

Compulsory licensing of patents in crisis situations

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The Committee on Legal Affairs adopted the report by Adrián VÁZQUEZ LÁZARA (Renew, ES) on the proposal for a regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) 816/2006.

The committee responsible recommended that the European Parliament's position adopted at first reading under the ordinary legislative procedure should amend the proposal as follows:

Subject matter

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

The Regulation aims to lay down rules on the procedure and conditions for the granting as a last resort of a Union compulsory licence of intellectual property rights that are necessary for the supply of crisis-relevant products to the Member States in the context of a Union crisis or emergency mechanism.

Union compulsory licence

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

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

- have a strict limitation concerning scope, field of use, necessary quantities, and a duration that is fully in line with the specific purpose for which the compulsory licence is issued, as well as strictly linked to the scope and duration of the crisis or emergency mode under which it is granted within the Union;
- be strictly limited to the relevant and properly justified activities of crisis-relevant products in the Union;
- only be granted against payment of an adequate remuneration to the rights-holder;
- be strictly limited to the precisely defined territory of the Union;
- clearly state that the licensee is responsible for any liability or warranties related to the production and distribution of crisis-relevant products, excluding the rights-holder from product liability claims.

Advisory body

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

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

Remuneration

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

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

Obligations to be fulfilled by the licensee

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

Additional measures complementing the Union compulsory licence

Where necessary, the Commission should decide, upon a reasoned request from the rights-holder or the licensee, or on its own initiative, on additional measures complementing the Union compulsory licence to ensure it achieves its objective as well as to facilitate and ensure the good collaboration between the rights-holder and the licensee.

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

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

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