirement under Union legislation applicable to the crisis-relevant products and allowing its identification.

(h) measures complementing the compulsory licence, which are necessary to achieve the objective of the compulsory licence.

2. By way of derogation from paragraph 1, point (e), the Commission may determine the remuneration after the granting of the licence, by way of an implementing act, where that determination requires, further investigation and consultation. This implementing act shall be adopted in accordance with the rules referred to in Article 7(6) (a) and (b), 7(7) and 7(8).

Article 9

Remuneration

1. The licensee shall pay an adequate remuneration to the rights-holder. The amount of the remuneration shall be determined by the Commission and specified in the Union compulsory licence.
2. The remuneration shall not exceed 4 % of total gross revenue generated by the licensee through the relevant activities under the Union compulsory licence.
3. When determining the remuneration, the Commission shall consider the following:
   (a) the economic value of the relevant activities authorised under the Union compulsory licence.
   (b) whether the rights-holder has received public support to develop the invention.
   (c) the degree to which development costs have been amortized by the rights-holder.
   (d) where relevant, the humanitarian circumstances relating to the granting of the Union compulsory licence.
4. If the published patent application for which a compulsory licence has been granted does not subsequently lead to the granting of a patent, the rights-holder shall refund the remuneration paid under this article to the licensee.

Article 10

Obligations to be fulfilled by the licensee

1. The licensee shall be authorised to exploit the protected invention covered by the Union compulsory license only under the following obligations:
   (a) the number of crisis-relevant products manufactured under the Union compulsory licence does not exceed what is necessary to meet the needs of the Union;
   (b) the relevant activities are carried out solely for the supply of the crisis-relevant products in the Union market;
   (c) the products manufactured under the Union compulsory licence are clearly identified, through specific labelling or marking, as being manufactured and marketed pursuant to this Regulation.
   (d) the products manufactured under the Union compulsory licence can be distinguished from products manufactured and marketed by the rights-holder or under a voluntary licence granted by the rights-holder by way of special packaging, colouring or shaping, provided that such distinction is feasible and does not have a significant impact on the price of the products;

(e) the packaging of the products manufactured under the Union compulsory licence and any associated marking or leaflet indicate that the products are subject to a Union compulsory licence under this Regulation and specify clearly that the products are exclusively for distribution in the Union and are not to be exported.

(f) before the marketing of the products manufactured under the Union compulsory licence, the licensee shall make available on a website the following information:

(1) the quantities of the products manufactured under the Union compulsory licence per Member State of manufacturing;

(2) the quantities of the products supplied under the Union compulsory licence per Member State of supply;

(3) the distinguishing features of the products under the Union compulsory licence.

The address of the website shall be communicated to the Commission. The Commission shall communicate the address of the website to the Member States.

2. In the event of a failure by the licensee to fulfil the obligations laid down in paragraph 1 of this Article the Commission may:

(a) terminate the Union compulsory licence in accordance with Article 14(3); or

(b) impose fines or periodic penalties on the licensee in accordance with Articles 15 and 16.

3. The European Anti-Fraud Office (OLAF) in cooperation with the relevant national authorities of the Member States may, at the request of the rights-holder or on its own initiative, request access to books and records kept by the licensee, for the purpose of checking whether the content and the conditions of the Union compulsory licence, and in general the provisions of this Regulation, have been complied with.

4. The Commission is empowered to adopt implementing acts establishing rules for the specific labelling or marking referred to in paragraph 1, point (c), and for the packaging, colouring and shaping referred to in point (d) as well as rules for their use and, where relevant, their positioning on the product. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 24(2).

Article 11

Prohibition of export

The export of products manufactured under a Union compulsory licence is prohibited.

Article 12

Customs control

1. The application of this article is without prejudice to other Union legal acts governing the export of products, in particular Articles 46, 47 and 267 of Regulation (EU) No 952/2013[14].

2. Customs authorities shall rely on the Union compulsory license and modifications thereof to identify products that may fall under the prohibition laid down in Article 11. For that purpose, risk information as regards each Union compulsory licence and any modification thereof shall be entered in the relevant customs risk management system. Customs authorities shall take such risk information into consideration when they carry out controls on products placed under the customs procedure 'export' in accordance with Articles 46 and 47 of Regulation (EU) No 952/2013.

3. Where customs authorities identify a product that may fall under the prohibition laid down in Article 11, they shall suspend its export. Customs authorities shall immediately notify the Commission of the suspension and provide it with all relevant information to enable it to establish whether the product was manufactured under a Union compulsory license. To assess whether the suspended products correspond to the Union compulsory license, the Commission may consult the relevant rights-holder.

4. Where the export of a product has been suspended in accordance with paragraph 3, the product shall be released for export provided that all the other requirements and formalities under Union or national law relating to such export have been fulfilled, and either of the following conditions is fulfilled:

   (a) the Commission has not requested the customs authorities to maintain the suspension within 10 working days after it was notified thereof;

   (b) the Commission has informed the customs authorities that the product is not manufactured under a Union compulsory licence.

