2023/0129(COD)

16.9.2023

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DRAFT REPORT

(COM(2023)0224 – C9-0151/2023 – 2023/0129(COD))

Committee on Legal Affairs

Rapporteur: Adrián Vázquez Lázara

Rapporteur for the opinion of the associated committee pursuant to Rule 57 of the Rules of Procedure
Helmut Scholz, Committee on International Trade
Symbols for procedures

* Consultation procedure
*** Consent procedure
***I Ordinary legislative procedure (first reading)
***II Ordinary legislative procedure (second reading)
***III Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

Amendments to a draft act

Amendments by Parliament set out in two columns

Deletions are indicated in **bold italics** in the left-hand column. Replacements are indicated in **bold italics** in both columns. New text is indicated in **bold italics** in the right-hand column.

The first and second lines of the header of each amendment identify the relevant part of the draft act under consideration. If an amendment pertains to an existing act that the draft act is seeking to amend, the amendment heading includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend.

Amendments by Parliament in the form of a consolidated text

New text is highlighted in **bold italics**. Deletions are indicated using either the symbol or strikeout. Replacements are indicated by highlighting the new text in **bold italics** and by deleting or striking out the text that has been replaced.

By way of exception, purely technical changes made by the drafting departments in preparing the final text are not highlighted.
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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION


(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2023)0224),
– having regard to Article 294(2) and Article 50(1) and (2)(g) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0151/2023),
– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
– having regard to the opinion of European Economic and Social Committee of 27 September 2023¹,
– having regard to Rule 59 of its Rules of Procedure,
– having regard to the opinion of the Committee on International Trade,
– having regard to the report of the Committee on Legal Affairs (A9-0000/2023),

1. Adopts its position at first reading hereinafter set out;
2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;
3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

Amendment 1

Proposal for a regulation
Recital 1

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<td>(1) Crises require the setting-up of exceptional, swift, and adequate measures</td>
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¹ Not yet published in the Official Journal.
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.

**Proposal for a regulation**

**Recital 4**

*Text proposed by the Commission*

(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.

**Amendment**

(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. In Germany, the Federal Ministry for Health was authorised to order the competent
authority to allow the use of patent-protected inventions to ensure the supply of various health technologies, including medicines, diagnostics and personal protection equipment, on the grounds of public interest or national security. That measure expired in April 2021. In France, Emergency Law No. 2020-290 of 23 March 2020 to combat the COVID-19 epidemic introduced Article L3131-15 into the Public Health Code, giving extraordinary powers to the French prime minister. That law enables the prime minister to order the seizure of all goods and services necessary to fight against sanitary disaster, temporarily control the prices of products and take any other measures necessary to make relevant medicines available to patients. Such measures go beyond compulsory licensing measures taken by other governments and could also affect other intellectual property rights, such as designs, which ensure the availability of personal protective equipment. In some countries, such as Italy and Hungary, such measures were introduced on a permanent basis\(^1\).


Amendment 3
Proposal for a regulation
Recital 7

*Text proposed by the Commission*

(7) In recent years, the European Union has adopted several crisis mechanisms to improve its resilience to crises or

*Amendment*

(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].

Moreover, Regulation (EU) 2022/123, which strengthens the European Medicines Agency's role in crisis preparedness and management, creates a framework aimed at mitigating shortages of medicinal products during significant events. 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].

Justification

The Doha Declaration on the TRIPS Agreement and Public Health asserts that nations possess the right to utilize compulsory licenses and other flexible measures to protect public health. They also have the discretion to define the reasons for granting compulsory licenses. The scope of compulsory licensing, as outlined in the Annex, such as 'public health emergencies,' should not be restrictive. It should also encompass the notion of 'major events' as specified in the Regulation that reinforces the European Medicines Agency's role in crisis preparedness and management. This inclusion is vital to ensure that compulsory licensing can be invoked in response to an event expected to seriously impact public health in multiple EU Member States. Such an event would likely lead to shortages necessitating an urgent and coordinated EU-level response. For instance, a significant incident affecting the production of a patented vaccine or priority antimicrobial that cannot be promptly resolved by the marketing authorization holder, resulting in an insufficient supply and posing a serious or imminent risk to the health of EU patients, would constitute a public health threat and should be covered by this proposal.
Amendment 4

Proposal for a regulation
Recital 8

Text proposed by the Commission

(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 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.

