Compulsory licensing of patents in crisis situations

2023/0129(COD) - 16/12/2025 - Text adopted by Parliament, 2nd reading

The European Parliament adopted a legislative resolution **approving** the Council's position at first reading with a view to the adoption of a regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) No 816/2006.

The proposed regulation aims to ensure that an EU compulsory license can be granted in the context of a crisis or emergency affecting the Union. To this end, it lays down rules concerning the conditions and procedure for granting a Union compulsory license for intellectual property rights that are necessary to supply Member States with essential products in the event of a crisis or emergency declared under a crisis or emergency mechanism provided for in a legal act of the Union listed in the Annex.

The regulation provides that an EU compulsory licence is granted in the public interest and as a measure of last resort when other means, including voluntary agreements to use a protected invention relating to products needed in a crisis, could not guarantee access to those products.

Scope

The regulation establishes the granting of compulsory Union licenses for the following intellectual property rights, in force in one or more Member States: (a) patents and published patent applications; (b) utility models and published utility model applications; or (c) supplementary protection certificates. The regulation does not impose any obligation to disclose **trade secrets**. It does not apply to defence-related products.

Addition of conditions to grant a compulsory licence

The granting of a Union compulsory licence is now subject to **four cumulative conditions**, namely:

(i) a crisis or emergency mode has been declared,

(ii) the use of a protected invention which concerns crisis-relevant products is required to secure the supply of those products in the Union,

(iii) means other than a Union compulsory licence, including voluntary agreements, could not be achieved within a reasonable timeframe and could not ensure access to the products,

(iv) the rightsholder concerned was given the opportunity to provide comments to the Commission and the competent advisory body.

Compulsory Licensing Procedure

The tasks of the advisory body tasked with assisting and advising the Commission are being restructured and clarified. For instance, experts from intellectual property offices and national authorities responsible for granting compulsory licences must now be involved in advisory body discussions on intellectual property. In addition, Parliament can also participate, as an observer, in the relevant meetings of the competent advisory body, including the ad hoc advisory body.

Where the Commission's decision to grant a Union compulsory licence departs from the opinion of the advisory body, it must indicate the reasons for this. Furthermore, where the Commission decides not to grant a Union compulsory licence, a notice must be published in the Official Journal of the European Union to provide information about the end of the procedure.

Lastly, it is possible to conclude voluntary licensing agreements at any time during or after the Union compulsory licensing procedure

Comitology

The implementing acts on the granting, modification and termination of the Union compulsory licence will be adopted using the examination procedure. A non-opinion clause was inserted to ensure that implementing acts cannot be adopted when the comitology committee does not deliver an opinion.

Remuneration

The licensee should pay appropriate remuneration to the rights holder. The Commission should determine the amount of this remuneration and the time limit within which it must be paid. The criteria for determining remuneration were adjusted to emphasise the economic value of the relevant activities authorised under the Union compulsory licence and public support received to develop the invention.

Fines and penalties

Fines and periodic penalty payments for failure of the licensee to comply with the obligations provided for in the Regulation were adjusted to result in lower payments than proposed by the Commission, as well as to account for SMEs. The Regulation does not envisage fines or periodic penalty payments for the right holders.

Assessment

The Commission is obliged to regularly assess the list of crisis instruments in the Annex to the Regulation and to report on the assessment to the co-legislators every five years. As part of the evaluation, the Commission will have to give specific regard to the issue of semiconductors for medical equipment.