Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2023/0129(COD)
Compulsory licensing of patents in crisis situations Amending Regulation 2006/816 2004/0258(COD) Subject 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	renew europe. VÁZQUEZ LÁZARA Adrián Shadow rapporteur epp DIDIER Geoffroy S&D WÖLKEN Tiemo HAUTALA Heidi MAUREL Emmanuel	26/06/2023
Committee for opinion	**Rapporteur for opinion**	**Appointed**
DEVE Development	The committee decided not to give an opinion.	
INTA International Trade (Associated committee)	SCHOLZ Helmut	24/05/2023
ENVI Environment, Public Health and Food Safety	The committee decided not to give an opinion.	
ITRE Industry, Research and Energy	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
European Economic and Social Committee		

Key events

27/04/2023	Legislative proposal published	COM(2023)0224	Summary
12/06/2023	Committee referral announced in Parliament, 1st reading		
05/10/2023	Referral to associated committees announced in Parliament		
13/02/2024	Vote in committee, 1st reading		
19/02/2024	Committee report tabled for plenary, 1st reading	A9-0042/2024	Summary
12/03/2024	Debate in Parliament		
13/03/2024	Results of vote in Parliament		
13/03/2024	Decision by Parliament, 1st reading	T9-0143/2024	Summary

Technical information

Procedure reference	2023/0129(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Amending Regulation 2006/816 2004/0258(COD)
Legal basis	Treaty on the Functioning of the EU TFEU 207; Treaty on the Functioning of the EU TFEU 114; Rules of Procedure EP 57
Mandatory consultation of other institutions	European Economic and Social Committee
Stage reached in procedure	Awaiting Council's 1st reading position
Committee dossier	JURI/9/11926

Documentation gateway

Legislative proposal		COM(2023)0224	27/04/2023	EC	Summary
Document attached to the procedure		SEC(2023)0173	27/04/2023	EC	
Document attached to the procedure		SWD(2023)0120	27/04/2023	EC	
Document attached to the procedure		SWD(2023)0121	27/04/2023	EC	
Document attached to the procedure		SWD(2023)0122	27/04/2023	EC	
Economic and Social Committee: opinion, report		CES2306/2023	20/09/2023	ESC	
Committee draft report		PE753.706	16/10/2023	EP	
Amendments tabled in committee		PE756.107	14/11/2023	EP	

Committee opinion	INTA	PE753.730	04/12/2023	EP	
Committee report tabled for plenary, 1st reading/single reading		A9-0042/2024	19/02/2024	EP	Summary
Text adopted by Parliament, 1st reading/single reading		T9-0143/2024	13/03/2024	EP	Summary

Additional information		
Research document	Briefing	02/02/2024

Compulsory licensing of patents in crisis situations

PURPOSE: to establish a new EU-wide compulsory licensing instrument.

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: 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.

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.

Voluntary licensing agreements usually suffice to licence the patent rights on these products and allow their supply in the Union territory. However, they 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.

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.

Currently, legislation on compulsory licensing of patents in the EU is fragmented: EU countries regulate their own national compulsory licensing schemes, subject to different conditions, scopes, and procedures. In addition, national compulsory licensing schemes are designed to meet the needs of the population of the issuing Member State and to satisfy the public interest of that Member State only. These purely national systems are unable to rely on cross-border value chains and therefore unfit to tackle EU crises.

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.

CONTENT: this proposal lays down the procedure and conditions for granting 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.

More specifically, it establishes Union compulsory licensing of the following intellectual property rights in force in one or more Member States:

- patents, including published patent applications;

- utility models; or

- supplementary protection certificates.

An effective EU compulsory licensing mechanism will:

- serve as an effective tool in crisis times as a last resort when voluntary agreements do not work;

- ensure an appropriate territorial reach of compulsory licensing to cover cross-border supply chains;

- build on EU crisis mechanisms.

Compulsory licensing of patents in crisis situations

The Committee on Legal Affairs adopted the report by Adrián VÁZQUEZ LÁZARA (Renew, ES) on 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.

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:

Subject matter

This Regulation has the objective to ensure that a temporary and non-exclusive Union compulsory license may be granted to protect the public interest in the context of cross-border crisis or emergency situations in the Union.

