



12 February 2025

Dear Members of the European Parliament,

As the Council and the European Parliament start their trilogue negotiations on the proposal for Compulsory Licencing for crisis management (Compulsory Licencing proposal) with a very ambitious schedule, BusinessEurope takes this opportunity to reiterate our major concerns regarding this file.

BusinessEurope appreciates and agrees with the need to be prepared for future crisis, meet the future challenges in different forms (e.g. health, environment and climate change), and help society to access crisis-relevant products or services, but the tools to meet these objectives need to be carefully designed. There are several important problems with this proposal that have been left unaddressed.

Patents are meant to stimulate innovation. 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 crises. However, if the co-legislators maintain their plan to introduce an EU regime for compulsory licences, it must be ensured that the European intellectual property right system is not disproportionately weakened.

We believe that the following **key principles** should be upheld in the ongoing trilogue negotiations:

- **Trade secrets, confidential business information, and know how must be clearly excluded from the scope of the proposed Regulation.** Any restrictions on the protection of trade secrets, confidential business information and know-how represent an interference in the freedom to conduct a business. The disclosure of trade secrets and confidential business information is generally accompanied by the weakening or loss of the economic value of the confidential information and is irreversible. The safeguards provided for in the European Parliament's negotiating position are not able to solve this problem, as the erosion of the protection of trade secrets would already occur in relation to the licensee of the compulsory licence, who would generally be a competitor of the right



- holder. In addition, compulsory licencing of trade secrets, confidential business information and know-how is not permitted under the WTO TRIPS agreement, and the EU agreeing to this would send a major negative signal globally which could potentially impact European innovation in other jurisdictions. In this regard, we welcome that the Council clearly provides that trade secrets and know-how shall not be included in the scope of an EU compulsory licence.
- It must be ensured that the **compulsory licencing is a last resort measure**, where is the only means to allow access to indispensable crisis-relevant products. Notably, the compulsory licence should only be granted once all the efforts to reach a voluntary agreement between the right holder(s) and the licensee(s) have failed within a reasonable timeframe and taking into account the circumstances of the specific case. In this regard, the four weeks deadline proposed by the European Parliament is far too static and too short.
 - **Clearer and well-defined definitions** (of e.g., “crises” and “additional measures complementing the Union compulsory licence”) are necessary to appropriately limit the wide discretion of the Commission and ensure legal certainty.
 - The Advisory Board which will be advising the Commission on its decisions should necessarily include industry experts in both the European-level and national-level procedures.
 - An **effective procedure for judicial review of a compulsory licence** should be explicitly provided for. Right holders should always be heard throughout the entire procedure, including e.g. prior to the adoption of any decision on a compulsory licence, to negotiate the “adequate remuneration”, or to propose an alternative measure, for instance around production capacity and cooperation agreements.
 - In determining “**adequate remuneration**” that the right holder(s) should receive from the licensee(s), the Commission should be bound to base its assessment on the criterion of the economic value of the relevant activity authorised under the compulsory licence without losing sight of the other circumstances of the individual case. We appreciate that the Council and the European Parliament have deleted the maximum royalty of 4% as there was no justification for such a cap.
 - Lastly, the enforcement system must be proportionate, and the penalties imposed on the right holders should not be excessive. In this regard, we welcome the amendments proposed by the Council to the provisions on penalties and fines which are intended to ensure a greater legal certainty and a more appropriate structure of the proposed regulatory framework.



BusinessEurope urges the co-legislators to consider these necessary points 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.

Yours sincerely,

Markus J. Beyrer