

CHAMBER OF DEPUTIES

COMMITTEE ON EUROPEAN UNION POLICIES

**DOCUMENT APPROVED BY THE COMMITTEE ON EU POLICIES
CONCERNING THE ASSESSMENT OF SUBSIDIARITY PURSUANT TO ARTICLE 6 OF
PROTOCOL NO 2 ANNEXED TO THE LISBON TREATY**

PROPOSAL FOR A
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
ON COMPULSORY LICENSING FOR CRISIS MANAGEMENT AND AMENDING REGULATION (EC) 816/2006
(COM(2023) 224 FINAL)

Adopted on 4 August 2023

**PROPOSAL FOR A
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DOCUMENT ADOPTED BY THE COMMITTEE

The Committee on European Union Policies,

Having examined the proposal for a Regulation of the European Parliament and of the Council on compulsory licensing for crisis management, amending Regulation (EC) No 816/2006, to verify compliance with the principle of subsidiarity;

Taking note of the report on the document submitted by the Government pursuant to Article 6(5) of Law No. 234 of 24 December 2012;

Considering that the proposal constitutes part of a broader package of legislative measures, known as the "European Union Patent Package", which includes a proposal for a Regulation on essential patents protecting technologies declared essential for the implementation of a technical standard adopted by a standard-setting organisation (COM(2023)232), as well as proposals for Regulations on supplementary protection certificates, which extend the term of a patent (up to five years) on a human or veterinary medicinal product, or a plant protection product, that has been authorised by the regulatory authorities;

whereas:

- we can support the overall objective of the proposal to establish an EU legal framework for the granting of compulsory licences for intellectual property rights in the event of cross-border crises and/or emergencies. Such a framework would rightly not replace the domestic systems of Member States, which could continue to grant compulsory licences for purely domestic crises;
- it is particularly important, to safeguard the interests of the Union and its Member States, to construct a coordinated and closely interlinked body of legislative instruments capable of rapidly ensuring adequate supplies of critical goods and services in unforeseen emergencies of a cross-border nature, both in the health and non-health sectors;

- we therefore welcome the fact that the proposal complements other EU legislative initiatives that have been put forward in the aftermath of the pandemic crisis, to strengthen the Union's resilience to crises, consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), which sets out the international legal framework on compulsory licensing;

Noting, with reference to compliance with the principle of attribution, that the proposal:

- is correctly based on Article 114 of the Treaty on the Functioning of the European Union (TFEU), as it aims to ensure the smooth functioning of the internal market, not least by ensuring that the territoriality and divergence of national systems of compulsory licensing do not prevent a crisis with a cross-border dimension from being properly addressed

- with reference to the provisions that have an impact on Regulation (EC) No 816/2006 on compulsory licensing for pharmaceutical products intended for export to third countries is also correctly based on Article 207 TFEU, which confers competence on the Union in matters of common commercial policy also with regard to intellectual property rights;

considering that the proposal is, on the whole, compliant with the principle of subsidiarity, since the Union's compulsory licence would not intervene in cases where the crisis is exclusively national in scope, but cross-border, while the Member States would fully retain their competence to act domestically;

noting, however, that the proposal confers significant implementing powers on the European Commission with regard to the granting, supplementing, amending or revoking of compulsory Union licences, determining the remuneration to be paid to the rights holder, the procedural rules for the ad hoc advisory body and the specifications for identifying products manufactured under a compulsory Union licence;

considering that the proposal also complies with the proportionality principle. However, we note, as the Regulatory Scrutiny Board has also pointed out, that the European Commission has not adequately examined the substance and functioning of the various regulatory options at EU level, has not demonstrated the overall efficiency gains and effectiveness of the intervention, and has not, finally, comprehensively assessed the impact on competitiveness and innovation, including investment in innovative products in the event of a crisis;

given, moreover, that the European Commission's impact assessment did not provide a monetary value due to the fact that crises are rare and above all unpredictable events;

further noting the need to make certain changes to the proposal during the negotiations in order to:

- clarify how and by what means the European Commission could decide to dissociate itself from the opinion of the advisory body, which is non-binding but has significant technical content;
- consider the appropriateness of involving the intellectual property rights holder in the compulsory licensing procedure to guarantee its right to be informed and to comment also in the light of the EU's commitment to supporting research and innovation;
- take into account the territorial scope of patent protection when identifying patents subject to licensing, which is currently not taken into account;
- better clarify the definition of the state of crisis and the definition of the 'exceptional use' of the instrument of compulsory licensing;
- identify more precisely the differences between activating the procedure at EU level and activating it at the request of at least two Member States. In this respect, it is unclear whether, in the latter case, coordination/collaboration with another Member State, prior to activation, would necessarily be needed, or whether each Member State could proceed autonomously and whether the identification of a supranational crisis situation would be done at EU level upon receiving several autonomous requests;

stressing, therefore, the advisability of conducting an EU-level in-depth analysis of the critical elements mentioned above in the further examination of the proposal, where appropriate updating the impact assessments carried out by the European Commission;

highlighting the need for the appropriate in-depth studies to be carried out also with reference to the aforementioned proposal for a regulation on essential patents (COM(2023)232) that is closely related to the one under consideration. Indeed, the technical report submitted by the Government on that proposal pursuant to Article 6, paragraph 5, of Law No. 234 of 2012, notes that:

- the identification of Article 114 TFEU as the legal basis for intervention has been questioned. Indeed, the latter proposal would apply to EU patents that are based on global standards and therefore its impact would not be limited to the internal market, on which it would only have an incidental effect, but would have wider implications;
- the indirect and far-reaching international effects of the proposal should be assessed with regard to compliance with the proportionality principle;

- clarification is needed regarding measures to minimise negative impacts on SMEs, which has also been requested by the Regulatory Scrutiny Board;
- the cost-benefit analysis in the Commission's impact assessment also lacks convincing data and evidence, and the conclusions are based on estimates;

noting the need for this document to be forwarded to the European Parliament, the Council and the European Commission,

CONSIDERS THE PROPOSAL COMPLIANT

with the subsidiarity principle as defined in Article 5 of the Treaty on the European Union.