POSITION PAPER

BUSINESSEUROPE

18 July 2023

Compulsory licencing for crisis management

KEY MESSAGES

- Compulsory licences weaken the protection granted by patents and they should only be used in mainly knowledge-based economies as a last resort and in very limited circumstances.
- The current international and EU frameworks as well as Member States legislations are sufficient to regulate compulsory licencing of patents.
- The Commission proposal on Compulsory Licencing represents a fundamental change of approach when it comes to balancing powers between the European Commission and Member States, with negative implications on the intellectual property rights of companies and their fundamental freedom of activity. We consider that this EU intervention is against the principles of proportionality and subsidiarity.
- The European patent law system, one the main enablers of EU innovation also in the areas of the digital and sustainable transition, should not be put at risk by this proposal.
- Trade secrets and know-how should clearly be excluded from the scope of the proposal on Compulsory Licencing.
- Clear definitions (of e.g., “crises”, “emergencies”, “crisis-relevant products”, “additional measures complementing the Union compulsory licence”) are necessary to limit the wide discretion of the European Commission and ensure legal certainty.
- If the proposed system is set in place, industry, as key players under the compulsory licensing mechanism, should be a permanent fully-fledged member of the Advisory Body that is meant to assist the Commission in the decision-making process.
- The “adequate remuneration” should be negotiated and determined by the right holder and the licencee(s). This should remain a prerogative of the parties to the contract. A determination by the Commission would run contrary to the principle of the parties’ autonomy in the determination of the essential parts of their contract.

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POSITION PAPER ON THE EUROPEAN COMMISSION'S PROPOSAL ON COMPULSORY LICENCING FOR CRISIS MANAGEMENT

BUSINESSEUROPE is the leading advocate for growth and competitiveness at the European level, standing up for companies across the continent and actively campaigning on the issues that most influence their performance. We speak for enterprises of all sizes in 35 European countries whose national business federations are our direct members.

Patents are meant to stimulate innovation. Compulsory licences weaken the protection granted by patents and they should only be used in mainly knowledge-based economies as a last resort and in very limited circumstances. This covers, for instance, situations whereby the patentee itself cannot supply enough to address the crisis, and voluntary licence arrangements have failed or are unavailable. If compulsory licences are imposed beyond last resort cases, including abuse of the patent and/or absent an adequate remuneration of the patentee, the risk is that innovation would no longer be stimulated especially for emergency situations. Society needs innovation to address the emergency and crises.

On 27 April 2023 the European Commission (Commission) published its proposal for a Regulation on compulsory licencing for crisis management and amending Regulation (EC) 816/2006 (Compulsory Licencing proposal). This proposal is intended to provide the Single Market with a compulsory licencing scheme for crisis management. The initiative aims to enable the European Union (EU) to rely on compulsory licencing in the context of the EU crisis instruments. In addition, it introduces a compulsory licencing scheme to allow allegedly appropriate response to crises, with a functioning Single Market, in view of guaranteeing the supply and the free movement of crisis-critical products subject to compulsory licencing in the internal market.

As a key business stakeholder, BUSINESSEUROPE is pleased to share the following comments on the Compulsory Licencing proposal also considering its possible impact on the ability of Europe to promote innovation and be able to tackle future crises.

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GENERAL COMMENTS

Departure from the usual compulsory licensing model

Compulsory licences are usually granted for a specific right or for a set of rights in a certain jurisdiction and defined territory. Thus, compulsory licences are usually coextensive with the right they apply to. The Compulsory Licencing proposal however takes an unprecedented product-based approach which is coupled with a defined territorial scope which is broader than any other existing right, i.e., the whole EU territory. It divorces the territoriality of the right from that of the Union-wide compulsory licence.

BUSINESSEUROPE is concerned that this approach may cause complexities with potential consequences which need to be further explored.

No need for a Union-wide instrument for compulsory licencing for crisis management

BUSINESSEUROPE believes that the current international and EU frameworks as well as Member States legislations are sufficient to regulate compulsory licencing of patents.

