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COVER NOTE

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To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
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Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on compulsory licensing for crisis management and amending Regulation (EC) 816/2006 REGULATORY SCRUTINY BOARD OPINION

Delegations will find attached document SEC(2023) 173 final.

Encl.: SEC(2023) 173 final

EUROPEAN COMMISSION

Brussels, 3.2.2023
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REGULATORY SCRUTINY BOARD OPINION

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}
{SWD(2023) 120 final} {SWD(2023) 121 final} {SWD(2023) 122 final}

EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels,
RSB

Opinion

Title: Impact assessment / Compulsory licensing for crisis management

Overall opinion: POSITIVE WITH RESERVATIONS

(A) Policy context

A Compulsory License (CL) is an authorisation granted under specific circumstances by a government to a party other than the Intellectual Property (IP) right holder to use a licence on patented invention without the consent of the IP right holder, against an adequate remuneration. The aim of such an authorisation is to secure in times of crisis the supply of and access to critical goods and / or components within the single market that could otherwise only be supplied by the IP right holder.

The aim of this initiative is to establish an EU-level CL with a streamlined procedure to address the current challenges of EU Member States to address supply-shortages of goods and components related to crises with a cross-border dimension. This incapacity is caused by the fact that EU Member States can only act nationally and therefore grant a CL only for their own territory. It is also caused by divergent and often sub-optimal CL schemes in place in EU Member States. This initiative aims to address these problems by establishing rules to grant an EU-level CL applicable in a cross-border crisis situation to ensure that critical products and components can be made available across EU countries.

(B) Summary of findings

The Board notes the additional information provided and commitments to make changes to the report.

However, the report still contains significant shortcomings. The Board gives a positive opinion with reservations because it expects the DG to rectify the following aspects:

(1) The problem definition is not sufficiently clear on the remaining scale of the problem.

(2) The report does not sufficiently describe the content and functioning of the EU level options, including the intended safeguards. The expected efficiency gains and overall effectiveness are not sufficiently demonstrated.

(3) The report does not comprehensively analyse the impact on competitiveness and innovation, including investments in innovative products in case of crisis.

This opinion concerns a draft impact assessment which may differ from the final version.

(C) What to improve

(1) The problem definition should be clearer on the scale of the problem and the likelihood that the envisaged EU CL rules will be needed, adequately reflecting the effects of other recent EU crisis management instruments, such as Single Market Emergency Instrument and Health Emergency Preparedness and Response Authority and clarifying what gap EU CL rules would cover. It should better illustrate which recent concrete crisis situations and/or crisis use cases would have clearly benefitted from the availability of EU CL rules. It should bring out more clearly the underlying narrative for the use of the instrument and its expected exceptional use. It should clarify the applicable definitions of the various crises covered as well as related critical products.

(2) The report should better describe the content and functioning of the EU level options. It should explain the necessary conditions for granting an EU CL, such as availability of adequate alternative manufacturing capacity or the lack of less intrusive measures. It should further develop the description of the safeguards that will be put in place to prevent any potential misuse of the EU CL (such as that the licensee will continue to take advantage of transferred knowhow during the post crisis period), and to address the observations of stakeholders. In particular, it should be clearer about the specific conditions that would provide the basis for such safeguards in the different phases of the CL process (i.e pre-granting, granting and post-granting phase). It should explain how adequate and fair renumeration will be ensured for the licence and the potential transfer of knowhow, while reflecting the investment risk situation that highly innovative critical products may face.

(3) The report should better describe the envisaged implementing acts for activation and granting decisions. It should better explain any content and procedural differences between an EU level triggered decision and a decision triggered upon request by more than one Member State. It should better justify the need for and proportionality of having two different trigger mechanisms for EU level CL.

(4) The report should better demonstrate how the new procedures for issuing the compulsory license can ensure an outcome in a timely manner, covering the different steps: critical product identification and their corresponding patents, the potential negotiation, a potential appeal, the potential transfer of knowhow and the provision of manufacturing capacity until the production of the first batches of the critical product. The envisaged efficiency gains in terms of decision-making, potential access to accelerated or streamlined procedures, and efficient procedures for legal redress should be clearly explained. The report should also better demonstrate the effectiveness of the preferred option by being clearer on how a CL would be implemented and effectively enforced, including in terms of necessary incentives.

