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#### **NOTE**

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From:	Presidency
To:	Working Party on Intellectual Property (Patents)

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Subject:	Proposal for a Regulation of the European Parliament and the Council on Compulsory Licensing for crisis management and amending Regulation (EC) 816/2006 - Presidency revised text (overview of amendments)
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Delegations will find attached an overview of the main amendments and the underlying reasoning of the changes made in the first Presidency revised text of the above-mentioned proposal as set out in document 7471/24.

## **Annex to WK 3706/2024**

### **Overview of the main amendments in the first Presidency revised text of the Compulsory Licensing proposal as contained in document 7471/24**

#### **Article 1 (Subject matter and aim)**

Based on delegations' suggestions, we have made some changes highlighting the exceptional nature of this measure and its use in the public interest. We have also clarified that it can only be used during a crisis or emergency mode activated or declared under crisis instruments listed in the Annex.

#### **Article 2 (Scope)**

We have provisionally put patent applications (and all other provisions in the text relating to such applications) in square brackets to indicate that the issue of whether or not patent applications should come within the scope of the Regulation requires further discussion. Patent applications were included in the Commission proposal in order to have access to the most recent technology. However, questions regarding TRIPS compliance should first be clarified before a decision can be made. Furthermore, we would consider useful to have more information about the practices in this regard under national laws. In several national legal systems, patent applicants have certain rights in respect of their invention on the basis of the patent application and thus the production of the crisis-relevant products concerned by these rights could be hindered. Certain Member States also have compulsory licences for patent applications. We believe that we need more clarity on the type of rights concerned, and on the reasons for providing for compulsory licences for patent applications in national systems in the concerned Member States before we can decide whether patent applications should be included in the scope of this regulation. The same reasoning applies to utility model applications.

A significant number of Member States have signalled that an obligation to disclose trade secrets mustn't result from this proposal. To that end and following requests from Member States, we added a paragraph 3 clarifying that this Regulation does not impose any obligation to disclose trade secrets. In addition, we clarified in paragraph 2 that this proposal is without prejudice to the Trade Secrets Directive (EU) 2016/943.

Paragraph 4 aims at clarifying that a Union compulsory licence is linked to the Union Acts listed in the Annex of the Regulation and should therefore only concern measures falling within the scope of the crisis or emergency mode of the relevant Act.

### **Article 3 (Definitions)**

At the request of several Member States, we have added a definition of "crisis" or "emergency". This definition refers to the various crisis instruments listed in the Annex, which determine how a crisis or emergency mode is activated.

We have also made some changes to the definition of "crisis-relevant products". Firstly, we provide a clarification as regards processes required to manufacture or produce crisis-relevant products. Secondly, we indicate that these products should only address *direct* impacts of the crisis or emergency.

In order to streamline the text in Articles 6 and 7, a definition of "competent advisory body" was added. It now comprises both the respective advisory body provided for in the (existing) crisis instrument listed in the Annex and the ad hoc advisory body, should a (future) crisis instrument not provide for one.

## **Article 4 (General conditions for granting a compulsory licence)**

We have added cumulative conditions which need to be fulfilled in order that a compulsory licence can be granted. This amendment aims at addressing delegations' concerns as regards the lack of clear requirements to grant a Union compulsory licence, despite a reference to such requirements being made in Article 7(7) of the Commission proposal.

- The first condition is the activation of a crisis or emergency mode under one of the instruments listed in the Annex. This is the initial trigger. A compulsory licence can only be granted when such a crisis or emergency mode has been activated.
- The second condition stipulates that the lack of adequate supply of crisis-relevant products must result from the exercise of IP rights.
- The third condition emphasises the absence of suitable means other than a compulsory licence, including voluntary agreements, to adequately, efficiently and swiftly remedy the lack of supply of crisis-relevant goods. This condition qualifies the nature of the measure as a last resort.
- The last condition guarantees the involvement of rights holders, who must have had the opportunity to present their observations to the advisory body and to the Commission.

It is necessary that the second and third conditions are evaluated and assessed. In accordance with the revised Article 7, it is the Commission that assesses the fulfilment of these conditions, with the assistance and advise of the competent advisory body referred to in Article 6. Article 4(b) and (c) further requires that the Commission reasonably comes to the conclusion that the said requirements are fulfilled. This aims at providing an extra guarantee for a Union Compulsory Licence being granted only on the basis of a reasonable and substantiated assessment of the Commission and for the compliance with the procedure of Article 7.

## **Article 5 (General terms of a Union compulsory licence)**

We have made some clarifications to further emphasise the limitations of the Union compulsory licence as regards its scope and the activities it covers. Further clarification is also provided as regards the required capacities of the licensee. Moreover, we have limited the possible uses of semi-conductor technology products, in compliance with the TRIPS Agreement.

