Basic information

2023/0130(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	Awaiting Council's 1st reading position
Supplementary protection certificate for medicinal products. Recast **Subject** 3.50.01.05 Research specific areas 3.50.16 Industrial property, European patent, Community patent, design and pattern 4.20.05 Health legislation and policy	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
JURI Legal Affairs	WÖLKEN Tiemo (S&D)	18/11/2024
	Shadow rapporteur ZARZALEJOS Javier (EPP) ZŁOTOWSKI Kosma (ECR) SAEIDI Arash (The Left)	

Former committee responsible	Former rapporteur	Appointed
JURI Legal Affairs	WÖLKEN Tiemo (S&D)	19/07/2023

Former committee for opinion	Former rapporteur for opinion	Appointed
INTA International Trade	The committee decided not to give an opinion.	
ENVI Environment, Public Health and Food Safety	The committee decided not to give an opinion.	
IMCO Internal Market and Consumer Protection	The committee decided not to give an opinion.	

Former committee for opinion on the recast technique	Former rapporteur for opinion	Appointed
JURI Legal Affairs	ADAMOWICZ Magdalena (EPP)	01/01/2023

Council of the European Union	
European Commission	Commission DG: Internal Market, Industry, Entrepreneurship and SMEs — Commissioner: BRETON Thierry
European Economic and Social Committee	

Key events

Date	Event	Reference	Summary
27/04/2023	Legislative proposal published	COM(2023)0231	Summary
11/09/2023	Committee referral announced in Parliament, 1st reading		
24/01/2024	Vote in committee, 1st reading		
01/02/2024	Committee report tabled for plenary, 1st reading	A9-0022/2024	Summary
27/02/2024	Debate in Parliament		
28/02/2024	Decision by Parliament, 1st reading	T9-0099/2024	Summary
28/02/2024	Results of vote in Parliament		
13/11/2024	Resumption of business from the previous parliamentary term		

Technical information

Procedure reference	2023/0130(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Recast
Legislative instrument	Regulation
Legal basis	Rules of Procedure EP 113 Treaty on the Functioning of the European Union TFEU 114-p1
Other legal basis	Rules of Procedure EP 165
Mandatory consultation of other institutions	European Economic and Social Committee
Stage reached in procedure	Awaiting Council's 1st reading position
Committee dossier	JURI/9/11937

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary

Committee draft report		PE753.704	13/10/2023	
Specific opinion	JURI	PE756.057	09/11/2023	
Amendments tabled in committee		PE756.105	14/11/2023	
Committee report tabled for plenary, 1st reading/single reading		A9-0022/2024	01/02/2024	Summary
Text adopted by Parliament, 1st reading/single reading		T9-0099/2024	28/02/2024	Summary

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2023)0231	27/04/2023	Summary
Document attached to the procedure	SWD(2023)0117	27/04/2023	
Document attached to the procedure	SWD(2023)0118	27/04/2023	
Document attached to the procedure	SWD(2023)0119	27/04/2023	
Commission response to text adopted in plenary	SP(2024)270	08/07/2024	

National parliaments

Document type	Parliament /Chamber	Reference	Date	Summary
Contribution	DE_BUNDESRAT	COM(2023)0231	09/11/2023	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES2306/2023	20/09/2023	

Additional information

Source	Document	Date
European Commission	EUR-Lex	

Meetings with interest representatives published in line with the Rules of Procedure

Other Members

Transparency

Name	Date	Interest representatives

PIPEREA Gheorghe	09/10/2024	MedTech Europe
VOSS Axel	18/12/2023	nv Roche sa

Supplementary protection certificate for medicinal products. Recast

2023/0130(COD) - 28/02/2024 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 518 votes to 29, with 70 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council on the supplementary protection certificate for medicinal products (recast).

As a reminder, this proposal for a recast of Regulation (EC) No 1610/96 lays down the rules on the supplementary protection 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 plant protection product, to an administrative authorisation procedure.

According to the Consultative Working Party of the legal services of the European Parliament, the Council and the Commission, the Commission proposal does not include any substantive amendments other than those identified as such in the proposal and whereas, as regards the codification of the unchanged provisions of the earlier acts together with those amendments, the proposal contains a straightforward codification of the existing texts, without any change in their substance.