Amendment

(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 grant a compulsory licence when a crisis or emergency mode, including in the event of a major event, 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.

Or. en

Amendment 5

Proposal for a regulation
Recital 18

Text proposed 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

Amendment

(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’).
Amendment 6
Proposal for a regulation
Recital 19

Text proposed by the Commission

(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.

Amendment

(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 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 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.

Justification

It should be a binding technical expert opinion issued by a body composed of experts from the national offices which already has experience in assessing applications for compulsory licences. In addition, there should be further checks on the Commission's power by the Council and/or the Parliament and procedures should be put in place to review and even suspend the execution of the Commission's decision.
Amendment 7

Proposal for a regulation
Recital 20

Text proposed by the Commission

(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.

Amendment

(20) The Commission should grant the Union compulsory licence in the light of the 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 to the advisory body upon receiving the case file and analyses presented to or conducted by the advisory body, and be provided with any other pertinent information they require for their evaluation of the potential repercussions of a proposed Union compulsory license on their intellectual property rights. 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

Justification

To protect their rights, including those outlined in Article 17 (right to property), Article 41 (right of access to the file and right to be heard), and Article 52 of the Charter (proportionality), rights-holders should have access to the file and all pertinent information before they offer feedback on the proposed Union compulsory license. The right of the right holder is limited to being informed and being heard, but not to enter into the procedure, as is the case in national compulsory licensing procedures. There is a lack of defence since the right holder cannot present arguments, which, if necessary, must be answered and justified in the event of rejection.
Amendment 8
Proposal for a regulation
Recital 21

Text proposed by the Commission
(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.

Amendment
(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 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.

Or. en

Justification
The right of the right holder is limited to being informed and being heard, but not to enter into the procedure, as is the case in national compulsory licensing procedures. There is a lack of defence since the right holder cannot present arguments, which, if necessary, must be answered and justified in the event of rejection.

Amendment 9
Proposal for a regulation
Recital 22

Text proposed by the Commission
(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

Amendment
(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.

Amendment 10
Proposal for a regulation
Recital 22 a (new)

_Text proposed by the Commission_

(22a) In order to guarantee the rights of rights-holders and licensees, their comments should in all circumstances be forwarded to the advisory body, including where the Commission considers documents or submissions to be irrelevant. If compulsory licensing is indeed an exceptional mechanism, that is to say only for cases where agreement is
not possible or sufficient to resolve a crisis or emergency, prior consultation of the parties should be included as part of the procedure.

Amendment 11
Proposal for a regulation
Recital 23

Text proposed by the Commission

(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.

Amendment

(23) The initiation of any compulsory licensing procedure should first involve the identification of the intellectual property rights concerned, the rights-holders concerned, as well as potential licensees, with the involvement of the national Intellectual Property Offices.

Or. en

Amendment 12
Proposal for a regulation
Recital 24

Text proposed by the Commission

(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

Amendment

(24) The Commission should, assisted by the advisory body, 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
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.

*Justification*

*The seriousness of the measure requires, in any case, that it be determined which product is necessary and which patents are involved in its production.*

**Amendment 13**

**Proposal for a regulation**

**Recital 25**

*Text proposed by the Commission*  
(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

*Amendment*  
(25) Where the rights-holder or not all the rights-holders could be identified in a reasonable period of time, the Commission should *not* grant the Union compulsory licence.
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.

Or. en

Justification

Coherence with the previous recitals

Amendment 14

Proposal for a regulation
Recital 32 a (new)

Text proposed by the Commission

(32a) 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. Indeed, it is possible that the detailed description of how to carry out the invention might not be sufficient and complete enough to enable the licensee to efficiently use that invention. This 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 each other's public interests. In cases where that additional information and know-how is necessary, some of which is an undisclosed trade secret, the disclosure of that necessary trade secret, with a view to only achieving the purpose of exercising the Union compulsory licence pursuant to
this Regulation, should be considered to be lawful within the meaning of Article 3(2) of Directive (EU) 2016/943 of the European Parliament and the Council. The Commission should require the rights-holders to put in place all appropriate measures, including 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. Any use, acquisition or disclosure of trade secrets which would not be necessary to fulfil the objective of the Union compulsory licence should be considered to be unlawful within the meaning of that Directive.