The Regulation aims to lay down rules on the procedure and conditions for the granting as a last resort 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.

Union compulsory licence

The Commission may grant a Union compulsory licence in the event of a crisis mode or an emergency mode in case no voluntary agreement with a view to ensuring the supply of crisis-relevant products has been reached between right-holder and the potential licensee within four weeks.

The Union compulsory license that may be granted by the Commission should:

- have a strict limitation concerning scope, field of use, necessary quantities, and a duration that is fully in line with the specific purpose for which the compulsory licence is issued, as well as strictly linked to the scope and duration of the crisis or emergency mode under which it is granted within the Union;

- be strictly limited to the relevant and properly justified activities of crisis-relevant products in the Union;

- only be granted against payment of an adequate remuneration to the rights-holder;

- be strictly limited to the precisely defined territory of the Union;

- clearly state that the licensee is responsible for any liability or warranties related to the production and distribution of crisis-relevant products, excluding the rights-holder from product liability claims.

Advisory body

The advisory body responsible for the EU crisis or emergency mechanism should assist and advise the Commission in identifying and consulting right-holders or their representatives and potential licensees and in consulting other stakeholders and economic operators, including industry, academia and civil society.

The Commission should invite representatives of the European Parliament as observers to the relevant meetings of the advisory bodies, where possible. It should take the utmost account of the opinion of the advisory body. Where the Commission does not follow the opinion of the advisory body, it shall explain the reasons for its decision to the advisory body.

Remuneration

The amended text stipulated that the rights-holder should receive the remuneration within a pre-established timeframe as agreed with the Commission. The remuneration should be determined based on the total gross revenue generated by the licensee from the pertinent activities governed by the Union compulsory licence.

Where appropriate, the Commission should oblige the rights-holder to disclose the trade secrets which are strictly necessary in order to achieve the purpose of the Union compulsory licence. In such cases, rights holders should receive an adequate remuneration.

Obligations to be fulfilled by the licensee

Information acquired in relation to the Union compulsory licence should be treated with utmost confidentiality, refraining, in particular, from making trade secrets available to a third party without the consent of the Commission, which should inform and consult the rights-holder in this regard.

Additional measures complementing the Union compulsory licence

Where necessary, the Commission should decide, upon a reasoned request from 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.

Where strictly necessary, the Commission should request the disclosure of the rights-holders trade secrets to the licensee to the extent required to provide him with the necessary know-how to achieve the objective for which the Union compulsory licence is granted under this Regulation. The lawful uses of the trade secrets by the licensee should be strictly limited to the manufacturing of the crisis-relevant products in view of fulfilling the objective for which the Union compulsory licence has been granted.

Where the rights-holder is requested to disclose his trade secrets, the Commission should, prior to the disclosure of trade secrets, order the licensee to put in place all appropriate technical and organisational measures that the rights-holder reasonably identifies as necessary to preserve the confidentiality of trade secrets, in particular in relation to third parties.

If the licensee fails to implement the necessary measures required by the Commission, the Commission may withhold or, as the case may be, suspend the disclosure of trade secrets until the situation is corrected by the licensee.

Compulsory licensing of patents in crisis situations

The European Parliament adopted by 484 votes 121, with 20 abstentions, a legislative resolution on 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.

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

Subject matter

The aim of the Regulation is to ensure access to crisis-relevant patented products needed to address crises in the internal market. In concrete terms, the Regulation aims to ensure that a temporary and non-exclusive Union compulsory license may be granted to protect the public interest in the context of cross-border crisis or emergency situations in the Union.

The Regulation aims to lay down rules on the procedure and conditions for the granting as a last resort 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.To this end, if no prior voluntary agreement has been reached within four weeks between right holder and licensee, the Commission may grant a Union compulsory license.

Union compulsory licence

The Union compulsory license that may be granted by the Commission should:

- have a strict limitation concerning scope, field of use, necessary quantities, and a duration that is fully in line with the specific purpose for which the compulsory licence is issued, as well as strictly linked to the scope and duration of the crisis or emergency mode under which it is granted within the Union;

- be strictly limited to the relevant and properly justified activities of crisis-relevant products in the Union;

- only be granted against payment of an adequate remuneration to the rights-holder;

- be strictly limited to the precisely defined territory of the Union;

- clearly state that the licensee is responsible for any liability or warranties related to the production and distribution of crisis-relevant products, excluding the rights-holder from product liability claims.