Article 5 of the Paris Convention provides that compulsory licences shall only be imposed in exceptional circumstances to prevent abuse which might result from the exercise of the exclusive rights conferred by the patent. The relevant provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)[1] refer to the Paris Convention and clearly state the limited and exceptional cases in which governments could decide about compulsory licences. The EU is bound by both the Paris Convention and the TRIPS Agreement.

The combined reading of Article 17 of the Charter of Fundamental Rights of the European Union with the Article 5 of the Treaty on European Union (TEU) on the principles of proportionality and subsidiarity provides that any limitations to intellectual property should only be made when there is a clear need for doing so in the public interest. BUSINESSEUROPE believes that the public interest referred to in Article 17 of the EU Charter of Fundamental Rights and Article 5 TEU is sufficiently taken care of by the Paris Convention and TRIPS Agreement when it comes to determine whether the compulsory licences are needed.

The competence to impose compulsory licences mostly falls within the responsibility of the Member States. The fact that there is some discretion to regulate compulsory

[1] See Articles 2, 31 and 31b of the TRIPS Agreement.

licencing left to Member States and that their national legislations differ, does not mean in itself that there is a need for harmonisation. We consider that currently there are no problematic divergences between Member States' legislations on this matter and there is also no evidence that imposing compulsory licences at national level does cause any problems.

As the Commission highlights,[2] the COVID-19 pandemic has shown the importance of having a strong and balanced intellectual property system to provide the necessary incentives to develop new treatments and vaccines as well as a suitable framework for sharing technologies, know-how and data. The successful cooperation (also shown by the current overproduction of vaccines) observed in the context of the COVID-19 pandemic is a clear indication that no major legislative changes are necessary as regards compulsory licencing and that a new Union-wide mechanism is not necessary. Based on patent protection, voluntary technology transfers and multiple global collaborations between companies and with government agencies played key roles.

In this regard, we support the European Commission's Regulatory Scrutiny Board Opinion that 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*". In addition, the Scrutiny Board clearly states that "*the report should consider the possible impact on the willingness of businesses to invest in research and innovation in case of crisis*."[3]

BUSINESSEUROPE appreciates and agrees with the need to be better prepared to respond to future crises, to meet challenges in their different forms (e.g., health, environment and notably climate change). However, when it comes to patents, the perception of fragmentation among Member States' legislations is misleading as the road to implementation of patents requires more than licencing. Instead of adding an additional layer of legal constraints for compulsory licences (which would have to be TRIPS compliant), other instruments might be a better way forward for solving problem of lengthy procedures that may exist in certain countries.

Therefore, and considering the principles of subsidiarity and proportionality, BUSINESSEUROPE is of the view that there is no need of any additional action by the EU regarding compulsory licencing.

[2] See Explanatory Memorandum to the Compulsory Licencing proposal, page 1.
[3] See Regulatory Scrutiny Board Opinion to the Compulsory Licencing proposal, Brussels, 3.2.2023 SEC(2023) 173 final, page 2.

Objectives of the proposal

BUSINESSEUROPE acknowledges the attempt of the Commission to provide the Single Market with a compulsory licencing scheme for crisis management. We generally support the efforts of the Commission to ensure that Europe is able to take rapid and efficient measures to deal with crises, e.g., by supplying the population with complex products. Nevertheless, we believe that compulsory licencing is not a suitable instrument for tackling future crises.

We have very significant concerns in terms of the scope and disproportionately far-reaching interventionist measures envisaged in the Compulsory Licencing proposal.

The Compulsory Licencing proposal goes beyond the mere introduction of a last resort measure and creates a brand-new Union-level mechanism whose triggering is not regulated in the proposal itself but in other EU instruments, including the proposal for the Single Market Emergency Instrument (SMEI) proposal, which also contains very far-reaching and vague provisions. Contrary to the Commission's explanations, it cannot be argued that the Compulsory Licencing proposal has a narrow scope and is a last resort measure.

