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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on compulsory licensing for crisis management and amending Regulation (EC) 816/2006

(Text with EEA relevance)

{SEC(2023) 173 final} - {SWD(2023) 120 final} - {SWD(2023) 121 final} -
{SWD(2023) 122 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

Intangible assets such as inventions, trade secrets and know-how are the cornerstone of the EU economy and competitiveness. Patent rights, in particular, play a key role in supporting EU innovation and creating the right environment for investment. For European innovation to flourish, a solid, predictable, and flexible legal framework for intellectual property rights, including patents, needs to be created. The Unitary Patent system helps further improve and harmonise the EU legal framework on patents. Beyond this, the Commission action plan on intellectual property rights has identified several areas of patent law that need to be further improved and harmonised. One of these areas is compulsory licensing. 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. In other words, the question became: how we can preserve the balance and incentives for innovation while ensuring swift access to critical products and technologies in crises, even in the absence of voluntary agreements. Patent law already provides a solution: compulsory licensing.

A compulsory licence is the possibility for a government to allow a third party to use a patent without the authorisation of the rights-holder, subject to certain conditions. Compulsory licensing can therefore complement current EU efforts to improve its resilience to crises. In the aftermath of the COVID-19 crisis, the EU has tabled several EU crises instruments, such as the Proposal for a Regulation establishing a Single Market Emergency Instrument (SMEI) or Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level. These instruments provide the EU with a means of ensuring access to products needed to tackle a crisis in the Internal Market. The instruments focus on voluntary approaches. As evidenced by the COVID-19 crisis, voluntary agreements remain the most efficient tool to enable rapid manufacturing of patent-protected products, including in crises. However, there may be cases where such voluntary agreements are not available or appropriate. In such circumstances, compulsory licensing can provide a solution to allow the rapid manufacturing of products needed to tackle a crisis. However, to guarantee that such products can freely circulate within the Internal Market and reach all those in need, the compulsory licensing shall be granted at EU level.

Compulsory licensing has a dual role, as it can incentivise the conclusion of voluntary agreements and also enable the manufacturing of products needed to tackle a crisis in the absence of (appropriate) voluntary agreements. However, for compulsory licensing to fulfil this role, an efficient compulsory licensing scheme needs to be built in the EU, able to rely on the Single Market, complementing EU crisis instruments and in line with the EU's international obligations.

The Agreement on Trade-Related Aspects of Intellectual Property Rights ('TRIPS Agreement') sets the international legal framework on compulsory licensing. Article 31 of the TRIPS Agreement provides the framework for compulsory licensing in relation to the domestic market, while Article 31bis of the TRIPS Agreement provides the rules for

compulsory licensing for the manufacturing and export of pharmaceutical products to countries with public health problems.

There is currently no EU-wide harmonisation of compulsory licensing for the domestic market, including as regards European patents with a unitary effect. Instead, there is a patchwork of different national rules and procedures on compulsory licensing. National rules have insufficient territorial reach, since products manufactured under a compulsory licence in one Member State either cannot be supplied to another Member State, or can only be supplied in limited quantities. National procedures are also different from each other, and decision-making is not coordinated at EU level. This limits the ability to rely on the Internal Market to guarantee supplies across all the Union territory.

Against this background, this initiative aims to provide the Internal Market with an efficient compulsory licensing scheme for crisis management. The initiative has therefore two main objectives. First, it aims to enable the EU to rely on compulsory licensing in the context of the EU crisis instruments. Second, it introduces an efficient compulsory licensing scheme, with appropriate features, to allow a swift and appropriate response to crises, with a functioning Internal Market, guaranteeing the supply and the free movement of crisis-critical products subject to compulsory licencing in the internal market.

- **Consistency with existing policy provisions in the policy area**

In its intellectual property action plan, the Commission underlined 'the need to ensure that effective systems for issuing compulsory licences are in place'. The 2023 Commission work programme announced the establishment of clear rules for the compulsory licensing of patents. In the Council conclusions of 18 June 2021, the Council confirmed that the EU stood ready to discuss the flexibilities of compulsory licensing for the domestic market and for export purposes to third countries. It also confirmed the need to explore possible intellectual property tools and options to better coordinate the management of cross-border crises. In its resolution of November 2021, the European Parliament called on the Commission 'to analyse and explore possible options for ensuring effectiveness and better coordination of compulsory licensing in the EU'.

The TRIPS Agreement provides the international legal framework for compulsory licensing. This initiative is strictly in line with the boundaries of the TRIPS Agreement. Although the Unitary Patent system aims to further harmonise EU law on patents, it leaves the issue of compulsory licensing to national legislation. There are currently three other pieces of EU legislation that contain provisions on compulsory licensing:

- Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights: Article 29 of this Regulation provides for the possibility for the Community Plant Variety Office to grant a compulsory licence on a community plant variety right, on application by a Member State, by the Commission or by an organisation set up at EU level;
- Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions: Article 12 of this Directive provides for the possibility to apply for a compulsory licence, where a plant breeder cannot use a plant variety without infringing a patent or where the holder of a patent concerning a biotechnological invention cannot exploit it without infringing a prior plant variety right;
- Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of

pharmaceutical products for export to countries with public health problems: This Regulation sets out a procedure to grant compulsory licences in relation to patents and supplementary protection certificates concerning the manufacture and sale of pharmaceutical products, when such products are intended for export to eligible importing countries that need these products to address public health problems.

The first two EU acts cited above are not impacted by this proposal. The proposal would amend Regulation (EC) No 816/2006 in order to add the possibility, in the context of a cross-border manufacturing process, to rely on a compulsory licence granted by the Commission and applicable in the territory of the Union.

Member States have implemented different compulsory licensing schemes in national legislation, only applicable to their national territory. The proposal leaves these national compulsory licensing systems untouched. The Union compulsory licensing system introduced by this proposal does not aim at addressing purely national crises. The proposal instead aims to address crises that have a cross-border dimension within the EU, which do not fall within the scope of national compulsory licensing schemes.

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. The proposal complements the Unitary Patent system, which is a major step towards the completion of the Single Market for patents. Against this backdrop of increasing completion of the Single Market for patents, the initiative on compulsory licensing is therefore at the crossroads between the different EU crisis instruments and the international obligations and discussions on IP rights and compulsory licensing.

- **Consistency with other Union policies**

The Commission has recently tabled proposals to improve the EU's resilience to crises and better guarantee well-functioning supply chains in the Single Market. In that respect, reference can be made to the following key EU legislations:

- Proposal for a Regulation establishing a Single Market emergency instrument ('SMEI');
- Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU ('SCBTH');
- Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level ('Emergency Framework Regulation');
- Proposal for a Regulation of the European Parliament and of the Council establishing a framework of measures for strengthening Europe's semiconductor ecosystem ('Chips Act').

These pieces of legislations can either qualify as crisis instruments or as containing a crisis mechanism, setting up emergency mechanisms to ensure the supply of and access to critical products in the Single Market. None of these EU crisis instruments explicitly includes the use of compulsory licensing to address a crisis. This proposal makes compulsory licencing one of the tools available to respond to a crisis within the respective emergency frameworks, by closely linking compulsory licencing to EU crisis instruments.

The reform of the pharmaceutical legislation also provides for the suspension of regulatory data and market protection where a compulsory licence has been granted for a patent relating

to a medicinal product in order to address a public health emergency (see Article 80 para. 4 of Directive (EU) XXX/XX [COM(2023)192]). This increases the effectiveness of a compulsory licence, as rules on regulatory data and market protection can impede the authorisation of generic medicinal products.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

• Legal basis

The proposal is based on Articles 114 and 207 of the Treaty on the Functioning of the EU ('TFEU'). Article 114 TFEU empowers the European Parliament and the Council to adopt measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States, which have as their object the establishment and functioning of the internal market. Article 207 TFEU confers on the EU competence in the field of common commercial policy, including as regards IP rights which is relevant, since the proposal has an impact on Regulation (EC) No 816/2006, relating to the compulsory licensing of medicines for export purposes to third countries.