The European Parliament's position adopted at first reading under the ordinary legislative procedure amends the Commission's proposal as follows:

Content of the application for a certificate

The application for a certificate should contain if applicable, the consent of the third party as well as information on any direct public financial support received for research related to the development of the product. The authority should publish, without undue delay, notification of the fact that a certificate has been granted.

Publication of the centralised application

If the centralised application complies, or if an application for an extension of the duration of certificates complies with the provisions laid down in the Regulation, the Office should publish the application, in the Register without undue delay and no later than five working days after.

Examination of the centralised application

The Office should adopt an examination opinion within 6 months after publication of the centralised application in the Register. Whenever duly justified for reasons of urgency, the applicant may submit a request for an expedited procedure. Where the request for an expedited examination procedure is deemed justified, the Office should adopt an examination opinion within 4 months from the publication of the application for a unitary certificate. Whenever the expedited procedure applies, observations should be submitted within six weeks after publication of the application in the Register.

Opposition

Within a period of 2 months following the publication of the examination opinion in respect of a centralised application, any person may file with the Office a notice of opposition to that opinion. The notice of opposition should contain any evidence the opponent relies on in support of the opposition. The Office should issue a decision on the opposition including a detailed reasoning for that decision within 6 months, unless the complexity of the case requires a longer period.

In cases where several oppositions have been filed against an examination opinion, the Office should deal with the oppositions jointly and issue one single decision in regards to all oppositions filed. Full transparency should be ensured throughout the whole opposition proceeding, which shall be open, whenever possible, to public participation.

Competent national authorities

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, that authority should designate one or more examiners to be involved in the examination of one or more centralised applications, on the basis of their relevant expertise and of their experience in the field.

Examination panels

The assessments should be carried out by an examination panel consisting of one member of the Office and two examiners from two different participating national competent authorities. When setting up an examination panel, the Office should ensure the following:

- **relevant expertise and sufficient experience** in the examination of patents and supplementary protection certificates, ensuring, in particular, that at least one examiner has a minimum of five years of experience in the examination of patents and supplementary protection certificates;

- where possible, **geographical balance** amongst the participating offices.

Appeal

Any reply to statement of the grounds of appeal should be submitted in writing within three months from the date of the notification of the statement of the grounds of appeal. Where applicable, the Office should set a date for an oral hearing within three months after the filing of the reply to the grounds of appeal or within six months of the filing of grounds of appeal, whichever is earlier. The Office should issue a written decision within three months of the oral hearing or of the filing of the reply to the statement of grounds of appeal, as applicable.

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.

Implementation of an examination of a centralised application at national level

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. The Office should ensure the transmission takes place within a timeframe allowing national patent offices to grant the certificate or reject the application, as applicable, before the expiry of the basic patent.

Register

The information provided in the register should not be used in regards to practices of patent linkage and no regulatory or administrative decisions related to **generics or biosimilars**, such as marketing authorisations, pricing and reimbursement decisions or tender bids to the existence of the SPC, should be based on information provided for in the register.

Supplementary protection certificate for medicinal products. Recast

2023/0130(COD) - 27/04/2023 - Legislative proposal

PURPOSE: to simplify the EU's supplementary protection certificates (SPC) system as regards national SPCs for medicinal products and improve its transparency and efficiency.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: a **supplementary protection certificate** (SPC) is an intellectual property right that extends the term of a patent (up to five years) for a human or veterinary pharmaceutical or plant protection product that has been authorised by regulatory authorities, thereby encouraging innovation and promoting growth and employment in these sectors.

However, SPC protection is only available at national level. As a result, the current system suffers from fragmentation, leading to complex and costly procedures and legal uncertainty.

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.

The Commission's intellectual property action plan of November 2020, which builds on the SPC evaluation, highlighted the need to tackle the remaining fragmentation of the EU's intellectual property system.

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.

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.

In addition to this proposal, parallel proposals are being made to create a centralised procedure for the grant of national certificates for medicinal products, a unitary certificate for plant protection products and a unitary certificate for medicinal products.

CONTENT: this **proposal for a recast of Regulation (EC) No 1610/96** lays down the rules on the supplementary protection 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 plant protection product, to an administrative authorisation procedure.

The SPC reform introduces a **centralised examination procedure**, implemented by the EU Intellectual Property Office (EUIPO), in close cooperation with the EU's national intellectual property (IP) offices. Under this scheme, a single application will be subject to a **single examination** process which, if positive, will result in the **grant of a unitary SPC and of national SPCs** in further Member States.

