



1<sup>st</sup> February 2024

Dear Member of the Legal Affairs Committee,

BusinessEurope has been following the developments with regard to the Commission proposal for a regulation on compulsory licencing for crisis management (Compulsory Licencing proposal) from its inception. The European business community appreciates and agrees with the need to be prepared for future crisis, meet the future challenges in different forms (e.g. health, environment and notably climate change) and help society to access crisis-relevant products or services. To this end, we refer to our position paper of 17 January 2023, addressing key issues of the Commission proposal on compulsory licencing.

As the Council has just started its discussions on the Compulsory Licencing proposal with a very ambitious schedule to possibly reach a general approach by the end of this legislature, BusinessEurope takes this opportunity to reiterate the major concerns regarding this proposal.

Patents are meant to stimulate innovation by protecting necessary investments. Compulsory licences weaken the protection granted by patents and should only be used as a last resort and in very limited circumstances. If compulsory licences are imposed beyond these situations, and an adequate remuneration of the patentee is not guaranteed, the risk is that the innovative impulse of European industry will be jeopardised and the objectives of this EU initiative will not be met. Society needs thriving innovative companies to address emergencies and crises.

BusinessEurope believes that the Compulsory Licencing proposal would weaken innovation and competitiveness of European companies and ultimately Europe's ability to tackle future crisis.

We strongly believe that this proposal represents a fundamental change of approach when it comes to balancing powers between the European Commission and Member States, with negative implications on the intellectual property rights of companies and their fundamental freedom of activity. The European patent law system, one of the main enablers of EU innovation also in the areas of the digital and sustainable transition, should not be put at risk by this initiative.



We believe that certain provisions of the Commission proposal are of particular concern:

- The Compulsory Licencing proposal fails to provide clear and well-defined definition (of e.g., “crises”, “emergencies”, “crisis-relevant products”, “additional measures complementing the Union compulsory licence”) which are necessary to limit the wide discretion of the Commission and ensure legal certainty. For example, the definition of “crisis” should be consistent with the Single Market Emergency Instrument (SMEI) Regulation.
- Trade secrets and know how must be clearly excluded from the scope of the proposed Regulation.
- If the proposed system is set in place, industry, as key players under the compulsory licencing mechanism, should be a permanent fully-fledged member of the Advisory Body that is meant to assist the Commission in the decision-making process. In addition, the Advisory Body should be composed by experts in the field concerned and should be given decision-making powers and not simply a consultative role.
- Right holders should always be heard prior to the adoption of any decision on a compulsory licence.
- The “adequate remuneration” should be negotiated and determined by the right holder and the licensee(s), and there should not be any predetermined cap. This determination should remain a prerogative of the parties to the contract. A determination by the Commission would run contrary to the principle of the parties’ autonomy in the determination of the essential parts of their contract.
- The duration of the crisis mode and thereby the end of the compulsory licence must be set in a binding manner and be determined in a transparent and foreseeable way by the parties involved.

BusinessEurope urges the European Parliament to consider these necessary changes to ensure that the principles of proportionality and subsidiarity as well as legal certainty are duly respected. In addition, we believe that the discussion on this file requires a deep consideration of the various interests involved and should in no way be rushed.

BusinessEurope considers that only a significantly improved version of the Compulsory Licencing proposal could bring the value added at EU level, and that Member States are well-placed to ensure such an improvement.

Yours sincerely,



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