

# Compulsory licensing of patents in crisis situations

2023/0129(COD) - 13/03/2024 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 484 votes 121, with 20 abstentions, a legislative resolution 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 European Parliament's position adopted at first reading under the ordinary legislative procedure amends the proposal as follows:

## *Subject matter*

The aim of the Regulation is to ensure access to crisis-relevant patented products needed to address crises in the internal market. In concrete terms, the Regulation aims 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. To this end, if no **prior voluntary agreement** has been reached within four weeks between right holder and licensee, the Commission may grant a Union compulsory license.

## *Union compulsory licence*

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 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.

Disclosure could encompass, without being exhaustively limited to, the comprehensive transfer of necessary technology, expertise, data, samples, and reference products essential for production and obtaining market authorisation in collaboration with the licensee, taking into account both the rights-holder and the licensee's interests.

The Commission should require the licensee(s) to put in place all appropriate measures reasonably identified by the rights-holder, including contractual, technical and organisational measures, to ensure the confidentiality of trade secrets, in particular vis-à-vis third parties and the protection of the legitimate interests of all parties. To that end, right holders should identify trade secrets prior to the disclosure.

Where the licensee fails to implement the measures required for preserving the confidentiality of the trade secrets, the Commission should be able to withhold or suspend the disclosure of trade secrets until the situation is corrected by the licensee. Any use, acquisition or disclosure of trade secrets which would not be necessary to fulfil the objective of the Union compulsory licence or which would go beyond the duration of the Union compulsory licence should be considered to be unlawful.

### ***Conditions***

The compulsory licence should specify that it is applicable to the whole territory of the Union and should be subject to the following conditions: (i) the licence granted is non-assignable; (ii) the expected amount of product(s) manufactured under the licence are not exceed what is necessary to meet the needs of the importing country or countries cited in the application; (iii) the duration of the licence is indicated; (iv) the licence is strictly limited to all acts necessary for the purpose of manufacturing the product in question for export and distribution in the country or countries cited in the application; (v) products made under the licence are clearly identified, through specific labelling or marking, as being produced pursuant to this Regulation.