Or. en

Justification

To facilitate the prompt availability of the generic or alternative version of the medical product within the Union, the rights holder, subject to a compulsory license, should furnish adequate and essential information and in certain cases disclose the trade secrets which are strictly needed to fulfil the objective of the Union compulsory licence. This will guarantee the efficient and timely replication of the medical product protected by the intellectual property mentioned in Article 1 of the regulation. The information should encompass various aspects, including but not restricted to the technical specifications of the product, requisite tests, and other data essential for securing registration and/or market authorization from the competent authorities.

Amendment 15

Proposal for a regulation
Recital 32 b (new)

Text proposed by the Commission

Amendment

(32b) This Regulation should guarantee that the Commission has the authority to compel rights-holders to provide all necessary information to facilitate the rapid and efficient production of critical crisis-related products, such as pharmaceuticals and other health-related items. This information should encompass
details about know-how, particularly when it is essential for the effective implementation of compulsory licensing. While patent licensing alone might suffice to enable other manufacturers to quickly produce simple pharmaceuticals, in the case of more intricate pharmaceutical products, such as vaccines during a pandemic, it is often insufficient. In such instances, the alternative producer will also require immediate access to know-how information to effectively utilise compulsory licensing.

Or. en

Amendment 16

Proposal for a regulation
Recital 41 a (new)

Text proposed by the Commission

(41a) Since the objective of this Regulation, namely to ensure access to crisis-relevant patented products needed to address crises in the internal market, cannot be sufficiently achieved by the Member States because of the fragmentation of compulsory licensing in the Union and the insufficient territorial scope of national compulsory licensing but can rather, by reason of the scale and effects of the necessary solution, 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.

Or. en
Amendment 17

Proposal for a regulation
Article 3 – paragraph 1 – introductory part

Text proposed by the Commission
For the purposes of this Regulation, the following definitions shall apply:

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

Or. en

Amendment 18

Proposal for a regulation
Article 3 – paragraph 1 – point -a (new)

Text proposed by the Commission

Amendment
(-a) ‘crisis mode or emergency mode’ means a crisis mode or an emergency mode, as applicable, listed in the Annex to this Regulation, which has been activated or declared in the context of a Union crisis or emergency mechanism listed in that Annex in accordance with one of the Union acts listed therein;

Or. en

Amendment 19

Proposal for a regulation
Article 3 – paragraph 1 – point a

Text proposed by the Commission

Amendment
(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;

(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 as determined by the Commission through the guidance of the advisory body in accordance with Article 6;

EN
Amendment 20
Proposal for a regulation
Article 4 – paragraph 1

Text proposed by the Commission

The Commission may grant a Union compulsory licence \textit{where} a crisis mode or an emergency mode \textit{listed in the Annex to this Regulation has been activated or declared in accordance with one of the Union acts listed in that Annex.}

Amendment

\textit{The Commission shall not issue a Union compulsory license for any crisis or emergency-related product until the rights holder has been given a fair chance to engage in negotiations for a voluntary agreement with the licensee. The timeframe for reaching a voluntary agreement shall be adequate for discussions with potential partners, considering the urgency of the situation, and shall be a reasonable period of time from the initial notification to the relevant rights holder.}

\textit{In the event of a failure of a voluntary agreement between the rights-holder and the licensee pursuant to the first subparagraph, the Commission may grant a Union compulsory licence in the event of a crisis mode or an emergency mode.}

Justification

\textit{In times of crisis, voluntary agreements should be promoted, and the best way to achieve this is by stipulating a reasonable time frame for the rights holder to negotiate a voluntary agreement during a crisis.}

Amendment 21
Proposal for a regulation
Article 5 – paragraph 1 – introductory part

Text proposed by the Commission

1. The Union compulsory licence

Amendment

1. Where a voluntary agreement
shall **cannot be reached between the rights-holder and the licensee pursuant to Article 4 (-1a),** the Union compulsory license that may be granted by the Commission in accordance with the first subparagraph of Article 4 shall, notwithstanding the obligations to be fulfilled by the licensee in accordance with Article 10

**Or. en**

**Justification**

(CLs) must maintain proportionality, targeting only the patents essential for addressing the crisis, avoiding excessive breadth that encompasses patents associated with specific products. Additionally, they should be limited to the crisis’s immediate requirements, preventing potential market distortions once the CL’s scope expires. Furthermore, the license should hold responsibility for the production and distribution of crisis-related products, ensuring accurate product tracking, while also safeguarding the rights holders from undue liability for unrelated business activities over which they have no control, thereby preventing any discouragement from investing in crisis-related products.