Concerning the exoneration of the rights-holder for product liability, we consider that this is already regulated by specific legislation. Therefore, instead of including this into the operative part of the Regulation, and for the sake of coherence with other existing pieces of EU legislation relating to product liability, we propose to insert an explanation in the recitals referring to relevant pieces of legislation in the field of product liability.

## **Article 6 (Advisory body)**

Following Member States' requests for more clarity, we have reshuffled and streamlined the procedure for the granting of a Union compulsory licence. To this end, certain paragraphs of the former Articles 6 and 7 have been merged or reordered and reworded.

The tasks of the advisory body are listed in Article 6(1). The tasks of the advisory body include (a) the identification of relevant IP rights and rights-holders, (b) informing the identified rights-holders, (c) the identification of potential licensees capable of exploiting the licence in an effective manner, (d) the consultation of rights-holders, potential licensees, and other relevant actors, (e) the consultation of the EP, economic operators and other relevant actors, (f) the involvement of IP experts, national authorities in charge of granting compulsory licences, (g) the gathering and analysis of data, including information obtained under Article 22 of the regulation, (h) various types of facilitation.

In paragraph 2, we clarified that an ad hoc advisory body can only be set up if a (future) crisis instrument triggering the crisis or emergency mode does not provide for one.

## **Article 7 (Procedure)**

We have restructured Article 7 to have a chronological overview of the procedure with clearly defined requirements, following requests for more clarity. The procedure can now be summarised as follows:

- Paragraph 1 relates to the initiation of the granting procedure through the publication of a notice on the website of the Commission. This notice aims at informing citizens and especially the rights-holders as the very first step of the procedure.
- Paragraph 2 provides what the notice shall include, namely (a) information on the crisis and crisis-relevant products, (b) information on IP rights and rights-holders where available, (c) an invitation to rights-holders, potential licensees and other persons to submit their comments, along the lines of the initial Article 7(3), and (d) information on the competent advisory body.
- Paragraph 3 provides that, upon publication of the notice on the Commission's website, the Commission shall request the competent advisory body to provide its opinion, within a set time limit.
- Paragraph 4 provides that, without undue delay, the notice will also be published in the *Official Journal of the European Union* to ensure that it is disseminated as widely as possible.
- Paragraph 5 relates to the content of the opinion of the advisory body, which shall be based on the results of its tasks and contain an assessment of the need for a compulsory licence and the modalities thereof.
- Paragraph 6 provides for the obligation of the advisory body to submit its opinion to the Commission within a set time limit.
- Paragraph 7 provides for the non-binding nature of the opinion.

- Paragraph 8 concerns the assessment to be made by the Commission as regards the granting of a Union compulsory licence. Where the Commission considers that there is a need to pursue the granting procedure, it has the obligation to individually inform rights-holders (where possible) and possible licensees about the fact that a Union compulsory licence may be granted. This information includes the modalities of the compulsory licence and the opinion of the advisory body. The rights-holders and the potential licensees have the opportunity under this article to submit their comments to the Commission.
- Paragraph 9 relates to the granting of the Union compulsory licence, subject to the fulfilment of the conditions set out in Article 4 and taking into account the public interest and the rights and interests of the rights-holders and licensee. The Union compulsory licence shall be granted by means of an implementing act, using the examination procedure. Where the decision of the Commission departs from the opinion of the advisory body, the Commission shall provide its reasons therefor in the implementing act.
- Paragraph 10 relates to the case where no Union compulsory licence is deemed necessary. In such case, the Commission shall publish on its website and in the *Official Journal of the European Union* a notice informing about the end of the procedure.
- Paragraph 11 entails a general confidentiality principle.

### **Article 8 (Content of the Union compulsory licence)**

Following Member States' comments a clarification has been made concerning the proprietary name, which does not exist outside the field of medicines. Moreover, a requirement to provide the maximum number of crisis-relevant products to be produced under the Union compulsory licence has been added.

We have also adapted the derogation regarding the remuneration set out in paragraph 2 to solely concern a possible delayed identification of the IP rights and rights-holders while clarifying that the Commission shall pursue its identification efforts. If it becomes apparent, after further investigation and consultation, that the initial remuneration is not correctly calculated, it can always be amended in accordance with the procedure set out in Article 14.

### **Article 9 (Remuneration)**

A number of Member States have argued that the cap of 4% of total gross revenue in Article 9(2) would not be justified. Some Member States have also indicated that the introduction of such a cap might not be TRIPS-compliant. We have therefore put this paragraph in square brackets to await further clarification on TRIPS-compliance from the Council Legal Service before deciding on how to proceed with this paragraph. Furthermore, we suggest clarifying that the remuneration shall be calculated based on the opinion of the advisory body, as the advisory body will possess the necessary IP expertise for making this calculation. Finally, we added some additional factors while clarifying the non-exhaustive nature of the list.

