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Delegations will find attached document SWD(2023) 120 final.

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COMMISSION STAFF WORKING DOCUMENT

Subsidiarity Grid

Accompanying the document

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} - {SEC(2023) 173 final} - {SWD(2023) 121 final} - {SWD(2023) 122 final}

1. Can the Union act? What is the legal basis and competence of the Unions' intended action?
1.1 Which article(s) of the Treaty are used to support the legislative proposal or policy initiative?
The proposed initiative will be based on Articles 114 and 207 of the Treaty on the Functioning of the EU ('TFEU'). Article 114 TFEU confers on the EU the power to adopt measures, which have as their object the establishment and functioning of the internal market and has provided legal basis for a wide range of EU instruments in the area of IP rights. Since the envisaged initiative aims at ensuring that compulsory licensing is fit for purposes as regards the Single Market, this initiative should be based on Article 114 TFEU. Article 207 TFEU confers on the EU competence in the field of common commercial policy, including as regards IP rights. Regulation (EC) No 816/2006, relating to the compulsory licensing of medicines for export purposes to third countries, is based on Articles 95 and 133 of the TEC (i.e. Article 114 and 207 of the TFEU). Since the envisaged initiative would have an impact on Regulation (EC) No 816/2006, and on the possibility to export goods manufactured in the EU, the initiative should also take article 207 TFEU as a basis.
1.2 Is the Union competence represented by this Treaty article exclusive, shared or supporting in nature?
In the case of both Article 207 and Article 114 TFEU, the Union's competence is shared.
*Subsidiarity does not apply for policy areas where the Union has **exclusive** competence as defined in Article 3 TFEU[1]. It is the specific legal basis which determines whether the proposal falls under the subsidiarity control mechanism. Article 4 TFEU[2] sets out the areas where competence is shared between the Union and the Member States. Article 6 TFEU[3] sets out the areas for which the Union has competence only to support the actions of the Member States.*
2. Subsidiarity Principle: Why should the EU act?
2.1 Does the proposal fulfil the procedural requirements of Protocol No. 2[4]: - Has there been a wide consultation before proposing the act? - Is there a detailed statement with qualitative and, where possible, quantitative indicators allowing an appraisal of whether the action can best be achieved at Union level?
The Commission conducted a Call for evidence between 1 April and 29 April 2022 to gather views, opinions and evidence from public and private sector stakeholders. The European Commission also held an Open Public Consultation from 7 July 2022 to 29 September 2022. In addition, the Commission launched the study 'Compulsory licensing of intellectual property rights' [CEIPI(2023)]. The objective of the study was to assist the Commission in defining potential problems as regards compulsory licensing in the EU as well as identifying and assessing policy options to improve coherence and effectiveness in the field. To this end, the study aimed at collecting data through desk research, case studies, interviews with stakeholders as well as organising two workshops. Both the explanatory memorandum of the proposal and the impact assessment report contain a section on the principle of subsidiarity.

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12008E003&from=EN
[2] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12008E004&from=EN
[3] https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12008E006:EN:HTML
[4] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12016E/PRO/02&from=EN

2.2 Do the explanatory memoranda (and impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the conformity with the principle of subsidiarity?

Yes, subsidiarity is explained in section 3.2 of the impact assessment as well as in the explanatory memorandum accompanying the proposal.

2.3 Based on the answers to the questions below, can the objectives of the proposed action be achieved sufficiently by the Member States acting alone (necessity for EU action)?

No, the objectives of the proposed action cannot be achieved sufficiently by the Member States alone.
Action at EU level is justified to ensure a more efficient functioning of the Single Market in crises. Currently, Member States can only act nationally meaning that they can grant a compulsory licence for their own territory. This can be sufficient for purely national crises, where both the crisis and the manufacturing capacities are in the same Member State. However, this will not be sufficient when a crisis has a cross-border dimension – the latter is highly probable due to prevalence of cross-border supply chains. The incapacity of Member States to properly address a crisis with a cross-border dimension finds its origin in the territoriality of national compulsory licensing schemes and the divergent, sometimes sub-optimal, compulsory licensing schemes in place to tackle a crisis. The proposed EU action will act on these specific points by creating an EU-level compulsory licence with a streamlined procedure. Without action at EU level, Member States would remain vulnerable to crises with a cross-border dimension. In contrast, introducing an EU compulsory licensing scheme will contribute to building a more resilient EU by providing an additional collective tool in support of other crisis instruments such as SMEI or the Emergency Framework Regulation.