• Subsidiarity (for non-exclusive competence)

Action at EU level is justified to ensure the smooth functioning of the Single Market in crises. Currently, Member States can only act nationally, meaning that they can grant a compulsory licence for their own territory only. This can be sufficient for purely national crises, where both the crisis and the manufacturing capacities are in the same Member State. However, this will not be sufficient when a crisis has a cross-border dimension – this is considered highly probable due to the prevalence of cross-border supply chains. The inability of Member States to properly address a crisis with a cross-border dimension originates in the territoriality of national compulsory licensing schemes and the divergent, sometimes sub-optimal, compulsory licensing schemes in place to tackle a crisis. The proposed EU action will act on these specific points by creating a Union compulsory licence with a streamlined procedure. Without action at EU level, Member States would remain vulnerable to crises that have a cross-border dimension. Introducing an EU compulsory licensing scheme will help build a more resilient EU by providing an additional collective tool that supports other crisis instruments such as SMEI or the Emergency Framework Regulation.

• Proportionality

The adoption of a Regulation establishing a Union compulsory licensing scheme for crisis management does not go beyond what is necessary to achieve the identified objectives. It is limited to the aspects that Member States cannot achieve satisfactory on their own and where the EU can act more effectively, efficiently and with greater added value. The initiative's objective is to build a Union compulsory licensing scheme able to tackle crises with a cross-border dimension, in addition to the existing compulsory licensing national schemes for grounds other than crises. The proposal is therefore limited to what is necessary to tackle crisis with a cross-border dimension, only when such action cannot be implemented at national level or when such implementation would be inefficient.

• Choice of the instrument

The chosen instrument is a Regulation establishing a compulsory licencing system for crisis management at EU level with its own triggers, procedure and conditions. It leaves national compulsory licencing schemes in the Member States untouched but ensures coherence with other crisis and emergency instruments at EU level and is fully compliant with the international requirements for compulsory licencing laid down in the TRIPS Agreement.

Alternative regulatory methods such as a Directive harmonising national compulsory licencing schemes of the Member States are not considered appropriate.

First, a Directive would only create a certain degree of harmonisation. While the harmonisation of key aspects of compulsory licencing could help improve and clarify the features of national schemes, Member States' competent authorities would remain in charge of determining whether a crisis exists and whether to grant a compulsory licence. Hence, there would be a risk that the Directive would not be implemented and applied in a uniform manner due to existing differences in national law proceedings and judicial traditions.

Second, a Directive would only improve the situation of cross-border supply of products to a limited extent, as both the compulsory licence granted in the manufacturing country and those granted in the importing country would be based on harmonised rules. However, the lack of exhaustion of the patent right would still require several compulsory licences in all manufacturing and importing Member States.

Other measures like the adoption of recommendations aiming to bring about more uniformity of national laws would neither satisfactorily address the fragmentation of compulsory licensing in the EU nor the insufficient territorial reach of a national compulsory licence and coherence with existing and upcoming EU crisis instruments at EU level.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

• Stakeholder consultations

The Commission conducted a call for evidence between 1 April and 29 April 2022, to gather views, opinions and evidence from public and private sector stakeholders. 57 stakeholders submitted feedback.

The European Commission also held an open public consultation between 7 July 2022 and 29 September 2022. This public consultation aimed to collect views from all stakeholders on how to build the most efficient compulsory licensing scheme in the EU and to ensure that it is fit to tackle EU-wide and global crises. This consultation was available on the Commission's better regulation portal and open to everybody. The public consultation received 74 replies. The results of the public consultation show that a large majority of respondents consider that public authorities should be entitled to allow production of critical products through a compulsory licence. Respondents are usually more in favour of a coordinating role for European institutions than a decision-making role. This can be explained by the fact that businesses and industry representatives expressed low levels of support for a decision-making role, and they were the dominant group of respondents to the consultation. Stakeholders generally consider the option of granting a compulsory licence at EU level, as proposed in this initiative, more positively in relation to the EU's ability to tackle crises than the granting of a compulsory licence at national level. There is a clear difference between among stakeholder views on this, with low support from industry representatives: a majority of companies and business associations consider that the impact would be negative. In contrast, no respondent in any other category considers the impact to be negative. A large majority considers it positive.

• Collection and use of expertise

In March 2022, the Commission launched the 'Compulsory licensing of intellectual property rights' study [CEIPI(2023)]. The study's objective was to assist the Commission in identifying potential problems as regards compulsory licensing in the EU and identifying and assessing policy options to improve coherence and effectiveness in the field. To this end, the study aimed to collect data through desk research, case studies, interviews with stakeholders

as well as organising two workshops. The study was conducted by the Centre for International Intellectual Property Studies (CEIPI), the Université de Strasbourg (UNISTRA), the Impact Licensing Initiative (ILI) and Ecorys Nederland BV (ECORYS).

During the study, Member State experts were asked to complete a questionnaire**.** The questions focused on the national experiences with compulsory licensing, the scope of application of compulsory licences and procedural aspects. In addition, a series of 25 semi-structured interviews of national experts, academia, policy representatives and industry experts were conducted. These interviews focused on gathering 'non-published' data on national procedures and legal requirements of compulsory licensing.

Two workshops were held:

- A first workshop on 'information collection on specific compulsory licence cases with exchange of views and experiences in the field of IPRs' was held in Brussels on 28/29 April 2022;
- A second workshop on 'policy options for compulsory licensing in Europe in case of a crisis' was held in Brussels on 9/10 June 2022.

A total of 24 participants attended both workshops, representing patent attorneys from multiple Member States, policy officials and representatives from different industries.

- **Impact assessment**

An impact assessment was carried out for the initiative, which received a positive opinion with reservations from the Regulatory Scrutiny Board on 3 February 2023. The impact assessment considered four policy options, in addition to the policy option consisting of no policy change:

- Option 1: Recommendation on compulsory licensing for crisis management. This would identify good national practices on compulsory licensing for crisis management and good coordination practices, with a view to increasing their uptake in Member States. This option was deemed insufficient, as it would not have a sufficient harmonising effect nor an appropriate territorial reach. In addition, it would not fully embed compulsory licensing in the EU crisis instruments.
- Option 2: Harmonisation of national laws on compulsory licensing for crisis management. The legislative initiative would harmonise national laws on the grounds, scope, procedure, and conditions for granting a compulsory licence for crisis management. The compulsory licence would remain within the remit of Member States and have predominantly a national effect. Although this option would further harmonise national compulsory licensing schemes, the territorial reach and coherence with EU crisis instruments of this option were still considered suboptimal.
- Option 3: Harmonisation and EU level binding measure to grant a compulsory licence for crisis management. The compulsory licence could be triggered: (i) by an EU-level decision activating a crisis mode or declaring an emergency under an existing EU crisis instrument (e.g. activation of the emergency mode under SMEI); or (ii) upon a request made to the Commission by more than one Member State in case of a cross-border crisis. The Commission, assisted by the relevant advisory body, would adopt an activation measure requiring one or several Member States to issue a compulsory licence. Option 3 would lead to several national compulsory licences, each applying to the territory of several EU countries or the whole EU. This option provided an appropriate territorial reach and ensured good coherence with EU crisis instruments. In addition, it would provide increased harmonisation compared to

Option 2. However, this harmonisation, and resulting coherence and efficiency of the Union compulsory licence, was limited compared to the optimal solution provided under Option 4.

- Option 4: Union compulsory licence to complement existing EU crisis instruments. The triggers would be the same as under Option 3. However, the Commission, assisted by the relevant advisory body, would adopt an activation measure granting a compulsory licence. This option would lead to the issuance, by the Commission, of one compulsory licence, with its own procedure and conditions and applicable to the territory of several EU countries or the whole EU.