(5) The report should further investigate the potential trade-off under the preferred option between keeping the incentives for innovation through IP protection while ensuring at the same time access to critical products in cross-border crisis situations through compulsory licensing. The report should draw upon existing literature on both potential positive and negative impacts on innovation of compulsory licensing to provide a basis for a balanced assessment, and by better presenting the divergent views of affected stakeholders. In particular the report should consider the possible impact on the willingness of businesses to invest in research and innovation in case of crisis. The analysis of competitiveness and trade impacts should be strengthened, including by differentiating between potential short and long term effects. The report should also assess any unintended consequences that may result from the preferred option.

(6) The classification of the costs should be clarified clearly distinguishing and explaining both the adjustment and administrative costs. Costs and cost savings in scope of the One In, On Out approach should be specified.

The Board notes the estimated costs and benefits of the preferred option(s) in this initiative, as summarised in the attached quantification tables.

Some more technical comments have been sent directly to the author DG.

(D) Conclusion

The DG must revise the report in accordance with the Board's findings before launching the interservice consultation.

If there are any changes in the choice or design of the preferred option in the final version of the report, the DG may need to further adjust the attached quantification tables to reflect this.

Full title	Proposal for a Regulation of the European Parliament and the Council on compulsory licensing for crisis management
Reference number	PLAN/2021/11425
Submitted to RSB on	09/01/2023
Date of RSB meeting	01/02/2023

ANNEX: Quantification tables extracted from the draft impact assessment report

The following tables contain information on the costs and benefits of the initiative on which the Board has given its opinion, as presented above.

If the draft report has been revised in line with the Board's recommendations, the content of these tables may be different from those in the final version of the impact assessment report, as published by the Commission.

I. Overview of Benefits (total for all provisions) – Preferred Option		
Description	***Amount***	***Comments***
Direct benefits		
Reduction in administrative cost of CL granting	75%-80% less resources than in the baseline, in case of a cross border crisis.	Fragmented CL procedures will be replaced by an EU-level CL (single procedure). **Main recipients**: firms involved in CL granting process.
Access to critical goods in times of crisis.	Impossible to quantify	Availability of products that otherwise would not be accessible, which also prevent other costs from occurring. **Main recipients:** Citizens or firms in need of the critical goods.
Indirect benefits		
Better overall EU-level response to crisis due to availability of critical goods.	Impossible to quantify	Wide socio-economic benefits due to limited scale of a crisis **Main recipients:** Citizens / the entire society.
Administrative cost savings related to the 'one in, one out' approach *		
n.a.	n.a.	n.a.

II. Overview of costs – Preferred option							
		Citizens/Consumers		**Businesses**		**Administrations (Member States)**	
		One-off	**Recurrent**	**One-off**	**Recurrent**	**One-off**	**Recurrent**
Create EU-level CL for crisis management	Direct adjustment costs	0.	0	0	0	Cost of implementing the legislation	0
	Direct administrative costs[1]	0	0	0	Costs of CL negotiations (but lower than in *status quo* as a single procedure at EU level would replace multiple procedures in each MS concerned)	0	Cost of MS involvement in the committee for the adoption of the activation measure[2].

[1] The frequency of recurrent costs is expected to be extremely low, as they would be incurred only in case of a cross-border crisis and if there is a need to use compulsory licensing for crisis management.

[2] If establishing a separate committee necessary (otherwise the existing bodies would be used).

	Direct regulatory fees and charges	0	0	0	0	0	0
	Direct enforcement costs	0	0	0	0	0	0
	Indirect costs	0	0	0	0	0	0
Costs related to the 'one in, one out' approach							
Total	Direct adjustment costs	0	0	0	0		
	Indirect adjustment costs	0	0	0	0		
	Administrative costs (for offsetting)	0	0	0	0		