













Procedure file

Basic information	
COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2023/0129(COD) Awaiting committee decision
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	

Key players			
European Parliament	Committee responsible	Rapporteur	Appointed
	 Legal Affairs	 VÁZQUEZ LÁZARA Adrián	26/06/2023
		Shadow rapporteur	
		 DIDIER Geoffroy	
		 WÖLKEN Tiemo	
		 HAUTALA Heidi	
		 MAUREL Emmanuel	
	Committee for opinion	Rapporteur for opinion	Appointed
 Development		The committee decided not to give an opinion.	
 International Trade (Associated committee)			24/05/2023
	 SCHOLZ Helmut		
 Environment, Public Health and Food Safety		The committee decided not to give an opinion.	
 Industry, Research and Energy		The committee decided not to give an opinion.	
 Internal Market and Consumer Protection		The committee decided not to give an opinion.	

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		

Forecasts

26/02/2024	Indicative plenary sitting date
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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 committee decision
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	

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.

Transparency				
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