5. Where the Commission concludes that a product manufactured under a Union compulsory licence does not comply with the prohibition laid down in Article 11, customs authorities shall not authorise its release for export. The Commission shall inform the concerned rights-holder of such non-compliance.

6. Where the release for export of a product has not been authorised:

   (a) where appropriate in view of the crisis or emergency context, the Commission may require customs authorities to oblige the exporter to take specific actions at their own costs, including supplying them to designated Member States, if need be, after rendering them compliant with Union law.

   (b) in all other cases, customs authorities may take any necessary measure to ensure that the product concerned is disposed of in accordance with national law consistent with Union law. Articles 197 and 198 of Regulation (EU) No 952/2013 shall apply accordingly.

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[14] REGULATION (EU) No 952/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 October 2013 laying down the Union Customs Code.

Article 13

Relations between rights-holder and licensee

1. The relations between the rights-holder and the licensee who has been granted a Union compulsory license shall act and cooperate with each other in good faith when performing rights and obligations under this Regulation.

2. In compliance with the good faith obligation, the rights-holder and the licensee shall make their best efforts to fulfil the objective of the Union compulsory licence, taking into account each other's interests.

Article 14

Review and termination of the Union compulsory licence

1. The Commission shall review the Union compulsory licence upon reasoned request by the rights-holder or the licensee or on its own initiative and shall, where needed, modify the specifications referred to in Article 8 by means of an implementing act. Where necessary, the Union compulsory licence shall be modified to indicate the complete list of rights and rights-holders covered by the compulsory licence.

2. Where necessary, the Commission shall decide upon reasoned request by the rights-holder or the licensee or on its own initiative on additional measures complementing the Union compulsory licence to ensure it achieves its objective as well as to facilitate and ensure the good collaboration between the rights-holder and the licensee.

3. A Union compulsory licence may be terminated by the Commission by means of an implementing act where the circumstances which led to it cease to exist and are unlikely to recur or where the licensee fails to comply with the obligations laid down in this Regulation.

4. When the Commission considers modifying, adopting additional measures as referred to in paragraph 2, or terminating the Union compulsory licence, it may consult the advisory body referred to in Article 6.

5. When terminating the Union compulsory licence, the Commission may require that the licensee, within a reasonable period of time, arrange for any goods in its possession, custody, power or control to be redirected or otherwise disposed of in the manner determined by the Commission in consultation with the rights-holder and at the expense of the licensee.

6. The implementing acts referred to in paragraph 1, 2 and 3 shall be adopted in accordance with the rules referred to in Article 7(6) (a) and (b), 7(7) and 7(8).

Article 15

Fines

1. The Commission may by decision impose on the licensee or the rights-holder fines not exceeding 6 % of their respective total turnover in the preceding business year where, intentionally or negligently:

(a) the licensee fails to comply with its obligations under Article 9(1) or Article 10(1);

(b) the rights-holder or the licensee fail to comply with the principle of good faith and cooperation referred to in Article 13; or

(c) the rights-holder or the licensee fail to comply with any obligation resulting from the additional measures complementing the Union compulsory licence as referred to in Articles 8(1)(h) and 14(2), as specified in the relevant implementing act.

2. In fixing the amount of the fine, regard shall be had to the gravity, to the recurrence of the infringement and to the duration of the infringement.

Article 16

Periodic penalty payments

1. The Commission may, by decision, impose on the licensee or the rights-holder periodic penalty payments not exceeding 5 % of their respective average daily turnover in the preceding business year per day and calculated from the date appointed by the decision, in order to compel:

(a) the licensee to put an end to an infringement of its obligations under Article 10(1);

(b) the licensee and the rights-holder to put an end to the infringement of Article 13; or

(c) the rights-holder or the licensee to comply with any obligation resulting from the additional measures complementing the Union compulsory licence as referred to in Articles 8(1)(h) and 14(2), as specified in the relevant implementing act.

2. Where the licensee or the rights-holder have satisfied the obligation which the periodic penalty payment was intended to enforce, the Commission may fix the definitive amount of the periodic penalty payment at a figure lower than that which would arise under the original decision.

Article 17

Limitation period for the imposition of fines and periodic penalty payments

1. The powers conferred on the Commission by Articles 15 and 16 shall be subject to a limitation period of five years.

2. Time shall begin to run on the day on which the infringement is committed. However, in the case of continuing or repeated infringements, time shall begin to run on the day on which the infringement ceases.

3. Any action taken by the Commission or by a competent authority of the Member States for the purpose of the investigation or proceedings in respect of an infringement shall interrupt the limitation period for the imposition of fines or periodic penalty payments.

4. Each interruption shall start time running afresh. However, the limitation period for the imposition of fines or periodic penalty payments shall expire at the latest on the day on which a period equal to twice the limitation period has elapsed without the Commission having imposed a fine or a periodic penalty payment. That period shall be extended by the time during which the limitation period has been suspended pursuant to paragraph 5.

5. The limitation period for the imposition of fines or periodic penalty payments shall be suspended for as long as the decision of the Commission is the subject of proceedings pending before the Court of Justice of the European Union.

