Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2023/0127(COD)
Unitary supplementary certificate for medicinal products Amending Regulation 2006/1901 2004/0217(COD) Amending Regulation 2013/608 2011/0137(COD) Amending Regulation 2017/1001 2016/0345(COD) Subject 3.50.15 Intellectual property, copyright 3.50.16 Industrial property, European patent, Community patent, design and pattern 4.20.04 Pharmaceutical products and industry Legislative priorities Joint Declaration 2023-24	Awaiting Council's 1st reading position

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
JURI Legal Affairs		19/07/2023
	S&D WÖLKEN Tiemo	
	Shadow rapporteur	
	epp ZARZALEJOS Javier	
	renew europe. VÁZQUEZ LÁZARA Adrián	
	TOUSSAINT Marie	
	MAUREL Emmanuel	

Committee for opinion	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.	

Council of the European Union

European Commission

Commission DG	Commissioner
Internal Market, Industry, Entrepreneurship and SMEs	BRETON Thierry

Key events

27/04/2023	Legislative proposal published	COM(2023)0222	Summary
11/09/2023	Committee referral announced in Parliament, 1st reading		
24/01/2024	Vote in committee, 1st reading		
31/01/2024	Committee report tabled for plenary, 1st reading	A9-0019/2024	Summary
27/02/2024	Debate in Parliament		
28/02/2024	Decision by Parliament, 1st reading	T9-0097/2024	Summary

Technical information

Procedure reference	2023/0127(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Amending Regulation 2006/1901 2004/0217(COD) Amending Regulation 2013/608 2011/0137(COD) Amending Regulation 2017/1001 2016/0345(COD)
Legal basis	Treaty on the Functioning of the EU TFEU 118-p1
Other legal basis	Rules of Procedure EP 159
Stage reached in procedure	Awaiting Council's 1st reading position
Committee dossier	JURI/9/11896

Documentation gateway

Legislative proposal		COM(2023)0222	27/04/2023	EC	Summary
Document attached to the procedure		SWD(2023)0117	27/04/2023	EC	
Document attached to the procedure		SWD(2023)0118	27/04/2023	EC	
Document attached to the procedure		SWD(2023)0119	27/04/2023	EC	
Economic and Social Committee: opinion, report		CES2306/2023	20/09/2023	ESC	
Committee draft report		PE753.703	13/10/2023	EP	
Amendments tabled in committee		PE756.103	13/11/2023	EP	
Committee report tabled for plenary, 1st reading/single reading		A9-0019/2024	31/01/2024	EP	Summary
Text adopted by Parliament, 1st reading/single reading		T9-0097/2024	28/02/2024	EP	Summary

Unitary supplementary certificate for medicinal products

PURPOSE: to simplify the EU Supplementary Protection Certificate (SPC) system and improve its transparency and efficiency, by creating a unitary certificate for medicinal products.

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 Commissions intellectual property action plan of November 2020, which builds on the SPC evaluation, highlighted the need to tackle the remaining fragmentation of the EUs 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.

There is a clear need to complement the unitary patent (European patent with unitary effect) with a unitary SPC. The proposed creation of a unitary SPC will be fully compatible with the unitary patent system provided for in Regulation (EU) No 1257/2012 and the Unified Patent Court Agreement (UPCA). The unitary patent will enter into force on 1 June 2023, allowing a single patent covering all participating Member States in a unitary manner.

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 centralised procedure for the grant of national certificates for plant protection products, and a unitary certificate for plant products.

CONTENT: this proposal lays down rules on the unitary supplementary protection 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.

The proposed SPC reform includes the creation of a unitary SPC, complementing the unitary patent that will enter into force on 1 June 2023. The unitary SPC will also incentivise innovators to use the unitary patent. In the absence of a unitary SPC, a unitary patent could be extended only by means of national SPCs, i.e. in a non-unitary manner, leading to greater administrative burden and costs.

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.

The SPC centralised procedure can be used by any company, start-up, research organisation, innovator, etc. that holds a valid patent on a medicinal product or a plant protection product, and a corresponding marketing authorisation in the EU. Applicants will be able to file a combined application' with a view to the grant of both a unitary SPC and national SPC for additional Member States not covered by the unitary patent. This application will be subject to a single examination which, if positive, will result in the grant of a unitary SPC (for those 17 Member States currently participating in the unitary patent system) and of national SPCs in further Member States.