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.

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 new rules, however, do not alter the competence of national IP Offices in granting national SPCs, following the binding opinion issued by the examination authority, run by the EUIPO. The reform of the national SPC regime does also not alter the eligibility criteria to obtain an SPC, which remain the ones currently foreseen in Article 3 in the existing legislation for both pharmaceutical products and plant protection products.

Supplementary protection certificate for medicinal products. Recast

2023/0130(COD) - 01/02/2024 - Committee report tabled for plenary, 1st reading/single reading

The Committee on Legal Affairs adopted the report by Tiemo WÖLKEN (S&D, DE) on the proposal for a regulation of the European Parliament and of the Council on the supplementary protection certificate for medicinal products (recast).

As a reminder, this proposal for a recast of Regulation (EC) No 1610/96 lays down the rules on the supplementary protection 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 plant protection product, to an administrative authorisation procedure.

According to the Consultative Working Party of the legal services of the European Parliament, the Council and the Commission, the Commission proposal does not include any substantive amendments other than those identified as such in the proposal and whereas, as regards the codification of the unchanged provisions of the earlier acts together with those amendments, the proposal contains a straightforward codification of the existing texts, without any change in their substance.

The committee responsible recommended that the European Parliament's position adopted at first reading under the ordinary legislative procedure should amend the proposal as follows:

Content of the application for a certificate

The application for a certificate should contain if applicable, the consent of the third party as well as information on **any direct public financial support received for research related to the development of the product**. The authority should publish, without undue delay, notification of the fact that a certificate has been granted. The notification should contain information on any direct public financial support received for research related to the development of the product.

Publication of the centralised application

If the centralised application complies, or if an application for an extension of the duration of certificates complies with the provisions laid down in the Regulation, the Office should publish the application, in the Register without undue delay and no later than five working days after.

Examination of the centralised application

The Office should adopt an examination opinion within 6 months after publication of the centralised application in the Register. Whenever duly justified for reasons of urgency, the applicant may submit a request for an **expedited procedure**. Where the request for an expedited examination procedure is deemed justified, the Office should adopt an examination opinion within 4 months from the publication of the application for a unitary certificate. Whenever the expedited procedure applies, observations should be submitted within six weeks after publication of the application in the Register.

Opposition

Within a period of 2 months following the publication of the examination opinion in respect of a centralised application, any person may file with the Office a notice of opposition to that opinion. The notice of opposition should contain any **evidence** the opponent relies on in support of the opposition. The Office should issue a decision on the opposition including a detailed reasoning for that decision within 6 months, unless the complexity of the case requires a longer period.

In cases where several oppositions have been filed against an examination opinion, the Office should deal with the oppositions jointly and issue one single decision in regards to all oppositions filed. Full transparency should be ensured throughout the whole opposition proceeding, which shall be open, whenever possible, to public participation.

Competent national authorities

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, that authority should designate one or more examiners to be involved in the examination of one or more centralised applications, on the basis of their **relevant expertise and of their experience** in the field.

Examination panels

The assessments should be carried out by an examination panel consisting of one member of the Office and two examiners from two different participating national competent authorities. When setting up an examination panel, the Office should ensure the following:

- **relevant expertise and sufficient experience** in the examination of patents and supplementary protection certificates, ensuring, in particular, that at least one examiner has a minimum of five years of experience in the examination of patents and supplementary protection certificates;

- where possible, geographical balance amongst the participating offices.

Appeal

Any reply to statement of the grounds of appeal should be submitted in writing within three months from the date of the notification of the statement of the grounds of appeal. Where applicable, the Office should set a date for an oral hearing within three months after the filing of the reply to the grounds of appeal or within six months of the filing of grounds of appeal, whichever is earlier. The Office should issue a written decision within three months of the oral hearing or of the filing of the reply to the statement of grounds of appeal, as applicable.

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.

Implementation of an examination of a centralised application at national level

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. The Office should ensure the transmission takes place within a timeframe allowing national patent offices to grant the certificate or reject the application, as applicable, **before the expiry of the basic patent**.

Register

The information provided in the register should not be used in regards to practices of patent linkage and no regulatory or administrative decisions related to **generics or biosimilars**, such as marketing authorisations, pricing and reimbursement decisions or tender bids to the existence of the SPC, should be based on information provided for in the register.