According to the impact assessment, Option 4 would be the most effective and efficient to achieve the initiative's objectives. This preferred option would create a single procedure to grant a Union compulsory licence with the necessary features to tackle a crisis. The Commission activation measure would ensure that conditions are the same across the EU and would avoid national discrepancies that are likely to slow down or prevent an efficient compulsory licensing scheme to tackle cross-border crises. This single compulsory licence would apply in all relevant territories, covering cross-border situations. This would be the case for both the EU market and for export purposes. Coherence with EU crisis instruments would be ensured by the possibility to use their trigger and by reference to the (advisory) bodies set-up by the EU crisis instruments to discuss a Union compulsory licence. The proposed procedure would also cover crises with a cross-border dimension in the EU but which do not reach the activation threshold for an EU crisis instrument (e.g. a crisis spreading across several Member States). In the option described in the impact assessment, the procedure could be also initiated by the Member State(s) affected. However, following internal discussions within the Commission, the Member State right to initiate the procedure was not included in the legislative proposal. (as a result, the proposal partially deviates from Option 4 discussed in the impact assessment). Maintaining only the EU crisis instrument route was judged to be more coherent with the remaining EU crisis preparedness policy tools and more appropriate in terms of the exceptional nature of the proposed tool. The likely impacts of this change would be an even simpler procedure of initiation and more confidence among patent holders that the instrument would only be activated in case of major EU-wide crises. The latter would also limit potential detrimental effects of the proposal on competitiveness. No additional costs would be created by the change.

Under the preferred option, patent owners would see a reduction in costs and legal uncertainty, as negotiations would be limited to participation in one EU-level procedure. Potential licensees would benefit from the centralised procedure and the wide territorial scope of the licence that can bring economies of scale. Better sharing of information would also allow a reduction of costs for Member States as it could help identify best practices. On enforcement costs, Member States would benefit from the centralised procedure, as costs linked to the negotiations with the patent owners and the manufacturers would be incurred solely at EU level. EU residents would greatly benefit from this option as it would improve the EU's ability to issue an effective and efficient compulsory licence for the whole EU, including where there are cross-border supply chain disruptions. Third countries would also benefit from this option as this would provide the possibility of a compulsory licence covering a cross-border supply chain.

Improved EU readiness to tackle a major crisis would bring positive social impacts, as it would help limit various disruptions to everyday societal processes by curbing the crisis or eliminating it altogether. Although societal disruption can be caused by a crisis in any area (e.g. threats to the environment, national security, etc.), the recent COVID-19 pandemic provided multiple examples of disruptions that could have been avoided with a more effective

resilience tool. With regard to the environmental impact, the initiative's positive impacts could be decisive in increasing access to products and technologies that can tackle environmental crises. Since no environmental legislation is affected by this proposal and its principal objective is to streamline and harmonise compulsory licensing procedures in cross-border crises**,** no significant harm to the environment is expected under any of the options analysed.

- **Regulatory fitness and simplification**

The proposal creates a compulsory licencing system centralised at EU level. In crises a compulsory licence covering the whole EU can be granted by filing a single application and using a single procedure under unitary procedural rules and conditions. This means that one procedure can achieve what would otherwise only be achievable with the help of several national compulsory licencing procedures before different competent authorities of the Member States. If an unforeseen future crisis occurs, the compulsory licencing system established by the proposal would lower the costs of participation in compulsory licencing negotiations incurred by patent holders, manufacturers and Member States.

- **Fundamental rights**

The initiative would provide an additional tool to face crises. Through the improved supply of critical products and services, the most fundamental needs and rights of people in the EU (such as safety and health) would be more swiftly and efficiently catered for in a crisis setting.

This initiative impacts the right to intellectual property of patent and utility models owners (Article 17(2) of the EU Charter of fundamental rights – the 'Charter'), as compulsory licensing partially deprives patent owners of control over their rights. Intellectual property rights are not absolute rights, and limitations on the exercise of these rights are allowed under the Charter, provided that the proportionality principle is respected. In that respect, the proposal provides that compulsory licensing would remain an exceptional mechanism, with a scope limited to cross-border crises. In addition, compulsory licences would always be granted on a non-exclusive basis and subject to a definite duration. Finally, patent owners would be able to share their views on granting a compulsory licence and the conditions surrounding it. An important aspect of the conditions relates to patent owners being able to receive fair compensation for the limitation of their right. The proposal provides that patent owners would always be entitled to receive appropriate remuneration in respect of each compulsory licence granted under this initiative. This initiative may have a positive impact on other fundamental rights, as it would provide an additional tool to face crises, including health-related (right to health care – Article 35 of the Charter) or environmental crises (right to environmental protection – Article 37 of the Charter).

4. BUDGETARY IMPLICATIONS

If an unforeseen future crisis occurs, the proposed initiative would lower the costs incurred by patent holders, manufacturers and Member States of participating in compulsory licensing negotiations. These costs could be lower by roughly 75% to 80% for firms, compared to the *status quo* scenario (see impact assessment). For Member States, if national compulsory licensing negotiations were replaced by EU-level negotiations, the administrative costs are expected to stay unchanged or fall, as the same effort would be shared among several countries. The exact monetary value of cost savings for stakeholders is not possible to provide due to the rarity of such events and because the type and scale of any such future crisis are unknown. As the new instrument would only be used during major crisis affecting the EU, as a measure of last resort, its expected frequency of use is very low.

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

The proposed legislation includes a provision requiring an evaluation report no later than 3 years after the activation of a Union compulsory licence procedure. The preferred option requires Member States to inform the European Commission when they are considering granting and when they have granted a compulsory licence for crisis management, as well as providing information on the compulsory licence (i.e. transparency over the subject matter of the compulsory licence, the manufacturer, the conditions, etc.). Since recourse to compulsory licensing is expected to be rare, the overall number of compulsory licences issued on the basis of the proposed instrument is expected to be low. This means that monitoring of the basic descriptive indicators is not expected to require additional systems for data collection and monitoring (the collection and processing of information can be done manually).

- **Detailed explanation of the specific provisions of the proposal**

Article 1 specifies the subject matter of the proposal. It specifies that this proposal lays down the procedure and conditions for granting a Union compulsory licence to address a crisis in the EU.

Article 2 provides for the scope of the Union compulsory licence. To ensure the Union compulsory licence functions effectively during crises, the scope of the compulsory licence covers patents, published patent applications, supplementary protection certificates and utility models.

Article 3 provides definitions of key elements of this proposal. The definitions are based on existing definitions.

Article 4 provides the legal basis for the Commission to grant a Union compulsory licence for the whole EU. Under this provision, the Commission is entitled to grant a Union compulsory licence when a crisis mode or emergency mode is activated or declared at EU level. This aims to complement EU crisis mechanisms by allowing compulsory licensing to be used as part of such mechanisms.

Article 5 lays down the general conditions to be taken into account by the Commission when granting a Union compulsory licence.

Article 6 sets out rules for the consultation of an advisory body that is meant to provide the Commission with a non-binding opinion when considering a Union compulsory licence.

Article 7 sets out the procedure for granting a Union compulsory licence. The article states that the Union compulsory licence is granted by means of an implementing act. It also provides for sufficient participation by the rights-holder in order to guarantee their right to be informed and to provide comments. Further, it sets out the Commission’s obligation to identify relevant rights-holders with regards to the compulsory licence.

Article 8 lays down rules on the specifications of the Union compulsory licence. The article further specifies the aspects the Commission should consider in its decision and the details that need to be specified.

Article 9 obliges the licensee to pay appropriate remuneration to the rights-holder and lays down criteria for the Commission to determine such remuneration.

Article 10 provides for specific conditions of the Union compulsory licence, to be fulfilled by the licensee. The article includes conditions limiting the use of the invention covered by the Union compulsory licence.

Article 11 provides for an export ban on products manufactured under a Union compulsory licence. These products cannot be exported outside the European Union.

Article 12 details the control measures undertaken by custom services, including as regards the export ban.

Article 13 establishes the principle of good faith in the relationship between rights-holder and licensee.

Article 14 entitles the Commission to modify, complement with additional measures or terminate the compulsory licence under certain conditions.

Article 15 entitles the Commission to issue fines if any of the parties to the compulsory licence do not comply with their obligations under this Regulation.

Article 16 entitles the Commission to issue periodic penalty payments if any of the parties to the compulsory licence do not comply with their obligations under this Regulation.

Article 17 provides for the rules as regards the limitation period for the imposition of fines and periodic penalty payments.

Article 18 provides for the rules as regards limitation period for the enforcement of fines and periodic penalty payments

Article 19 provides for the rules as regards the right for the rights-holder and the licensee to be heard and to access to the file in relation with the imposition of fines and periodic penalty payments.

Article 20 requires that the Commission publish the decisions on the imposition of fines and periodic penalty payments.