**Amendment 22**

Proposal for a regulation

**Article 5 – paragraph 1 – point b**

Text proposed by the Commission

(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;

Amendment

(b) have a **strict limitation concerning** scope, field of application, necessary quantities, and a duration that is closely 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**.

**Or. en**

**Amendment 23**

Proposal for a regulation

**Article 5 – paragraph 1 – point f a (new)**
Text proposed by the Commission

(fa) clearly state that the licensee is responsible for any liability or warranties related to the production and distribution of crisis-relevant products, absolving the rights-holder from any claims arising as a result of product liability issues.

Amendment 24
Proposal for a regulation
Article 6 – paragraph 2 – point a a (new)

Text proposed by the Commission

(aa) the assessment of whether the obligation to afford the rights-holder an opportunity to engage in negotiations for a voluntary license, as specified in Article 4 (-1a), has been complied with;

Amendment 25
Proposal for a regulation
Article 6 – paragraph 2 – point b a (new)

Text proposed by the Commission

(ba) the determination of crisis-relevant products;

Amendment 26
Proposal for a regulation
Article 6 – paragraph 4 – point a a (new)
Amendment 27
Proposal for a regulation
Article 6 – paragraph 4 – point b

Text proposed by the Commission

(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.

Amendment

(b) may invite representatives of the national authorities responsible for issuing compulsory licences under national law, representatives of the European Parliament, representatives of economic operators, potential licensees, stakeholder organisations, social partners and experts to attend meetings of the advisory body as observers.

Or. en

Amendment 28
Proposal for a regulation
Article 6 – paragraph 5

Text proposed by the Commission

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

Amendment

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.

its secretariat. The ad hoc advisory body shall be composed of representatives of the institutions and bodies of each Member State that exercise the competence to grant national compulsory licences under national law.

Amendment 29

Proposal for a regulation
Article 7 – paragraph 2

Text proposed by the Commission

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.

Amendment

2. The opinion of the advisory body shall 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.

Amendment 30

Proposal for a regulation
Article 7 – paragraph 3 – introductory part

Text proposed by the Commission

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:

Amendment

3. Before issuing the opinion, the advisory body shall give the rights-holder and the licensee an opportunity to comment on the following:
Amendment 31
Proposal for a regulation
Article 7 – paragraph 3 – point a

Text proposed by the Commission

(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;

Amendment

(a) the possibility to promptly reach a voluntary licensing agreement with manufacturers on intellectual property rights for the purpose of manufacturing, using and distributing the crisis-relevant products;

Or. en

Amendment 32
Proposal for a regulation
Article 7 – paragraph 3 – subparagraph 1 a (new)

Text proposed by the Commission

Before issuing the opinion, the advisory body shall consider:

(a) the rights and interests of the rights-holder and the licensee;

(b) existing national compulsory licences reported to the Commission in accordance with Article 22.

Amendment

Justification

Moved from Article 7(6).

Amendment 33
Proposal for a regulation
Article 7 – paragraph 4

Text proposed by the Commission

4. The Commission shall notify the

Amendment

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.

Amendment 34

Proposal for a regulation
Article 7 – paragraph 6 – introductory part

Text proposed by the Commission

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.

Amendment

6. When assessing whether a Union compulsory licence is to be granted, the Commission shall follow the opinion referred to in paragraph 2.

Justification

Points (b) and (c) moved up to Article 7(3), subparagraph 1a.

Amendment 35

Proposal for a regulation
Article 8 – paragraph 1 – point h

Text proposed by the Commission

(h) measures complementing the compulsory licence, which are necessary

Amendment

(h) measures complementing the compulsory licence, as referred to in

to achieve the objective of the compulsory licence.  