Unitary supplementary certificate for medicinal products

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 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.

As a reminder, the proposal lays down rules on the unitary supplementary protection 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.

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:

Application for a unitary certificate

The application for a unitary certificate should be lodged electronically, using the formats made available by the Office.

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 for which the SPC is requested.

The application for a unitary certificate and, where applicable, the application for an extension of the duration of a unitary certificate, should be lodged in electronic form with the Office. The Office should put the necessary arrangements in place in order to ensure that exchanges of data and information are done electronically and that the commercially confidential nature of the information exchanged is protected.

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 an application for a unitary certificate, any person may file with the Office a notice of opposition to that opinion. The notice of opposition should include any evidence the opponent relies on in support of the opposition.

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 respect of all oppositions filed.

Full transparency should be ensured throughout the whole opposition proceeding, which shall be open, whenever possible, to public participation.

Examination panels

The assessments should be conducted by an examination panel including one member of the Office as well as two examiners from two different participating competent national 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.

Appeals

Any reply to the statement of grounds of appeal should be submitted in writing no later than three months from the date of the filing of the statement of grounds of appeal. The Office should, where applicable, fix a date for oral proceedings within three months of the filing of the reply or within six months following the filing of the statement of grounds of appeal, whichever is earlier. The Office should issue a written decision within three months of the date 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 concerning applications for unitary certificates, due consideration should be given to their previous experience in matters concerning supplementary protection certificates or patent law.

Register

Public authorities should not use information in the Register for practices of patent linkage. No regulatory or administrative decisions related to generics or biosimilars should be based on information in the Register. Information in the Register should not be used for refusal, suspension, delay, withdrawal or revocation of marketing authorisations, pricing and reimbursement decisions or tender bids.

Taking of evidence

If the Office or the relevant panel considers it necessary for a party, witness or expert to give evidence orally, it should issue a summons to the person concerned to appear before it. Where an expert is summonsed, the Office or the relevant panel, as the case may be, should verify that that expert is free of any conflict of interest.

Evaluation

By five years after the date of application, and every five years thereafter, the Commission should present a report on the main findings. Special emphasis should be given to the effects of opposition and whether the possibility of opposition leads to significant delays in granting unitary certificates and to the effects of this Regulation on the recovery of research and development investments.

Unitary supplementary certificate for medicinal products

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 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.

As a reminder, the proposal lays down rules on the unitary supplementary protection 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.

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

Conditions for obtaining a certificate

The proposal provides that 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.

According to Members, the same principle should apply mutatis mutandis to applications submitted by the holder concerning the same product for which one or more certificates or unitary certificates have been previously granted to other different holders of different patents.

Content of the application for a unitary 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 for which the SPC is requested.

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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 publish the notice of examination in the register as soon as possible after it is issued. It 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 an application for a unitary certificate, any person may file with the Office a notice of opposition to that opinion. The notice of opposition should include any evidence the opponent relies on in support of the opposition.

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Full transparency should be ensured throughout the whole opposition proceeding, which should be open, whenever possible, to public participation.

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Transparency

ZARZALEJOS Javier	Shadow rapporteur	JURI	23/01/2024	Chamber of Commerce of the United States of America
ZARZALEJOS Javier	Shadow rapporteur	JURI	05/12/2023	European Federation of Pharmaceutical Industries and Associations
ZARZALEJOS	Shadow	JURI	04/12/2023	Bristol-Myers Squibb

Javier	rapporteur			Company
VÁZQUEZ LÁZARA Adrián	Shadow rapporteur	JURI	08/11/2023	MEDICINES FOR EUROPE
ZARZALEJOS Javier	Shadow rapporteur	JURI	08/11/2023	European Federation of Pharmaceutical Industries and Associations
ZARZALEJOS Javier	Shadow rapporteur	JURI	07/11/2023	Johnson & Johnson
ZARZALEJOS Javier	Shadow rapporteur	JURI	06/11/2023	Bristol-Myers Squibb Company
WÖLKEN Tiemo	Rapporteur	JURI	11/10/2023	EUIPO
WÖLKEN Tiemo	Rapporteur	JURI	04/10/2023	Bristol-Myers Squibb Company
WÖLKEN Tiemo	Rapporteur	JURI	19/07/2023	European Federation of Pharmaceutical Industries and Associations
WÖLKEN Tiemo	Member	26/06/2023	Permanent Representation of the Federal Republic of Germany to the European Union	