### **Article 10 (Obligations to be fulfilled by the licensee)**

We have added a paragraph imposing an obligation upon the licensee regarding the treatment and protection of confidential information.

### **Article 11 (Prohibition of export)**

We have added a non-prejudice clause as regards Regulation (EC) No 816/2006.

### **Article 12 (Customs control)**

In Article 12 it is clarified that the Commission enters the information in the European customs risk management system.

## **Article 13 (Good faith cooperation and conduct)**

The Article aims to ensure cooperation in good faith, as required under a regular licence.

It is suggested that a future recital will provide a non-exhaustive list of behaviour that falls within the scope of the principle of good faith ( e.g., not to engage in dilatory tactics, or the obligation of the rights-holder and the licensee to provide information to the Commission and competent advisory body during and after the procedure for the granting of a Union compulsory licence).

The article also imposes obligations upon the Commission to encourage and facilitate the good faith cooperation between the rights-holder and the licensee, as well as to provide crisis-relevant information.

## **Article 14 (Review and termination)**

In the new paragraph 2a, we provide for the possibility for the rights-holder to request additional measures to protect confidential information that is shared between the rights-holder and the licensee on a voluntary basis.

In paragraph 3, we have provided for an automatic expiry of the compulsory licence if the underlying crisis or emergency ceases to exist, considering the legitimate interests of the licensee, in accordance with Article 31 (g) TRIPS.

In paragraph 4, it is now ensured that the advisory body shall be consulted on modifications, additional measures and/or the termination of the compulsory licence, in place of the mere possibility for consultation in the Commission's proposal.

We have also replaced the reference to the advisory procedure in paragraph 6 with the reference to the examination procedure, as to ensure Member States' involvement. In addition, the protection of confidential information in the procedure is ensured.

## **Article 15 (Fines)**

The Article was amended to clarify the information that must be taken into account for the calculation of fines. Furthermore, in new paragraph 1a we introduced a cap which sets the maximum amount for fines at 300,000 EUR and 50,000 EUR for SMEs.

## **Article 16 (Periodic penalty payments)**

In paragraph 1, under (a), a reference to Article 9(1) and Article 11 was added.

In the new paragraph 1a, a percentage cap was introduced with a separate cap for SMEs. This was to some extent aligned with the wording of the Chips Act.

## **Article 17, 18 (Limitation period for imposing fines and enforcement)**

We have made a small clarification in the wording, replacing "time" with "the limitation period" based on the wording used in the Chips Act.

## **Article 19 (right to be heard and access to the file)**

We have made some small changes based on delegations' suggestions to clarify the calculation of the 14-days time limit.

## **Article 20 (Publication of decisions)**

In accordance with Article 297 TFEU, Commission Decisions that specify to whom they are addressed shall be notified to those to whom they are addressed and shall take effect upon such notification. For this reason, we consider it is not necessary to include the requirement of individual notification in the draft Regulation, as this is already required in accordance with the TFEU. Under the TFEU, such a decision will, however, not necessarily be published in the *Official Journal of the European Union*, which is why Article 20 was amended to ensure such a publication.

## **Article 21 (Review of the fines or periodic penalty payments by the CJEU)**

We have clarified in the title of Article 21 that the review by the Court of Justice of the European Union (CJEU) provided for in this article concerns fines and periodic penalty payments. Article 21 makes use of the possibility provided for in Article 261 TFEU, according to which Regulations may give the CJEU unlimited jurisdiction with regard to the penalties provided for in such regulations. We do not consider it necessary including an explicit reference to Article 263 TFEU in the text of the Compulsory Licence Regulation, as Article 263 TFEU is a general rule applying to all acts of the Commission (hence, no need for further implementation or repetition in secondary legislation). For this reason, we consider that the actions rights-holders and licensees may take could instead be clarified in the recitals with an explicit reference to Article 263 TFEU.

## **Article 23 (Amendments to Regulation (EC) No 816/2006)**

Recital 11 of Regulation (EC) No 816/2006 clarifies that competent authorities should consider existing compulsory licences for the same products and countries, as well as parallel applications by the same applicant. We therefore consider that the issue of duplication has already been addressed and that there is no need for further clarification.

The corresponding comitology procedure has been changed into the examination procedure, to ensure the involvement of Member States.

## **Article 24 (Committee Procedure)**

We have removed the reference to the articles corresponding to the advisory procedure.

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