Article 18

Limitation period for the enforcement of fines and periodic penalty payments

1. The power of the Commission to enforce decisions taken pursuant to Articles 15 and 16 shall be subject to a limitation period of five years.

2. Time shall begin to run on the day on which the decision becomes final.

3. The limitation period for the enforcement of penalties shall be interrupted:

   (a) by notification of a decision varying the original amount of the fine or periodic penalty payment or refusing an application for variation;

   (b) by any action of the Commission, or of a Member State acting at the request of the Commission, designed to enforce payment of the fine or periodic penalty payment.

4. Each interruption shall start time running afresh.

5. The limitation period for the enforcement of penalties shall be suspended for so long as:

   (a) time to pay is allowed;

   (b) enforcement of payment is suspended pursuant to a decision of the Court of Justice of the European Union or to a decision of a national court.

Article 19

Right to be heard and access to the file

1. Before adopting a decision pursuant to Article 15 or 16, the Commission shall give the licensee or the rights-holder the opportunity of being heard on the alleged infringement which is to be made subject to a fine or periodic penalty payments.

2. The licensee or the rights-holder may submit its observations on the alleged infringement within a reasonable period set by the Commission, which may not be less than 14 days.

3. The Commission shall base its decisions only on objections on which the parties concerned have been able to comment.

4. The rights of defence of the parties concerned shall be fully respected in the proceedings. They shall be entitled to have access to the Commission's file under the terms of a negotiated disclosure, subject to the legitimate interest of the licensee or

the rights-holder or other person concerned in the protection of their commercially sensitive information and trade secrets. The Commission shall have the power to adopt decisions setting out such terms of disclosure in case of disagreement between the parties. The right of access to the file of the Commission shall not extend to confidential information and internal documents of the Commission, other competent authorities or other public authorities of the Member States. In particular, the right of access shall not extend to correspondence between the Commission and those authorities. Nothing in this paragraph shall prevent the Commission from disclosing and using information necessary to prove an infringement.

5. If the Commission considers it necessary, it may also hear other natural or legal persons. Applications to be heard on the part of such persons shall, where they show a sufficient interest, be granted.

Article 20

Publication of decisions

1. The Commission shall publish the decisions it adopts pursuant to Article 15 and Articles 16. Such publication shall state the names of the parties and the main content of the decision, including any fines or penalties imposed.

2. The publication shall have regard to the rights and legitimate interests of the licensee, the rights-holder or any third parties in the protection of their confidential information.

Article 21

Review by the Court of Justice of the European Union

In accordance with Article 261 TFEU, the Court of Justice of the European Union has unlimited jurisdiction to review decisions by which the Commission has imposed fines or periodic penalty payments. It may cancel, reduce or increase the fine or periodic penalty payment imposed.

Article 22

Reporting on national compulsory licences

When a national compulsory licence has been granted for the purpose of addressing a national crisis or emergency, the Member State shall notify the Commission of the granting of the licence and of the specific conditions attached to it. The information provided shall include the following:

(a) the purpose of the national compulsory licence and its legal basis in national law;

(b) the name and address of the licensee;

(c) the products concerned and, to the extent possible, the concerned intellectual property rights and rights-holders;

(d) the remuneration to be paid to the rights-holder;

(e) the quantity of products to be supplied under the licence;

(f) the duration of the licence.

Article 23

Amendments to Regulation (EC) No 816/2006

Regulation (EC) No 816/2006 is amended as follows:

(a) The following Article 18a is inserted:

"Article 18a

Union compulsory licence

1. The Commission may grant a compulsory licence where the activities of manufacture and sale for export spread across different Member States and would therefore require compulsory licences for the same product in more than one Member State.

2. Any person may submit an application for a compulsory licence under paragraph 1. The application shall fulfil the requirements laid down in Article 6 (3) and shall specify the Member States to be covered by the compulsory licence.

3. The compulsory licence granted in accordance with paragraph 1 shall be subject to the conditions set out in Article 10 and shall specify that it is applicable to the whole territory of the Union.

4. In the event of an application referred to in paragraph 2 under this Article, the competent authority referred to in Articles 1 to 11, 16 and 17 shall be the Commission.

5. The Commission is empowered to adopt implementing acts in order to:

(a) grant a compulsory licence;

(b) reject the application for a compulsory licence;

(c) amend or terminate the compulsory licence.

Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 18b (2). On duly justified imperative grounds of urgency relating to the impacts of the public health problems, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 18b (3)."

(b) The following Article 18b is inserted:

"Article 18b
Committee Procedure

1. The Commission shall be assisted by a committee ('the Compulsory Licensing Committee'). That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 4 thereof, shall apply."

Article 24

Committee Procedure

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.
3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.
4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 4 thereof, shall apply.

Article 25

Evaluation

The Commission shall, by the last day of the third year following the granting of the Union compulsory licence in accordance with Article 7, present an evaluation report to the Council, the European Parliament and the European Economic and Social Committee on the application of this Regulation.

Article 26

Entry into force

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*