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EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT REPORT

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) 120 final} -
{SWD(2023) 121 final}

Executive summary
Impact assessment on compulsory licensing for crisis management.
A. Need for action
Why? What is the problem being addressed?
<p>In the context of the COVID-19 crisis the role of intellectual property (IP) rights in providing access to vital products was debated. Although voices were raised to waive IP rights, the EU considered that another solution was already available, should voluntary agreements fail.</p> <p>The TRIPS Agreement provides the possibility to issue, in certain circumstances, compulsory licensing. A compulsory licence of patents is an authorisation granted by a government to a party other than the patent holder to use a patented invention without the consent of the patent holder.</p> <p>The Commission IP action plan¹ of 2020 underlined <i>‘the need to ensure that effective systems for issuing compulsory licences are in place’</i>. In its resolution of November 2021², the European Parliament called on the Commission <i>‘to analyse and explore possible options for ensuring effectiveness and better coordination of compulsory licensing in the EU’</i>.</p> <p>And the Council³ confirmed that the EU stood ready to discuss the flexibilities of compulsory licensing for the domestic market and export purposes. In parallel, the Commission tabled proposals to ensure the EU’s resilience and to guarantee well-functioning supply chains in the single market and abroad⁴. Against the backdrop of the increasing completion of the single market for patents through the upcoming launch of the unitary patent, the initiative described in this document situates itself at the intersection between the different EU crisis instruments and the international obligations and discussions on IP rights and compulsory licensing.</p> <p>Current EU compulsory licensing rules are characterised by inadequate territorial coverage and uncoordinated national procedures and decision-making. This is especially problematic in view of the cross-border value chains increasingly predominant in the EU single market.</p> <p>This results from:</p> <p>(1) Divergent national schemes on compulsory licensing: compulsory licensing is allowed under different procedures and conditions in different EU member countries;</p> <p>(2) Inadequate territorial reach of compulsory licensing: despite the flexibility that exists at international level, 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 compulsory licence products;</p> <p>(3) No dedicated forums to deal with compulsory licensing that could bolster EU resilience in times of crisis: the current compulsory licensing system that could complement and support the EU’s ability to tackle crises appears disconnected from EU crisis instruments.</p>

¹ IP action plan, [COM\(2020\) 760 final, 25.11.2020](#).

² The resolution on the IP action plan to support the EU’s recovery and resilience (2021/2007(INI)).

³ Council conclusions of 18 June 2021.

⁴ [Proposal](#) for a regulation of the European Parliament and of the Council establishing a Single Market emergency instrument (SMEI) and repealing Council Regulation No (EC) 2679/98, [Regulation](#) (EU) 2022/2371 of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU and [Council Regulation](#) (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level

In addition, there is no coordination at EU level should several EU countries wish to coordinate their measures for national compulsory licensing. Consequently, it would be difficult for an EU country with manufacturing capacities to produce goods to help another EU country or to issue a compulsory licensing covering a manufacturing process spanning several EU countries.

What is this initiative expected to achieve?

The general objective is to enable the EU to respond to crisis situations in a timely manner using the full potential of the single market and to ensure that in a crisis, critical products and components can be made available across EU countries and supplied without delay to EU citizens and firms or even to non-EU countries.

In connection with the general objectives and with the problems identified earlier, 3 specific objectives have been defined:

- (1) Improve the key features of compulsory licensing, such as the trigger, scope and conditions for compulsory licensing, and make compulsory licensing a more consistent tool for tackling a crisis in the EU.
- (2) Ensure that the territorial reach of a compulsory licence, including for export purposes, can accommodate the reality of cross-border value chains operating in the single market.
- (3) Support EU resilience by improving coordination, streamlining decision making and allowing compulsory licences to better complement EU action in crises, including for export purposes to non-EU countries. This objective would also aim to ensure suitable consistency between (national) compulsory licensing schemes and EU crisis instruments.

What is the value added of action at the EU level?

Action at EU level is justified to ensure the smooth functioning of the single market in crisis situations.

Currently, EU countries can only act nationally (i.e. compulsory licensing for their own territory). This might suffice for national crises. However, it will not be optimal when a crisis has a cross-border dimension – and this is highly probable due to prevalence of supply chains that span multiple countries in the single market.