Article 21 provides that the Court of Justice of the European Union is entitled to review decisions by which the Commission has imposed fines or periodic penalty payments.

Article 22 requires Member States to notify the Commission if a national compulsory licence has been granted in order to address a crisis situation.

Article 23 amends existing Regulation (EC) No 816/2006 by Article 18a and Article 18b. Article 18a lays down rules on the grant of a Union compulsory licence for purposes of exporting medical products to third countries with public health problems. The article states that the Union compulsory licence is granted by means of an implementing act. Article 18b establishes a reference to the comitology committee as well as the reference to Regulation (EU) No 182/2011.

Article 24 establishes a committee for comitology procedure as well as the reference to the respective provisions in Regulation (EU) No 182/2011.

Article 25 requires the Commission to carry out a review where a Union compulsory licence has been granted due to a cross-border crisis in the EU.

Article 26 sets out the date when the regulation enters into force.

2023/0129 (COD)

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REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on compulsory licensing for crisis management and amending Regulation (EC) 816/2006

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114 and 207 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[1],

Having regard to the opinion of the Committee of the Regions[2],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) 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. 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.

(2) In the context of the Union crisis or emergency mechanisms, the Union should therefore have the possibility to rely on compulsory licensing. The activation of a crisis or an emergency mode or the declaration of a crisis or a state of emergency addresses obstacles to free movement of goods, services, and persons in crises and shortages of crisis-relevant goods and services. In cases where access to crisis-relevant products and processes protected by a patent cannot be achieved through voluntary cooperation, compulsory licensing can help in lifting any patent-related barriers and thus ensure the supply of products or services needed to confront an ongoing crisis or emergency. 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. This would guarantee a functioning internal market, ensuring the supply and the free movement of crisis-critical products subject to compulsory licencing in the internal market.

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1 OJ C , , p. .

2 OJ C , , p. .

(3) The possibility of using compulsory licences in situations of national emergency or other circumstances of extreme urgency is explicitly envisaged under the Agreement on Trade-Related Aspects of Intellectual Property Rights ('TRIPS Agreement')[3].

(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.

(5) National compulsory licensing systems only operate within the national territory. They are designed to meet the needs of the population of the issuing Member State and to satisfy the public interest of that Member State. This limited territorial reach of a national compulsory licensing system is reinforced by the fact that there is no exhaustion of the patent right regarding products manufactured under a compulsory licence. Consequently, compulsory licensing schemes do not provide an adequate solution for cross-border manufacturing processes, and therefore there is no functioning internal market for product manufactured under a compulsory licence. Apart from the fact that the issuance of multiple national compulsory licences is a high hurdle for cross-border supply within the single market, it also bears the risk of contradicting and incoherent decisions among Member States. Consequently, the current compulsory licensing framework appears inadequate to address the realities of the internal market and its inherent cross-border supply chains. This suboptimal compulsory licensing framework prevents the Union from relying on an additional instrument when facing crises, in particular when voluntary agreements are unavailable or inadequate. At a time where the Union and its Member States are striving to improve their resilience to crises, it is necessary to provide for an optimal compulsory licensing system for crisis management that takes the full advantage of the internal market and allows Member States to support one another in crises.

(6) Therefore, it is necessary to establish a compulsory licence for crisis or emergency management at Union level. Under this system, the Commission should be empowered to grant a compulsory licence that is valid throughout the Union and that allows the manufacturing and distribution of products necessary to address a crisis or emergency in the Union ('Union compulsory licence').

(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].

(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

[3] OJ L 336, 23.12.1994, p. 214

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.

(9) To ensure optimal efficiency of the Union compulsory licence as a tool to address crises, it should be made available in respect of a granted patent or utility model, of a published patent application or a supplementary protection certificate. The Union compulsory licence should equally apply to a national patents, European patents and European patents with unitary effect.

(10) Utility model systems protect new technical inventions that do not fulfil the patentability requirements through the granting of an exclusive right to prevent others, for a limited period of time, from commercially exploiting the protected inventions without consent of the right holders. The definition of utility models varies from one country to another, and not all Member States provide for utility model systems. In general, utility models are suited for protecting inventions that make small improvements to, or adaptations of, existing products, or that have a short commercial life. However, similarly to patents, utility models can protect inventions that could prove necessary to address a crisis and should therefore be included in the scope of the Union compulsory licence.

(11) A Union compulsory licence for a patent should extend to the supplementary protection certificate where such protection is granted when the patent expires during the duration period of that compulsory licence. This would allow a compulsory licence on a patent to produce its effect should the crisis-relevant products no longer be protected by a patent while being protected through a supplementary protection certificate after the expiration of the patent. It should also apply to a supplementary protection certificate in isolation where the licence is granted after the expiry of the patent.

(12) The Union compulsory licence should also apply to published patent applications for national patents and for European patents. As the grant of a patent after the publishing of the patent application can take years, targeting only inventions protected by a granted patent could prevent an effective and timely crisis response. In crises, solutions can derive from the latest state-of-the-art technology. Moreover, certain national patent legislations, as well as the European Patent Convention, provide for protection of patent applicants with regard to unconsented use of their inventions and the corresponding possibility for such applicants to licence the use of their patent application rights. In order to ensure that a Union compulsory licence on a published patent application continues to keep its effects once the patent is granted, the Union compulsory licence for published patent applications should extend to the patent once granted to the extent that the crisis-relevant product still falls within the scope of the patent claims.

(13) It should be clarified that this Regulation is without prejudice to Union law on copyright and related rights, including Directives 96/9[4], 2009/24[5]

[4] Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases (OJ L 77, 27.3.1996, p. 20)

Directives 2001/29/EC[6], 2004/48/EC[7] and (EU) 2019/790[8] of the European Parliament and of the Council, which establish specific rules and procedures that should remain unaffected.

(14) When a compulsory licence has been granted, regulatory data protection may, if still in force, prevent the effective use of the compulsory licence as it impedes the authorisation of generic medicinal products. This would result in serious negative consequences for Union compulsory licences granted to tackle a crisis, as this could hamper access to the medicinal products needed to address the crisis. For this reason, Union pharmaceutical legislation (cf. Art. 80 para. 4 of Directive (EU) No XXX/XX [COM(2023)192]) provides for the suspension of data exclusivity and market protection when a compulsory licence has been issued to tackle a public health emergency. Such suspension is allowed only in relation to the compulsory licence granted and its beneficiary and must comply with the objectives, the territorial scope, the duration, and the subject-matter of the granted compulsory licence. The suspension means that the data exclusivity and market protection produce no effect in relation to the licensee of the compulsory licence while that licence is in effect. When the compulsory licence ends, the data exclusivity and market protection resume their effect. The suspension should not result in an extension of the original duration of the regulatory data protection.

(15) In order to ensure as much coherence as possible with existing crisis mechanisms and with other Union legislation, the definition of a 'crisis-relevant product' should be based on the definition adopted in the Single Market Emergency Instrument (SMEI) but should be more general in order to cover products related to different kinds of crises or emergencies.

(16) A Union compulsory licence authorises the use of a protected invention without the consent of the rights-holder. Therefore, it must only be granted exceptionally and under conditions that take into account the interests of the rights-holder. This includes a clear determination of the scope, duration and territorial coverage of the licence. In the context of a Union level crisis mechanism, the crisis mode or emergency mode is activated or declared for a limited period of time. Where a Union compulsory licence is granted within such framework, the duration of the licence shall not extend beyond the duration of the activated or declared crisis or emergency mode. In order to ensure that the compulsory licence fulfils its objective as well as its conditions, the use of the invention should only be authorised to a qualified person able to manufacture the crisis-relevant product and to pay a reasonable remuneration to the rights-holder.

(17) When considering the granting of a Union compulsory licence, the Commission should, in order to be able to take a well-informed decision, be assisted by an advisory body. The consultation of the advisory body should arise early in the discussions on the need to issue a compulsory licence under the relevant instrument. Discussions on

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5 Directive 2009/24/EC of the European Parliament and of the Council of 23 April 2009 on the legal protection of computer programs (OJ L 111, 5.5.2009, p. 16)

6 Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the information society (OJ L 167, 22.6.2001, p. 10).

