

Compulsory licensing of patents in crisis situations

2023/0129(COD) - 27/04/2023 - Legislative proposal

PURPOSE: to establish a new EU-wide compulsory licensing instrument.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: 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.

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.

Voluntary licensing agreements usually suffice to licence the patent rights on these products and allow their supply in the Union territory. However, they 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.

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.

Currently, legislation on compulsory licensing of patents in the EU is fragmented: EU countries regulate their own national compulsory licensing schemes, subject to different conditions, scopes, and procedures. In addition, national compulsory licensing schemes are designed to meet the needs of the population of the issuing Member State and to satisfy the public interest of that Member State only. These purely national systems are unable to rely on cross-border value chains and therefore unfit to tackle EU crises.

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](#).

CONTENT: this proposal lays down the procedure and conditions for granting 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.

More specifically, it establishes Union compulsory licensing of the following intellectual property rights in force in one or more Member States:

- patents, including published patent applications;
- utility models; or

- supplementary protection certificates.

An effective EU compulsory licensing mechanism will:

- serve as an effective tool in crisis times as a last resort when voluntary agreements do not work;
- ensure an appropriate territorial reach of compulsory licensing to cover cross-border supply chains;
- build on EU crisis mechanisms.