B. Solutions

What legislative and non-legislative policy options have been considered? Is there a preferred choice or not? Why?

- Option 0: **No policy change.**
- Option 1: **Recommendation on compulsory licensing for crisis management.** This would identify (i) good national practices for compulsory licensing as part of crisis management and (ii) good coordination practices, with a view to encourage their use in all EU countries.
- Option 2: **Harmonisation of national laws on compulsory licensing for crisis management.** The legislative initiative would align national laws as regards the grounds, scope, procedure, and conditions for granting a compulsory licence for crisis management. The compulsory licensing would remain in the remit of the EU country and have a predominantly national effect.
- Option 3: **Harmonisation plus a binding EU-level measure on compulsory licensing for**

crisis management. Compulsory licensing could be triggered:

(i) by an EU-level decision activating crisis mode or declaring an emergency under an existing EU crisis instrument (e.g. activation of the emergency mode under the Single Market Emergency Instrument (SMEI))

(ii) on a request made to the Commission by more than one EU country, in the event of a crisis affecting multiple countries. The Commission, assisted by the relevant advisory body, would adopt an activation measure requiring one or more EU countries to issue a compulsory licence. This option would lead to several national compulsory licences, each applicable to the territory of several EU countries or to the whole EU

- **Option 4: EU-level compulsory licensing to complement existing EU crisis instruments:** The triggers would be the same as under option 3. However, the Commission, assisted by the relevant advisory body, would adopt an activation measure granting a compulsory licensing. This option would lead to the issuance, by the Commission, of a single compulsory licence, with its own procedure and conditions and applicable to the territory of several EU countries or the whole EU.

It appears that **Option 4** would be the most effective and efficient way of achieving the objectives of this initiative.

This option would create a single procedure to grant an EU-level compulsory licence with the features required to tackle a crisis. The Commission activation measure would ensure that conditions are the same across the EU and would avoid national discrepancies likely to slow down or prevent an efficient compulsory licensing scheme from tackling cross-border crises.

This single compulsory licence 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. Consistency with EU crisis instruments would be ensured by the possibility to use them to trigger the licence procedure and by reference to the (advisory) bodies set-up by those instruments to discuss an EU-level compulsory licence.

Who supports which option?

The results of the public consultation show that a large majority (82%, N=61) of respondents consider that public authorities should be entitled to allow production of critical goods through a compulsory licence.

Respondents are usually less in favour of a decision-making role for European institutions (28%, N= 21) compared to a coordinating role (36%, N=27). This can be explained by the fact that businesses and industry representatives expressed low support in this respect, whereas they were the dominant group of respondents to the consultation (54% of all participants).

That being said, the option of granting a compulsory licence at EU level is generally deemed more positive by stakeholders as regards the EU's ability to tackle crises (35%, N=26) than the granting of compulsory licences at national level (respectively, 11%, N=8).

Stark contrast exists among stakeholders with again low support for the option among industry representatives: a majority (around 50%) of companies and business associations consider that the impact would be negative. In contrast, no respondent in other categories considers the impact would be negative. A large majority (65%, N=22) rates it positive (4% thinks the impact would be neutral and the rest did not reply).

C. Impacts of the preferred option

What are the benefits of the preferred option (if any, otherwise main ones)?

The preferred option would fully address the three identified problems and objectives. It would:

(i) entitle the Commission to directly grant a compulsory licence and specify the conditions under which this licence is granted. These conditions would be the same for all territories where the licence applies. This would ensure optimal clarity and consistency as regards the conditions for the licence.

(ii) provide an optimal solution as regards the territorial scope of the licence. One single compulsory licence would cover all EU countries affected by the crisis and all EU countries with the relevant manufacturing capacities.

(iii) complement other EU crisis instruments: the activation of a crisis mode by an EU crisis instrument, such as SMEI, can be the trigger leading to the granting of a compulsory licence. Relying on the existing advisory body when the trigger originates in an EU crisis instrument also ensures optimal consistency with EU crisis instruments.

Under the preferred option, patent owners would benefit from fewer costs and less legal uncertainty, as negotiations would be limited to participation in a single EU-level procedure.

Potential licensees would benefit from the centralised procedure and the wide territorial scope of the licence, bringing economies of scale.