7 Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (OJ L 157, 30.4.2004, p. 45).

8 Directive (EU) 2019/790 of the European Parliament and of the Council of 17 April 2019 on copyright and related rights in the Digital Single Market and amending Directives 96/9/EC and 2001/29/EC (OJ L 130, 17.5.2019, p. 92).

whether there is a need for a Union compulsory licence will often start already in the context of the work of the advisory body involved in the context of the relevant Union crisis or emergency mechanisms. In such case, there is no need for the Commission to convene the advisory body but rather to swiftly indicate that that body also has the competence to assess the need for compulsory licensing at Union level, and the conditions thereof. Clarification as regards the competence of the advisory body should be given early in the process, as soon as concrete consideration of using compulsory licensing at Union level is expressed 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 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').

(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.

(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.

(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.

(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.

(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.

(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 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.

(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 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.

(26) The Union compulsory licence should also include information allowing the identification of the crisis-relevant product for which it is granted, as well as details on the licensee to whom the Union compulsory licence is granted, including details about the description, name or brand of the product; the commodity codes under which the crisis-relevant products are classified, as defined in Council Regulation (EEC) No 2658/87; details on the licensees (and, where applicable, the manufacturers) to whom the compulsory licence is granted, including their name, trade name or registered trade mark, their contact details, their unique identification number in the country where they are established and, where available, their Economic Operators Registration and Identification (EORI) number. Where required under Union legislation, other information should be included, such as a type, reference, model, batch or serial number, or unique identifier of a product passport.

(27) The licensee should pay an adequate remuneration to the rights-holder as determined by the Commission. The amount of the remuneration should be determined considering the economic value of the exploitation authorised under the licence to the licensee and to the Member States concerned by the crisis, any public support received by the rights-holder to develop the invention, the degree to which development costs have been amortized as well as humanitarian circumstances relating to the granting of the Union compulsory licence. In addition, the Commission should consider the comments made by the rights-holder and the assessment made by the advisory body with regard to the amount of the remuneration. In any case, the remuneration should not exceed 4 % of the total gross revenue generated by the licensee through the acts under the Union compulsory licence. This percentage is the same as the one provided for under Regulation 816/2006. In the event of a compulsory licence granted on the basis of a published patent application that ultimately does not lead to the granting of a patent, the rights-holder would have no ground to receive remuneration under the compulsory licence, as the subject matter for the receipt of the remuneration has not materialised. In such circumstances, the rights-holder should refund the remuneration it received under the compulsory licence.

(28) It is imperative that products manufactured under a Union compulsory licence reach only the internal market. The Union compulsory licence should therefore impose clear conditions upon the licensee as regards the activities authorised under the licence, including the territorial reach of those activities. The rights-holder should be able to challenge actions and uses of the rights concerned by the Union compulsory licence that do not comply with the conditions of the licence, as infringement of its intellectual property rights in accordance with Directive 2004/48/EC of the European Parliament and of the Council[9]. In order to facilitate monitoring of the distribution of products manufactured under a Union compulsory licence, including controls by customs authorities, the licensee should ensure that such products have special characteristics

[9] Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (OJ L 157 30.4.2004, p. 45).

that make them easily identifiable and distinguishable from the products marketed by the rights-holder.

(29) A Union compulsory licence in the context of a Union crisis or emergency mechanism should only be granted to supply the internal market with crisis-relevant products. Therefore, it should be prohibited to export products manufactured under a Union compulsory licence.

(30) Customs authorities should ensure, through a risk analysis approach, that products manufactured under a Union compulsory license are not exported. To identify such products, the main source of information to feed such customs risk-analysis should be the Union compulsory license itself. Information on each implementing act granting or modifying a Union compulsory license should thus be entered in the Electronic Customs Risk Management System (CRMS) referred to in Article 36 of Commission Implementing Regulation (EU) 2015/2447[10]. When customs authorities identify a product that is suspected not to comply with the export prohibition, they should suspend the export of that product and notify the Commission immediately. The Commission should reach a conclusion on the compliance with the export prohibition within 10 working days, but should have the possibility of requiring the customs authorities to maintain the suspension where necessary. To help its assessment the Commission may consult the relevant rights-holder. Where the Commission concludes that a product does not comply with the export prohibition, customs authorities should refuse its export.

(31) The legal validity of the implementing act granting the Union compulsory license, or any subsequent implementing act, should be subject to judicial review.

(32) The relation between the rights-holder and the licensee should be governed by the principle of good faith. The rights-holder and licensee should work towards the success of the Union compulsory licence and collaborate, where necessary, to ensure that the Union compulsory licence effectively and efficiently fulfils its objective. The Commission may act as an enabler in achieving the good-faith cooperation between the rights-holder and the licensee, taking into account interests of all parties. In that respect, the Commission should also be entitled to take additional measures in line with Union law to ensure that the compulsory licence meets its objective and ensure that necessary crisis-relevant goods can be made available in the Union. Such additional measures may include requesting further information which is deemed indispensable to achieve the objective of the compulsory licence. These measures should always include adequate safeguards to ensure the protection of the legitimate interests of all parties.

(33) In order to respond appropriately to the crisis situations, the Commission should be authorised to review the conditions of the Union compulsory licence and adapt them to changed circumstances. This should include the modification of the compulsory licence to indicate the complete list of rights and rights-holders covered by the compulsory licence, where this complete identification had not be done initially. This should also include the termination of the licence if the circumstances which led to it cease to exist and are unlikely to recur. When deciding on the revision of the Union compulsory licence, the Commission may decide to consult the competent advisory body for that purpose. If the Commission intends to change essential components of

[10] Commission Implementing Regulation (EU) 2015/2447 of 24 November 2015 laying down detailed rules for implementing certain provisions of Regulation (EU) No 952/2013 of the European Parliament and of the Council laying down the Union Customs Code (OJ L 343, 29.12.2015, p. 558).

the Union compulsory licence, such as its duration or remuneration or if the change itself could be the subject of a separate compulsory licence, it should be required to consult the advisory body.

(34) To prevent and stop any misuse of the Union compulsory licence, specific safeguards should be in place to allow the Commission to take action. In addition to the possibility to terminate the Union compulsory licence, the Commission should be authorised to impose fines and periodic penalty payments on the rights-holder and the licensee in order to enforce the obligations under this Regulation. The penalties should be effective, proportionate and dissuasive.

(35) Compliance with the relevant obligations imposed under this Regulation should be enforceable by means of fines and periodic penalty payments. To that end, appropriate levels of fines and periodic penalty payments should be laid down and the imposition of fines and periodic penalty payments should be subject to appropriate limitation periods in accordance with the principles of proportionality and *ne bis in idem*. All decisions taken by the Commission under this Regulation are subject to review by the Court of Justice of the European Union in accordance with the TFEU. The Court of Justice of the European Union should have unlimited jurisdiction in respect of fines and penalty payments in accordance with Article 261 TFEU.

(36) When a national compulsory licence has been granted for the purpose of addressing a crisis, the Member State or its competent authority should be required to notify the Commission of the granting of the licence, and of the specific conditions attached to it, since it allows the Commission to get an overview of national compulsory licences in the Member States and to take those compulsory licences into account when considering a Union compulsory licence, and in particular when setting the conditions for such licence.

(37) The possibility of a compulsory licence at Union level should not only be available for the supply of the Union market but also under certain conditions for export purposes concerning countries with public health problems, already regulated by Regulation (EC) No 816/2006 of the European Parliament and of the Council[11]. Under that Regulation, the granting of such compulsory licences is decided and performed nationally by the competent authorities of the Member States that have received a corresponding application from a person that intends to manufacture and sell pharmaceutical products covered by a patent or a supplementary protection for export to eligible third countries. Regulation (EC) No 816/2006 only allows compulsory licensing covering the manufacturing of products across several Member States through national procedures. In the context of a cross-border manufacturing process different national compulsory licences would be needed. This can lead to a burdensome and lengthy process as this would require the launch of different national procedures with possibly different scope and conditions. In order to achieve the synergies and efficient process as for the Union crisis mechanisms, a Union compulsory licence should also be available, in the context of Regulation (EC) No 816/2006. This will facilitate manufacturing of the relevant products across several Member States and provide Union-level solution in order to avoid a situation where several compulsory licences for the same product in more than one Member States would be required for licensees to manufacture and export the products as planned.