Advisory body

The advisory body responsible for the EU crisis or emergency mechanism should assist and advise the Commission in identifying and consulting right-holders or their representatives and potential licensees and in consulting other stakeholders and economic operators, including industry, academia and civil society.

The Commission should invite representatives of the European Parliament as observers to the relevant meetings of the advisory bodies, where possible. It should take the utmost account of the opinion of the advisory body. Where the Commission does not follow the opinion of the advisory body, it shall explain the reasons for its decision to the advisory body.

Remuneration

The amended text stipulated that the rights-holder should receive the remuneration within a pre-established timeframe as agreed with the Commission. The remuneration should be determined based on the total gross revenue generated by the licensee from the pertinent activities governed by the Union compulsory licence.

Where appropriate, the Commission should oblige the rights-holder to disclose the trade secrets which are strictly necessary in order to achieve the purpose of the Union compulsory licence. In such cases, rights holders should receive an adequate remuneration.

Obligations to be fulfilled by the licensee

Information acquired in relation to the Union compulsory licence should be treated with utmost confidentiality, refraining, in particular, from making trade secrets available to a third party without the consent of the Commission, which should inform and consult the rights-holder in this regard.

Additional measures complementing the Union compulsory licence

Where appropriate, the Commission should oblige the rights-holder to disclose the trade secrets which are strictly necessary in order to achieve the purpose of the Union compulsory licence. In such cases, rights holders should receive an adequate remuneration.

Disclosure could encompass, without being exhaustively limited to, the comprehensive transfer of necessary technology, expertise, data, samples, and reference products essential for production and obtaining market authorisation in collaboration with the licensee, taking into account both the rights-holder and the licensees interests.

The Commission should require the licensee(s) to put in place all appropriate measures reasonably identified by the rights-holder, including contractual, technical and organisational measures, to ensure the confidentiality of trade secrets, in particular vis-à-vis third parties and the protection of the legitimate interests of all parties. To that end, right holders should identify trade secrets prior to the disclosure.

Where the licensee fails to implement the measures required for preserving the confidentiality of the trade secrets, the Commission should be able to withhold or suspend the disclosure of trade secrets until the situation is corrected by the licensee. Any use, acquisition or disclosure of trade secrets which would not be necessary to fulfil the objective of the Union compulsory licence or which would go beyond the duration of the Union compulsory license should be considered to be unlawful.

Conditions

The compulsory licence should specify that it is applicable to the whole territory of the Union and should be subject to the following conditions: (i) the licence granted is non-assignable; (ii) the expected amount of product(s) manufactured under the licence are not exceed what is necessary to meet the needs of the importing country or countries cited in the application; (iii) the duration of the licence is indicated; (iv) the licence is strictly limited to all acts necessary for the purpose of manufacturing the product in question for export and distribution in the country or countries cited in the application; (v) products made under the licence are clearly identified, through specific labelling or marking, as being produced pursuant to this Regulation.

Transparency

WÖLKEN Tiemo	Shadow rapporteur	JURI	24/04/2024	Health Action International
DIDIER Geoffroy	Shadow rapporteur	JURI	25/01/2024	U.S. Chamber of Commerce
DIDIER	Shadow	JURI	10/01/2024	Association Française des Entreprises

Geoffroy	rapporteur			Privées / French Association of Large Companies
DIDIER Geoffroy	Shadow rapporteur	JURI	29/11/2023	Gilead Sciences
DIDIER Geoffroy	Shadow rapporteur	JURI	24/10/2023	EFPIA
DIDIER Geoffroy	Shadow rapporteur	JURI	18/10/2023	Pfizer Inc.
SCHOLZ Helmut	Rapporteur	INTA	05/10/2023	Médecins Sans Frontières International Stichting Health Action International
SCHOLZ Helmut	Rapporteur	INTA	04/10/2023	Drugs for Neglected Diseases initiative Médecins Sans Frontières International Stichting Health Action International Medicine Law and Policy
VAN BREMPT Kathleen	Shadow rapporteur for opinion	INTA	14/09/2023	Medecins Sans Frontieres and Health Action International