(a) Are there significant/appreciable transnational/cross-border aspects to the problems being tackled? Have these been quantified?

Yes. The average number of Member States in which European Patents are active is estimated at around 5.2 (based on a selection of COVID-related products, as quantified in the impact assessment). This means that licensing of patent rights for a given product in the EU might require a coordinated action among four to five Member States. The number of patents active in several countries are not the only element to be considered. Additionally, the Single Market is based on complex multi-step cross-border supply chains, as products are increasingly manufactured across several Member States, as illustrated in the problem definition of the impact assessment. Yet, current EU CL rules are characterised by inadequate territorial architecture, uncoordinated national procedures and decision-making, which is especially problematic in view of cross-border value chains increasingly predominant in the EU Single Market. This results from: (1) Divergent national schemes on compulsory licensing, (2) Inadequate territorial reach of compulsory licensing (compulsory licensing in the EU is designed to exclusively supply national territories, meaning that there is currently no Single Market and no free movement of goods for CL products), (3) No dedicated fora to deal with CL in support of EU resilience.

(b) Would national action or the absence of the EU level action conflict with core objectives of the Treaty[5] or significantly damage the interests of other Member States?

The absence of an EU level action would damage the ability of the EU and its Member States to rely

[5] https://europa.eu/european-union/about-eu/eu-in-brief_en

on compulsory licensing to tackle a crisis, should voluntary agreements not be available nor adequate. Without action at EU level, Member States' action would be limited to the national territory, without the possibility to take advantage of the single market.
(c) To what extent do Member States have the ability or possibility to enact appropriate measures?
Member States' action would not be able to enact adequate measures on compulsory licensing to address EU-wide or cross-border crises. In the absence of an EU action, compulsory licensing schemes for crisis management would remain purely national, also for cross-border or EU-wide crises. There would be no coordination between Member States and compulsory licensing would remain mainly applicable to national territories. This would result in maintaining an inefficient tool for addressing crises in the Single Market, unfit for the cross-border nature of EU supply chains
(d) How does the problem and its causes (e.g. negative externalities, spill-over effects) vary across the national, regional and local levels of the EU?
The current landscape of EU compulsory licensing is characterised by a fragmented landscape when it comes to compulsory licensing for crisis management, especially concerning the trigger, the scope, the procedure and conditions of national rules. As illustrated in the impact assessment, not all Member States provide for compulsory licensing for crisis management, some do only for certain types of crises (i.e. health) while other provide for general basis, differently worded, for which uncertainty remains as to their concrete application to crisis. Many divergences exist across the EU in respect of the scope of a compulsory licence, which has a direct influence on the ability to use compulsory licensing to tackle crises. Differences between national granting authorities and procedures result in different delays applicable to grant a compulsory licence and to review the granting decision. Member States' law also considerably vary when it comes to conditions under which a compulsory licence can be granted.
(e) Is the problem widespread across the EU or limited to a few Member States?
As follows from the information provided for under point (d), the problem results from great fragmentation of rules across the EU.
(f) Are Member States overstretched in achieving the objectives of the planned measure?
No, as the proposed initiative would add to the existing national schemes.
(g) How do the views/preferred courses of action of national, regional and local authorities differ across the EU?
In its resolution of November 2021[6], the European Parliament called on the Commission 'to analyse and explore possible options for ensuring effectiveness and better coordination of compulsory licensing in the EU. The Council[7] confirmed that the EU stood ready to discuss the flexibilities of

[6] The resolution on the intellectual property action plan to support the EU's recovery and resilience (2021/2007(INI)).
[7] Council conclusions of 18 June 2021, available here.

compulsory licensing for the domestic market and export purposes to third countries[8]. It also confirmed the need to explore possible IP tools and options to better coordinate the management of cross-border crises.

2.4 Based on the answers to the questions below, can the objectives of the proposed action be better achieved at Union level by reason of scale or effects of that action (EU added value)?

To achieve the objectives of this initiative (i.e. to provide the EU with an effective compulsory licensing scheme for crisis management), national actions do not offer viable solutions.

(a) Are there clear benefits from EU level action?

Yes. EU-level action would allow overcoming the limitations of national actions. The EU-level action will create a single procedure to grant an EU-level CL with adequate features to tackle a crisis. This would ensure that conditions are the same across the EU and would avoid national discrepancies likely to slow down or prevent an efficient CL scheme to tackle cross-border crises. This single CL would be applicable in all relevant territories, therefore covering cross-border situations. This would be the case for both the EU market and for export purposes. Coherence with EU crisis instruments would be ensured by the possibility to use their trigger and by reference to the (advisory) bodies set-up by the EU crisis instruments to discuss an EU-level CL.