[11] Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems (OJ L 157, 9.6.2006, p. 1).

Any person considering to apply for a compulsory licence under, for the purposes and within the scope of Regulation (EC) No 816/2006 should have the possibility to request, with a single application, a compulsory licence under that Regulation that is valid throughout the Union, if that person, when relying on national compulsory licencing schemes of the Member States, would otherwise need to apply for multiple compulsory licences for the same crisis-relevant product in more than one Member State in order to realise its intended activities of manufacture and sale for export under Regulation (EC) No 816/2006. Therefore, Regulation (EC) No 816/2006 should be amended accordingly.

(38) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the granting, complementing, modification or termination of a Union compulsory license, the determination of the remuneration to be paid to the rights-holder, the procedural rules for the ad hoc advisory body and the characteristics allowing the identification of products produced under a Union compulsory licence. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[12]. The advisory procedure should be used for the adoption of implementing acts granting, complementing, modifying or terminating a Union compulsory licence, and implementing acts determining the remuneration. The choice of the advisory procedure is justified given that those implementing acts would be adopted in the context of a procedure with considerable participation of the Member States through the consultation of the advisory body. The examination procedure should be used for the adoption of implementing acts establishing procedural rules for the ad hoc advisory body and implementing acts establishing the characteristics allowing the identification of products produced under a Union compulsory licence.

(39) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the granting, modification or termination of a Union compulsory licence or the determination of the remuneration, imperative grounds of urgency so require.

(40) Union compulsory licensing for crisis management is a tool that is only used in exceptional circumstances. The evaluation should therefore be conducted only where a Union compulsory licence has been granted by the Commission. The evaluation report should be submitted by the last day of the third year following the granting of the Union compulsory licence, to allow an adequate and substantiated assessment of this Regulation.

(41) Since a period of time is required to ensure that the framework for the proper functioning of the system for Union compulsory licencing is in place, the application of this Regulation should be deferred.

[12] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

HAVE ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation has the objective to ensure that in crises the Union has access to crisis-relevant products. To this end, this Regulation lays down rules on the procedure and conditions for the granting 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.

Article 2

Scope

1. This Regulation establishes Union compulsory licensing of the following intellectual property rights in force in one or more Member States:
   (a) patents, including published patent applications;
   (b) utility models; or
   (c) supplementary protection certificates;
2. This Regulation is without prejudice to the rules laid down by other Union legal acts regulating copyright and related rights, including Directive 2001/29, Directive 2009/24 and the *sui generis* rights granted by Directive 96/9/EC on the legal protection of databases.

Article 3

Definitions

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

(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;

(b) 'relevant activities' means the acts of making, using, offering for sale, selling or importing.

(c) 'rights-holder' means a holder of any of the intellectual property rights referred to in Article 2(1);

(d) 'protected invention' means any invention protected by any of the intellectual property rights referred to in Article 2(1);

(e) 'Union compulsory licence' means a compulsory licence granted by the Commission to exploit a protected invention of crisis-relevant products for any of the relevant activities in the Union;

(f) ‘customs authorities’ means customs authorities as defined in Article 5, point (1), of Regulation (EU) No 952/2013 of the European Parliament and of the Council[13];

Article 4

Union compulsory licence

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

Article 5

General conditions of a Union compulsory licence

1. The Union compulsory licence shall

   (a) be non-exclusive and non-assignable, except with that part of the enterprise or goodwill which enjoys such compulsory licence;

   (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;

   (c) be strictly limited to the relevant activities of crisis-relevant products in the Union;

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

   (e) be limited to the territory of the Union;

   (f) only be granted to a person deemed to be in a position to exploit the protected invention in a manner that permits the proper carry out of the relevant activities of the crisis-relevant products and in accordance with the obligations referred to in Article 10.

2. A Union compulsory licence for an invention protected by a published patent application shall cover a patent granted based on that application, provided that the granting of that patent takes place while the Union compulsory licence is valid.

3. A Union compulsory licence for an invention protected by a patent shall cover a supplementary protection certificate issued with reference to that patent, provided that the transition from patent protection to protection conferred by a supplementary protection certificate takes place while the Union compulsory licence is valid.

Article 6

Advisory body

1. When the Commission considers the granting of a Union compulsory licence, it shall without undue delay consult an advisory body.

[13] Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (OJ L 269, 10.10.2013, p. 1).

2. The advisory body referred to in paragraph 1 shall be the advisory body competent for the Union crisis or emergency mechanism as listed in Annex I to this Regulation (the 'competent advisory body'). For the purposes of the present Regulation, the competent advisory body shall assist and advise the Commission as regards the following tasks:

   (a) the gathering of crisis-relevant information, market intelligence and the analysis of those data;

   (b) the analysis of the crisis-relevant information gathered by Member States or the Commission and aggregated data received by other crisis-relevant bodies at Union and international level;

   (c) the facilitation of exchanges and sharing of information with other relevant bodies and other crisis-relevant bodies at Union and national level, as well as at international level, where appropriate;

   (d) the identification of the rights protecting the crisis-relevant product;

   (e) the establishment of whether there is a need to grant a Union compulsory licence;

   (f) the identification and consultation of the representatives of right holders or their representatives as well as potential licensees and consulting other economic operators, and the industry;

   (g) the establishment, if relevant, of whether the criteria for termination or modification of the Union compulsory licence set out in Article 15 have been fulfilled.

3. The advisory body shall cooperate and coordinate closely, where appropriate, with other relevant crisis-related bodies and with intellectual property offices at Union and national level.

4. For the purpose of the present Regulation, the Commission:

   (a) shall ensure participation and invite representatives of other crisis-relevant bodies at Union level as observers to the relevant meetings of the advisory body in order to ensure coherence with the measures implemented through other Union mechanisms; and

   (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.

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.

6. The Commission shall adopt an implementing act laying down the rules of procedure for the ad hoc advisory body referred to in paragraph 5. The rules of procedure shall specify that the ad hoc advisory body shall not be set up for a period exceeding the duration of the crisis or emergency. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 24 (3).

Article 7

Procedure for granting a Union compulsory licence

1. The competent or, where relevant ad hoc, advisory body referred to in Article 6 shall provide the Commission with an opinion without undue delay. That opinion shall be issued in accordance with the rules of procedure of the advisory body and shall contain an assessment of the need for a Union compulsory licence and the conditions for such licence. The opinion shall take account of the following:

   (a) the nature of the crisis or emergency;

   (b) the scope of the crisis or emergency and how it is expected to evolve;

   (c) the shortage of crisis-relevant products and the existence of other means than a Union compulsory licence that could adequately and swiftly remedy such shortage.

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.

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:

   (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;

   (b) the need to grant the Union compulsory licence;

   (c) the conditions under which the Commission intends to grant the Union compulsory licence, including the amount of the remuneration.

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.

5. When the Commission considers the granting of a Union compulsory licence, it shall without undue delay publish a notice to inform the public about the initiation of the procedure under this article. This notice shall also include, where already available and relevant, information on the subject of the compulsory licence and an invitation to submit comments in accordance with paragraph 3. The notice shall be published in the Official Journal of the European Union.

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.

7. Where the Commission finds that the requirements for a Union compulsory licence are met, the Commission shall grant it by means of an implementing act. The

implementing act shall be adopted in accordance with the advisory procedure referred to in Article 24(2). On duly justified imperative grounds of urgency relating to the impacts of the crisis, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 24(4). In case of procedure under Article 24(4), the implementing act shall remain in force for a period not exceeding 12 months.

8. When adopting the implementing act, the Commission shall ensure the protection of confidential information. While respecting the confidentiality of the information, the Commission shall ensure that any information relied on for the purpose of its decision is disclosed to an extent that allows to understand the facts and considerations that led up to the adoption of the implementing act.