*Article 13a, including, where relevant, the obligation for the rights-holder to disclose trade secrets to the licensee only to the extent to which it is strictly necessary to achieve the objective of the compulsory licence.*

**Amendment 36**

Proposal for a regulation  
Article 9 – paragraph 1 a (new)

*Text proposed by the Commission*  

1a. The rights-holder shall receive the remuneration within a pre-established timeframe as agreed with the Commission.

**Amendment**

*Or. en*

**Amendment 37**

Proposal for a regulation  
Article 9 – paragraph 2

*Text proposed by the Commission*  

2. The remuneration shall *not exceed* 4 % of total gross revenue generated by the licensee *through the relevant* activities under the Union compulsory licence.

**Amendment**

2. The remuneration shall be *determined based on the* total gross revenue generated by the licensee *from the pertinent* activities governed by the Union compulsory licence.

**Or. en**

**Amendment 38**

Proposal for a regulation  
Article 9 – paragraph 3 – point d a (new)
Text proposed by the Commission

Amendment

(da) the possible disclosure of trade secrets for the purpose of exercising the Union compulsory licence pursuant to Article 13a(1); that disclosure shall give rise to adequate compensation for the rights-holder.

Or. en

Amendment 39

Proposal for a regulation
Article 10 – paragraph 1 – subparagraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(ca) a detailed account of the products produced under the Union compulsory licence;

Or. en

Amendment 40

Proposal for a regulation
Article 10 – paragraph 1 – subparagraph 1 – point c b (new)

Text proposed by the Commission

Amendment

(cb) treat the information acquired in relation to the Union compulsory licence with utmost confidentiality and implement all necessary measures to safeguard such confidential information;

Or. en
Amendment 41
Proposal for a regulation
Article 13 – paragraph 2

Text proposed by the Commission

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.

Amendment

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 public interests.

Or. en

Amendment 42
Proposal for a regulation
Article 13 a (new)

Text proposed by the Commission

Article 13a
Additional measures complementing the Union compulsory licence

1. Where necessary, the Commission shall decide, upon a 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.

2. Where necessary, the Commission shall request from the rights-holder the disclosure of trade secrets to the licensee in order to provide him with the necessary know-how to strictly achieve the objective of the Union compulsory licence as provided for in this Regulation. In such cases, the Commission shall order all appropriate measures necessary to preserve the confidentiality of trade secrets, in particular in relation to third
parties.

3. Where the Commission considers modifying or adopting additional measures as referred to in paragraphs 1 and 2, it shall consult the advisory body referred to in Article 6.

4. The implementing acts referred to in paragraphs 1 and 2 shall be adopted in accordance with the rules referred to in Article 7(6), points (a) and (b), and Article 7(7) and (8).

Or. en

Justification

Paragraphs 1, 3 and 4 moved from article 14.

Amendment 43

Proposal for a regulation
Article 14 – paragraph 2

Text proposed by the Commission

Amendment

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.

Or. en

Justification

Moved up to article 13a new.

Amendment 44

Proposal for a regulation
Article 14 – paragraph 4
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.

Amendment

4. When the Commission considers terminating the Union compulsory licence, it shall consult the advisory body referred to in Article 6.

Justification

Deletion moved up to article 13a new

Amendment 45

Proposal for a regulation
Article 14 – paragraph 6

Text proposed by the Commission

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).

Amendment

6. The implementing acts referred to in paragraph 1 and 3 shall be adopted in accordance with the rules referred to in Article 7(6) (a) and (b), 7(7) and 7(8).

Justification

Deletion moved up to article 13a new.

Amendment 46

Proposal for a regulation
Article 15 – paragraph 1 – point c

Text proposed by the Commission

(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)

Amendment

(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 Article 14(2), as specified in the relevant implementing act.

Amendment 47
Proposal for a regulation
Article 16 – paragraph 1 – point c

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
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<tbody>
<tr>
<td>(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.</td>
<td>(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 Article 13a(1) and (2), as specified in the relevant implementing act.</td>
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</tbody>
</table>

Amendment 48
Proposal for a regulation
Article 19 – paragraph 1

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
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<tr>
<td>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.</td>
<td>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 and fully involved on the alleged infringement which is to be made subject to a fine or periodic penalty payments.</td>
</tr>
</tbody>
</table>

Amendment 49
Proposal for a regulation
Article 19 – paragraph 2 a (new)
2a. The Commission shall reply to the observations made by the licensee or the right holder and in case of a rejection provide a justification within a reasonable period of time which shall not exceed 7 days.