(b) Are there economies of scale? Can the objectives be met more efficiently at EU level (larger benefits per unit cost)? Will the functioning of the internal market be improved?

Member States would benefit from the centralised procedure, as costs linked to the negotiations with the patent owners and the manufacturers would be incurred solely at EU level (although costs of participating in the EU level negotiations would remain). The new compulsory licensing rules would also strengthen EU bargaining position as 27 countries would run negotiations together and at once.

(c) What are the benefits in replacing different national policies and rules with a more homogenous policy approach?

The proposed initiative will not replace national policies (which cannot provide a solution for EU-wide crisis) but rather add a layer to allow a Union-level compulsory licence for EU-wide crisis management.

(d) Do the benefits of EU-level action outweigh the loss of competence of the Member States and the local and regional authorities (beyond the costs and benefits of acting at national, regional and local levels)?

Member States would not lose their competence to act at national level.

(e) Will there be improved legal clarity for those having to implement the legislation?

[8] Where reference is made hereinafter to exports to third countries, this refers to third countries covered by Regulation (EC) No 816/2006.

See above point.

3. Proportionality: How the EU should act

3.1 Do the explanatory memoranda (and any impact assessment) accompanying the Commission's proposals contain an adequate justification regarding the proportionality of the proposals and a statement allowing appraisal of the compliance of the proposals with the principle of proportionality?

Yes. As stated in the explanatory memorandum, the adoption of a Regulation establishing an EU-level compulsory licensing scheme for crisis management does not go beyond what is necessary to achieve the identified objectives. It is limited to the aspects that Member States cannot achieve satisfactory on their own and where the Union can act more effectively, efficiently and with greater added value. The objective of the initiative is to build an EU-level compulsory licensing scheme able to tackle crises with a cross-border dimension, in addition to the existing compulsory licensing national schemes for grounds other than crises. The proposal is therefore limited to what is necessary to tackle crisis with a cross-border dimension, only when such action cannot be implemented at national level or when such implementation would be inefficient.

3.2 Based on the answers to the questions below and information available from any impact assessment, the explanatory memoranda or other sources, is the proposed action an appropriate way to achieve the intended objectives?

The proposed action is clearly an appropriate way to achieve the objectives. The EU-level compulsory licensing cannot be achieved at national level.

(a) Is the initiative limited to those aspects that Member States cannot achieve satisfactorily on their own, and where the Union can do better?

Yes. The initiative leaves untouched compulsory licensing at national level.

(b) Is the form of Union action (choice of instrument) justified, as simple as possible, and coherent with the satisfactory achievement of, and ensuring compliance with the objectives pursued (e.g. choice between regulation, (framework) directive, recommendation, or alternative regulatory methods such as co-legislation, etc.)?

The chosen instrument is a Regulation establishing a compulsory licencing system for crisis management at Union level with its own triggers, procedure and conditions. While leaving national compulsory licencing schemes in the Member States untouched, it ensures coherence with other crisis and emergency instruments at Union level and is fully compliant with the international requirements for compulsory licencing laid down in the TRIPS Agreement. Alternative regulatory methods such as a Directive harmonising national compulsory licencing schemes of the Member States are not considered appropriate, as explained in the explanatory memorandum.

(c) Does the Union action leave as much scope for national decision as possible while achieving satisfactorily the objectives set? (e.g. is it possible to limit the European action to minimum standards or use a less stringent policy instrument og approach?)

Yes, action at national level is left to Member States.

(d) Does the initiative create financial or administrative cost for the Union, national governments, regional or local authorities, economic operators or citizens? Are these costs commensurate with the objective to be achieved?
The initiative does not create financial nor administrative cost for the Union, national governments, regional or local authorities, economic operators or citizens. Member States would need to bear limited adjustments costs as the initiative would provide an EU-level CL, through a regulation, on top of existing national legislation. They would face some enforcement costs in case of crisis, linked to the transparency obligation. Patent owners could face an incremental loss of control of their patent rights due to the broadened geographical scope of the Union-level compulsory licence, as compared to the status quo of a thicket of national CLs.
(e) While respecting the Union law, have special circumstances applying in individual Member States been taken into account?
No as it was not needed.