Therefore, the business community cannot support many provisions in the Compulsory Licencing proposal as they do not correspond to the underlying objectives.

Level of intervention and principle of proportionality

The Compulsory Licencing proposal is a high public intervention measure which significantly shifts the powers among the EU, Member States, and industry.

While BUSINESSEUROPE accepts that public intervention measures may be necessary in crisis situations, many provisions in this proposal do not meet the proportionality and necessity criteria.

The interventionist measures foreseen in the proposal at hand deprive right holders and licencees from agreeing on the conditions of their relations, for instance the determination of the adequate remuneration, the obligations of the parties, the complementary measures and penalties. Some of these measures override contract law and the right to conduct a business. BUSINESSEUROPE cannot support this overall approach of putting obligations and burdens on companies especially in times of crises, instead of helping them. Ultimately, this may have a negative impact on industry's ability to innovate and provide effective instruments to tackle future crises or emergencies.

We consider that these provisions confirm our concerns in terms of proportionality. BUSINESSEUROPE maintains that the shift of powers as proposed in Compulsory Licencing proposal is excessive.

Stakeholder consultation and EU Parliament

The Commission has disregarded the outcome of the stakeholder consultation run between 1st April and 29 April 2022.

The Explanatory Memorandum accompanying the proposal states that the respondents to the consultation "*are usually more in favour of a coordinating role for European institutions than a decision-making role*". It also added that "*this can be explained by the fact that businesses and industry representatives expressed low levels of support for a decision-making role, and they were the dominant group of respondents to the consultation*." "*There is a clear difference between among stakeholder views on this, with low support from industry representatives: a majority of companies and business associations consider that the impact would be negative*".[4]

It follows that the Commission disregarded that the majority of the respondents preferred a coordinating role rather than a decision-making role. In addition, it ignored the negative opinion expressed by industry without providing an adequate justification.

Furthermore, the Commission failed to take into consideration the EU Parliament recommendation on the IP Action Plan.[5] In paragraph 50, the EU Parliament calls on the Commission, "*to analyse and explore possible options for ensuring effectiveness and better coordination of compulsory licensing in the EU, taking into account cases in which it has been used in the Union, the reasons for its use, the conditions under which it was granted, its economic consequences and whether it achieved the desired effect*." It is clear that the new Union-wide compulsory licencing scheme goes far beyond these recommendations.

Therefore, BUSINESSEUROPE maintains its significant concerns in terms of the scope and level of interventionist measures proposed in Compulsory Licencing proposal and stands ready to cooperate for improvements which are imperative.

We present our more detailed comments to the proposal below.

[4] See Explanatory Memorandum to the Compulsory Licencing proposal, page 5.
[5] European Parliament resolution of 11 November 2021 on an intellectual property action plan to support the EU's recovery and resilience (2021/2007(INI)), P9_TA(2021)0453.

SPECIFIC COMMENTS

Article 1 – Subject matter

Article 1 specifies that the Compulsory Licencing proposal lays down the procedural and other conditions for granting a Union compulsory licence of intellectual property rights to address a crisis in the EU.

The reference to “intellectual property rights” is too vague and might open the door to the extension of the scope to any knowledge-based assets, including e.g., trade secrets and know-how. We believe that the wording of “intellectual property rights” should be replaced with the specific intellectual property right that the proposal intends to cover.

Article 2 – Scope and the relation with trade secrets and know-how

This article provides that the Compulsory Licencing proposal applies to patents, published patent applications, utility models, and supplementary protection certificates.

BUSINESSEUROPE believes that Article 2(2) should clearly mention that trade secrets and know-how are excluded from the scope of the proposal.

The confidentiality of trade secrets protected by Directive (EU) 2016/943 is fundamental for companies. Any restriction on the protection of trade secrets represents an interference in the freedom to conduct a business. The disclosure of trade secrets is generally accompanied by the weakening or loss of the economic value of the confidential information and is irreversible. The secret character is thus essential for its protection. The publication of trade secrets inevitably results in the irreversible loss of the protective capacity and the loss of the right. Trade secrets should therefore be excluded from the scope of any compulsory licences or other coercive measures in the future.