Amendment 50
Proposal for a regulation
Annex – title

ANNEX - Crisis or emergency modes referred to in Article 4 and competent advisory bodies as referred to in Article 6(2) are listed below:

<table>
<thead>
<tr>
<th>Union crisis or emergency mechanism</th>
<th>Crisis mode or emergency mode</th>
<th>Competent Advisory Body</th>
</tr>
</thead>
</table>

Amendment 51
Proposal for a regulation
Annex
<table>
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<tr>
<td>3.</td>
<td>Regulation XXX/XX establishing a framework of measures for strengthening Europe's semiconductor ecosystem [COM(2022) 46]</td>
<td><strong>Crisis stage</strong> activated by a Commission implementing act [Article 18 of Regulation XXX/XXX] [COM(2022) 46]</td>
<td><strong>European Semiconductor Board</strong> [Article 23 of Regulation XXX/XXX] [COM(2022) 46]</td>
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<td>4.</td>
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EXPLANATORY STATEMENT

The balance between IP rights and other rights and public interest has continuously been discussed and reassessed amid societal changes, technological developments, and crises. Hence, it comes as no surprise that the COVID-19 crisis once again underscored this matter. During this period, the competing interests included ensuring access to health products while simultaneously safeguarding the vital innovation incentives required for the advancement of new health products, such as vaccines and therapeutics.

The main concern for the rapporteur revolves around how we can maintain the equilibrium and motivation for innovation while guaranteeing rapid access to essential products and technologies during crises.

The rapporteur acknowledges the Commission’s intention to establish a cohesive Union-level compulsory licensing framework aimed at efficiently managing crises. This Regulation, as outlined by the Commission, strives to ensure that during specific crises or emergencies, a Union compulsory license can be efficiently issued for certain products. Nevertheless, certain central aspects of the proposed Regulation require being further developed/clarified to ensure legal certainty and to be able to efficiently respond to crises.

The scope of the Regulation, particularly regarding the definition of a 'crisis', raises concerns, as article 4 relies on the definitions of 'crisis mode' and 'emergency mode' in the Annex, without providing a definition of these modes in the operational part of the proposal. Furthermore, the ambiguity surrounding the inclusion of know-how and trade secrets, vital to expand the production of certain products during times of crisis, requires more concrete action. Both as regards the definition of the know-how necessary for the manufacturing of certain products, and the conditions under which the Commission can oblige right-holders to disclose this information. The governance structure, notably the role of the advisory body, remains undefined, merely referencing the advisory bodies from the crisis instruments (SMEI, Regulation (EU) 2022/2371, Council Regulation (EU) 2022/2372, Chips Act and Regulation (EU) 2017/1938). Furthermore, questions arise concerning the manner in which the Compulsory Licensing Scheme fosters voluntary agreements. Moreover, the absence of a clear access to a judicial review of the Commission's licensing decisions is of significant concern.

In terms of conferred powers, the JURI rapporteur sees insufficient guidance regarding the calculation of remuneration and the variables to be considered therein. The vague description of the powers granted to the Commission under additional measures also requires further clarification.

On this basis, the rapporteur emphasizes the need to refine the Regulation to bolster its effectiveness and achieve a harmonious balance between ensuring swift crisis response and maintaining robust legal clarity.
ANNEX: LIST OF ENTITIES OR PERSONS
FROM WHOM THE RAPPORTEUR HAS RECEIVED INPUT

Gilead
European Federation Of Pharmaceutical Industries and Associations (EFPIA)
The European Consumer Organisation (BEUC)
Medecins Sans Frontieres
Medecines For Europe
American Chambre of Commerce to the EU (AMCHAM)
Permanent Representation of Spain
Pfizer
Health Action International
Johnson & Johnson
French Association of Large Companies (AFEP)
Medecins du Monde France
Business Europe
Salud Por Derecho