Article 8

Content of the Union compulsory licence

1. The Union compulsory licence shall specify the following:

(a) the patent, patent application, supplementary protection certificate or utility model for which the licence is granted or, where the identification of those rights would significantly delay the granting of the licence, the non-proprietary name of the products which are to be manufactured under the licence;

(b) the right-holder, provided they can be identified with reasonable efforts having regard to the circumstances, including the urgency of the situation;

(c) the licensee, in particular the following information:

(1) name, trade name and registered trade mark;

(2) contact details;

(3) unique identification number in the country where the licensee is established;

(4) where available, the Economic Operators Registration and Identification (EORI) number;

(d) the duration for which the Union compulsory licence is granted;

(e) the remuneration to be paid to the rights-holder determined in accordance with Article 9;

(f) the non-proprietary name of the crisis-relevant product which is to be manufactured under the Union compulsory licence and its commodity code (CN code) under which the crisis-relevant product is classified, as defined in Council Regulation (EEC) No 2658/87;

(g) the details referred to in Article 10(1)(c), (d) and (e) allowing the identification of the crisis-relevant product manufactured under the Union compulsory licence and, where applicable, any other specific requirement under Union legislation applicable to the crisis-relevant products and allowing its identification.

(h) measures complementing the compulsory licence, which are necessary to achieve the objective of the compulsory licence.

2. By way of derogation from paragraph 1, point (e), the Commission may determine the remuneration after the granting of the licence, by way of an implementing act, where that determination requires, further investigation and consultation. This implementing act shall be adopted in accordance with the rules referred to in Article 7(6) (a) and (b), 7(7) and 7(8).

Article 9

Remuneration

1. The licensee shall pay an adequate remuneration to the rights-holder. The amount of the remuneration shall be determined by the Commission and specified in the Union compulsory licence.

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

3. When determining the remuneration, the Commission shall consider the following:

   (a) the economic value of the relevant activities authorised under the Union compulsory licence.

   (b) whether the rights-holder has received public support to develop the invention.

   (c) the degree to which development costs have been amortized by the rights-holder.

   (d) where relevant, the humanitarian circumstances relating to the granting of the Union compulsory licence.

4. If the published patent application for which a compulsory licence has been granted does not subsequently lead to the granting of a patent, the rights-holder shall refund the remuneration paid under this article to the licensee.

Article 10

Obligations to be fulfilled by the licensee

1. The licensee shall be authorised to exploit the protected invention covered by the Union compulsory license only under the following obligations:

   (a) the number of crisis-relevant products manufactured under the Union compulsory licence does not exceed what is necessary to meet the needs of the Union;

   (b) the relevant activities are carried out solely for the supply of the crisis-relevant products in the Union market;

   (c) the products manufactured under the Union compulsory licence are clearly identified, through specific labelling or marking, as being manufactured and marketed pursuant to this Regulation.

   (d) the products manufactured under the Union compulsory licence can be distinguished from products manufactured and marketed by the rights-holder or under a voluntary licence granted by the rights-holder by way of special packaging, colouring or shaping, provided that such distinction is feasible and does not have a significant impact on the price of the products;

(e) the packaging of the products manufactured under the Union compulsory licence and any associated marking or leaflet indicate that the products are subject to a Union compulsory licence under this Regulation and specify clearly that the products are exclusively for distribution in the Union and are not to be exported.

(f) before the marketing of the products manufactured under the Union compulsory licence, the licensee shall make available on a website the following information:

(1) the quantities of the products manufactured under the Union compulsory licence per Member State of manufacturing;

(2) the quantities of the products supplied under the Union compulsory licence per Member State of supply;

(3) the distinguishing features of the products under the Union compulsory licence.

The address of the website shall be communicated to the Commission. The Commission shall communicate the address of the website to the Member States.

2. In the event of a failure by the licensee to fulfil the obligations laid down in paragraph 1 of this Article the Commission may:

(a) terminate the Union compulsory licence in accordance with Article 14(3); or

(b) impose fines or periodic penalties on the licensee in accordance with Articles 15 and 16.

3. The European Anti-Fraud Office (OLAF) in cooperation with the relevant national authorities of the Member States may, at the request of the rights-holder or on its own initiative, request access to books and records kept by the licensee, for the purpose of checking whether the content and the conditions of the Union compulsory licence, and in general the provisions of this Regulation, have been complied with.

4. The Commission is empowered to adopt implementing acts establishing rules for the specific labelling or marking referred to in paragraph 1, point (c), and for the packaging, colouring and shaping referred to in point (d) as well as rules for their use and, where relevant, their positioning on the product. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 24(2).

Article 11

Prohibition of export

The export of products manufactured under a Union compulsory licence is prohibited.

Article 12

Customs control

1. The application of this article is without prejudice to other Union legal acts governing the export of products, in particular Articles 46, 47 and 267 of Regulation (EU) No 952/2013[14].

2. Customs authorities shall rely on the Union compulsory license and modifications thereof to identify products that may fall under the prohibition laid down in Article 11. For that purpose, risk information as regards each Union compulsory licence and any modification thereof shall be entered in the relevant customs risk management system. Customs authorities shall take such risk information into consideration when they carry out controls on products placed under the customs procedure 'export' in accordance with Articles 46 and 47 of Regulation (EU) No 952/2013.

3. Where customs authorities identify a product that may fall under the prohibition laid down in Article 11, they shall suspend its export. Customs authorities shall immediately notify the Commission of the suspension and provide it with all relevant information to enable it to establish whether the product was manufactured under a Union compulsory license. To assess whether the suspended products correspond to the Union compulsory license, the Commission may consult the relevant rights-holder.

4. Where the export of a product has been suspended in accordance with paragraph 3, the product shall be released for export provided that all the other requirements and formalities under Union or national law relating to such export have been fulfilled, and either of the following conditions is fulfilled:

   (a) the Commission has not requested the customs authorities to maintain the suspension within 10 working days after it was notified thereof;

   (b) the Commission has informed the customs authorities that the product is not manufactured under a Union compulsory licence.

5. Where the Commission concludes that a product manufactured under a Union compulsory licence does not comply with the prohibition laid down in Article 11, customs authorities shall not authorise its release for export. The Commission shall inform the concerned rights-holder of such non-compliance.

6. Where the release for export of a product has not been authorised:

   (a) where appropriate in view of the crisis or emergency context, the Commission may require customs authorities to oblige the exporter to take specific actions at their own costs, including supplying them to designated Member States, if need be, after rendering them compliant with Union law.

   (b) in all other cases, customs authorities may take any necessary measure to ensure that the product concerned is disposed of in accordance with national law consistent with Union law. Articles 197 and 198 of Regulation (EU) No 952/2013 shall apply accordingly.

[14] REGULATION (EU) No 952/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 October 2013 laying down the Union Customs Code.

Article 13

Relations between rights-holder and licensee

1. The relations between the rights-holder and the licensee who has been granted a Union compulsory license shall act and cooperate with each other in good faith when performing rights and obligations under this Regulation.

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.

Article 14

Review and termination of the Union compulsory licence

1. The Commission shall review the Union compulsory licence upon reasoned request by the rights-holder or the licensee or on its own initiative and shall, where needed, modify the specifications referred to in Article 8 by means of an implementing act. Where necessary, the Union compulsory licence shall be modified to indicate the complete list of rights and rights-holders covered by the compulsory licence.

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.

3. A Union compulsory licence may be terminated by the Commission by means of an implementing act where the circumstances which led to it cease to exist and are unlikely to recur or where the licensee fails to comply with the obligations laid down in this Regulation.

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.

5. When terminating the Union compulsory licence, the Commission may require that the licensee, within a reasonable period of time, arrange for any goods in its possession, custody, power or control to be redirected or otherwise disposed of in the manner determined by the Commission in consultation with the rights-holder and at the expense of the licensee.

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).

Article 15

Fines

1. The Commission may by decision impose on the licensee or the rights-holder fines not exceeding 6 % of their respective total turnover in the preceding business year where, intentionally or negligently:

(a) the licensee fails to comply with its obligations under Article 9(1) or Article 10(1);

(b) the rights-holder or the licensee fail to comply with the principle of good faith and cooperation referred to in Article 13; or

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

2. In fixing the amount of the fine, regard shall be had to the gravity, to the recurrence of the infringement and to the duration of the infringement.