Better sharing of information would also allow a reduction of costs for EU countries as it could help identify best practice.

On enforcement costs, EU countries would benefit from the centralised procedure, as costs linked to the negotiations with patent owners and manufacturers would be incurred solely at EU level.

EU citizens would greatly benefit from the preferred option as it would improve the EU's ability to issue an effective and efficient compulsory licence for the whole EU, including in the event of cross-border supply chain disruptions.

Non-EU countries would also benefit as the option would provide the possibility to rely on a compulsory licence covering a cross-border supply chain.

Table 1: Positive impacts on stakeholders in the event of a cross-border crisis - Option 4 compared to the baseline

Patent owners	(+ +) Lower costs of negotiations, due to a single procedure at EU level instead of multiple procedures in each EU country concerned. (+ +) More legal certainty (e.g. clarity on what level of remuneration may be expected), due to the single procedure at EU level instead of multiple procedures in each country concerned.
Manufacturers – potential licensees	(+ +) Lower costs of negotiations, due to the single procedure at EU level. (+) Lower costs of adapting manufacturing facilities to the production of the item(s) covered by the licence, due to economies of scale, if EU-level compulsory licensing leads to wider geographical scope.
EU countries	(+ + +) Significantly lower costs of running the compulsory licensing procedure (no negotiations with the patent holders or manufacturers), as EU countries will only implement a single decision made at EU level (+) Better exchange of information about availabilities of product(s), in case of local shortages or cross-border value chain disruptions. (+) Better decision-making and cooperation in the context of compulsory licensing for export to non-EU countries.
The general public (EU citizens)	(+ + +) Significantly lower risk of delays or unavailability of critical products during crisis, as rules are consistent across all EU countries.

Non-EU countries	(+ + +) Increased legal certainty and administrative savings when accessing critical goods in case of cross-border supply chains, due to direct coordination at EU level.
Note: (0) neutral impact; (+) minor positive impact; (++) positive impact; (+++) significant positive impact; (-) minor negative impact; (- -) negative impact; (- - -) significant negative impact	
What are the costs of the preferred option (if any, otherwise main ones)?	
<p>Patent owners could face an incremental loss of control of their patent rights if the impact of the preferred option broadened the geographical scope of the compulsory licence, as compared to the current situation with a thicket of national licences.</p> <p>This greater territorial reach could also be produced by extending compulsory licensing for export to a non-EU country. EU countries would need to bear limited adjustment costs as the preferred option would provide an EU-level compulsory licence, through a regulation, on top of existing national legislation.</p> <p>They would also face some enforcement costs in the event of a crisis, linked to the transparency obligation.</p>	
<i>Table 2: Negative impacts on stakeholders in the event of a cross-border crisis - Option 4 compared to the baseline</i>	
Patent owners	(- -) In the event of a broader geographical scope for the licence (= wider loss of control over patent rights).
EU countries	(-) Cost of participating in the advisory committee assisting the single contact point. (-) Cost of reporting to the European Commission on the implemented compulsory licence.
Note: (0) neutral impact; (+) minor positive impact; (++) positive impact; (+++) significant positive impact; (-) minor negative impact; (- -) negative impact; (- - -) significant negative impact	
How will businesses, SMEs and micro-enterprises be affected?	
<p>Impacts that may materialise as a result of the preferred option will mainly concern patent holders, but the number of small/medium-sized enterprises that own IP rights in the EU is relatively low.</p> <p>Furthermore, apart from the fact that compulsory licensing is an extremely low probability event, it can be assumed that small enterprises are more prone to enter into voluntary agreements than larger firms, hence there could be no need to use the compulsory licensing at all.</p> <p>Furthermore, small/medium-sized enterprises are typically licensees, not licensors.</p>	
Will there be significant impacts on national budgets and administrations?	
<p>EU countries would bear limited adjustments costs as the preferred option would provide an EU-level compulsory licence, through a regulation, on top of existing national legislation.</p> <p>They would face some enforcement costs in the event of a crisis, linked to the transparency obligation. However, the benefits of a centralised procedure at EU level would outweigh these costs.</p>	
Will there be other significant impacts?	
There are no other significant impacts expected.	
D. Follow-up	

When will the policy be reviewed?
The first evaluation report should be done 5 years after the granting of the first EU-level compulsory licence.