Article 16

Periodic penalty payments

1. The Commission may, by decision, impose on the licensee or the rights-holder periodic penalty payments not exceeding 5 % of their respective average daily turnover in the preceding business year per day and calculated from the date appointed by the decision, in order to compel:

(a) the licensee to put an end to an infringement of its obligations under Article 10(1);

(b) the licensee and the rights-holder to put an end to the infringement of Article 13; or

(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.

2. Where the licensee or the rights-holder have satisfied the obligation which the periodic penalty payment was intended to enforce, the Commission may fix the definitive amount of the periodic penalty payment at a figure lower than that which would arise under the original decision.

Article 17

Limitation period for the imposition of fines and periodic penalty payments

1. The powers conferred on the Commission by Articles 15 and 16 shall be subject to a limitation period of five years.

2. Time shall begin to run on the day on which the infringement is committed. However, in the case of continuing or repeated infringements, time shall begin to run on the day on which the infringement ceases.

3. Any action taken by the Commission or by a competent authority of the Member States for the purpose of the investigation or proceedings in respect of an infringement shall interrupt the limitation period for the imposition of fines or periodic penalty payments.

4. Each interruption shall start time running afresh. However, the limitation period for the imposition of fines or periodic penalty payments shall expire at the latest on the day on which a period equal to twice the limitation period has elapsed without the Commission having imposed a fine or a periodic penalty payment. That period shall be extended by the time during which the limitation period has been suspended pursuant to paragraph 5.

5. The limitation period for the imposition of fines or periodic penalty payments shall be suspended for as long as the decision of the Commission is the subject of proceedings pending before the Court of Justice of the European Union.

Article 18

Limitation period for the enforcement of fines and periodic penalty payments

1. The power of the Commission to enforce decisions taken pursuant to Articles 15 and 16 shall be subject to a limitation period of five years.

2. Time shall begin to run on the day on which the decision becomes final.

3. The limitation period for the enforcement of penalties shall be interrupted:

   (a) by notification of a decision varying the original amount of the fine or periodic penalty payment or refusing an application for variation;

   (b) by any action of the Commission, or of a Member State acting at the request of the Commission, designed to enforce payment of the fine or periodic penalty payment.

4. Each interruption shall start time running afresh.

5. The limitation period for the enforcement of penalties shall be suspended for so long as:

   (a) time to pay is allowed;

   (b) enforcement of payment is suspended pursuant to a decision of the Court of Justice of the European Union or to a decision of a national court.

Article 19

Right to be heard and access to the file

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.

2. The licensee or the rights-holder may submit its observations on the alleged infringement within a reasonable period set by the Commission, which may not be less than 14 days.

3. The Commission shall base its decisions only on objections on which the parties concerned have been able to comment.

4. The rights of defence of the parties concerned shall be fully respected in the proceedings. They shall be entitled to have access to the Commission's file under the terms of a negotiated disclosure, subject to the legitimate interest of the licensee or

the rights-holder or other person concerned in the protection of their commercially sensitive information and trade secrets. The Commission shall have the power to adopt decisions setting out such terms of disclosure in case of disagreement between the parties. The right of access to the file of the Commission shall not extend to confidential information and internal documents of the Commission, other competent authorities or other public authorities of the Member States. In particular, the right of access shall not extend to correspondence between the Commission and those authorities. Nothing in this paragraph shall prevent the Commission from disclosing and using information necessary to prove an infringement.

5. If the Commission considers it necessary, it may also hear other natural or legal persons. Applications to be heard on the part of such persons shall, where they show a sufficient interest, be granted.

Article 20

Publication of decisions

1. The Commission shall publish the decisions it adopts pursuant to Article 15 and Articles 16. Such publication shall state the names of the parties and the main content of the decision, including any fines or penalties imposed.

2. The publication shall have regard to the rights and legitimate interests of the licensee, the rights-holder or any third parties in the protection of their confidential information.

Article 21

Review by the Court of Justice of the European Union

In accordance with Article 261 TFEU, the Court of Justice of the European Union has unlimited jurisdiction to review decisions by which the Commission has imposed fines or periodic penalty payments. It may cancel, reduce or increase the fine or periodic penalty payment imposed.

Article 22

Reporting on national compulsory licences

When a national compulsory licence has been granted for the purpose of addressing a national crisis or emergency, the Member State shall notify the Commission of the granting of the licence and of the specific conditions attached to it. The information provided shall include the following:

(a) the purpose of the national compulsory licence and its legal basis in national law;

(b) the name and address of the licensee;

(c) the products concerned and, to the extent possible, the concerned intellectual property rights and rights-holders;

(d) the remuneration to be paid to the rights-holder;

(e) the quantity of products to be supplied under the licence;

(f) the duration of the licence.

Article 23

Amendments to Regulation (EC) No 816/2006

Regulation (EC) No 816/2006 is amended as follows:

(a) The following Article 18a is inserted:

"Article 18a

Union compulsory licence

1. The Commission may grant a compulsory licence where the activities of manufacture and sale for export spread across different Member States and would therefore require compulsory licences for the same product in more than one Member State.

2. Any person may submit an application for a compulsory licence under paragraph 1. The application shall fulfil the requirements laid down in Article 6 (3) and shall specify the Member States to be covered by the compulsory licence.

3. The compulsory licence granted in accordance with paragraph 1 shall be subject to the conditions set out in Article 10 and shall specify that it is applicable to the whole territory of the Union.

4. In the event of an application referred to in paragraph 2 under this Article, the competent authority referred to in Articles 1 to 11, 16 and 17 shall be the Commission.

5. The Commission is empowered to adopt implementing acts in order to:

(a) grant a compulsory licence;

(b) reject the application for a compulsory licence;

(c) amend or terminate the compulsory licence.

Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 18b (2). On duly justified imperative grounds of urgency relating to the impacts of the public health problems, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 18b (3)."

(b) The following Article 18b is inserted:

"Article 18b
Committee Procedure

1. The Commission shall be assisted by a committee ('the Compulsory Licensing Committee'). That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 4 thereof, shall apply."

Article 24

Committee Procedure

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.
3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.
4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 4 thereof, shall apply.

Article 25

Evaluation

The Commission shall, by the last day of the third year following the granting of the Union compulsory licence in accordance with Article 7, present an evaluation report to the Council, the European Parliament and the European Economic and Social Committee on the application of this Regulation.

Article 26

Entry into force

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

EUROPEAN
COMMISSION

Brussels, 27.4.2023
COM(2023) 224 final

ANNEX

ANNEX

to 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

{SEC(2023) 173 final} - {SWD(2023) 120 final} - {SWD(2023) 121 final} -
{SWD(2023) 122 final}

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

Union crisis or emergency mechanism	Crisis mode or emergency mode	Competent Advisory Body
1. Regulation XXX/XX of the European Parliament and of the Council establishing a Single Market Emergency Instrument and repealing Council Regulation (EC) 2679/98 [COM(2022) 459]	**Single Market emergency mode** activated by means of a Council implementing act [Article 14 of Regulation XXX/XX] [COM(2022) 459]	**Advisory Group** [Article 4 of Regulation XXX/XX] [COM(2022) 459]
2. Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU	**Public health emergency at Union level** formally recognized by means of a Commission implementing act [Article 23 of Regulation (EU) 2022/2371]	**Health Security Committee** [Article 4 of Regulation (EU) 2022/2371]
3. Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at	**Emergency framework** activated by the adoption of a Council Regulation [Article 3 of Regulation (EU) 2022/2372]	**The Health Crisis Board** [Article 5 of Regulation (EU) 2022/2372]

Union level		
4. Regulation XXX/XX establishing a framework of measures for strengthening Europe's semiconductor ecosystem [COM(2022) 46]	**Crisis stage** activated by a Commission implementing act [Article 18 of Regulation XXX/XXX] [COM(2022) 46]	**European Semiconductor Board** [Article 23 of Regulation XXX/XXX] [COM(2022) 46]
5. Regulation (EU) 2017/1938 of the European Parliament and of the Council of 25 October 2017 concerning measures to safeguard the security of gas supply and repealing Regulation (EU) No 994/2010	**Union emergency** declared by the Commission [Article 12 of Regulation (EU) 2017/1938]	**Gas Coordination Group** [Article 4 of Regulation (EU) 2017/1938]