Article 3 - Definitions

The definition of “crisis-relevant products” is also too vague. It leaves a wide margin of discretion to the Commission to determine when and under which conditions a product or process is indispensable for responding to a crisis or emergency, or for addressing the impact of a crisis or emergency in the EU.

A definition with clear boundaries is needed to reduce such margin and ensure legal certainty.

Article 4 – Union compulsory licence

The Compulsory Licencing proposal fails to define the "crisis" or "emergency" which could trigger the granting of a Union compulsory licence by the Commission. Rather, it merely refers to the EU instruments listed in the Annex to the proposal.

BUSINESSEUROPE is concerned about the lack of these key definitions. This approach does not ensure legal certainly and predictability.

We are also concerned about the leeway given to modify possibly expand the list in the Annex to address undefined and potentially unlimited crises scenarios in the future.

In addition, the SMEI proposal referred to in the Annex has not been fully established yet and is in great need of improvement at this stage. Concerns cover – among other things - the lack of appropriate legal basis and the principle of proportionality.[6] Further, the SMEI proposal and the Compulsory Licencing proposal do not seem to be consistent as far as the crisis/emergency definitions and the management system are concerned.

For SMEI to be effective and targeted, so that the crisis mitigation measures are both proportionate and strictly defined in terms of their validity, a legally certain definition of "crisis" is crucial. The SMEI proposal provides a broad definition in Article 3(1) and leaves room for interpretation. It is unclear which events qualify as "crisis" and thus might trigger the vigilance or emergency modes. The "crisis" definition misses the crucial points related to the SMEI objectives, namely the protection of the Single Market.

The SMEI proposal follows three-level approach regarding crisis management with corresponding individual measures. The basis for all three levels is the existence of a crisis, whereby the definition is conceivably broad. At the highest escalation level, the Single Market emergency mode is envisaged. The activation requires a wide-ranging impact of a crisis with a serious disruption to the free movement on the Single market. Crisis and emergency are thus not equivalent under the SMEI proposal but are associated with graduated risks for the Single Market.

By contrast, the Compulsory Licencing proposal seems to link the triggering of a Union compulsory licence with "a crisis mode or an emergency mode". These terms appear to be used as quasi-synonyms. This approach undermines the principle of legal certainly and is in contradiction with the objective of granting compulsory licences only as last resort measures.

[6] We refer to the time this position has been discussed and adopted.

Article 6 – Advisory Body

Article 6 introduces the advisory body which shall be consulted by the Commission when the latter considers the introduction of a Union compulsory licence (Advisory Body). This Advisory Body is meant to be the same body competent for the EU crisis or emergency mechanism under the SMEI proposal.

The Advisory Body is the central advisory body in decision-making under the Compulsory Licencing proposal. The proposal as a whole should be re-focused to stronger cooperation among the Commission, Member States and industry, the latter bringing the market and technical knowledge as fully-fledged member of the Advisory Body rather than randomly invited observer to the meetings.

For efficient governance, the Advisory Body with Member States and industry could potentially serve as scrutiny body for the decisions to grant a Union compulsory licence, however it bears no significant powers (e.g., gathering information, facilitating exchanges, identification of the right holders and potential licencees).

The Advisory Body should be equipped with a more significant decision-making role, always include (business) stakeholders, have the EEA countries as members, and its activities be transparent. Its composition should be balanced and include users from the relevant area of technology.

Article 8(1)(h) – Content of the Union compulsory licence

Article 8 lists the elements which should be specified in the compulsory licence, including a generic reference to "*measures complementing the compulsory licence, which are necessary to achieve the objective of the compulsory licence*".

We are concerned that this reference to "complementing measures" is too broad and generic. It may give an extremely wide margin of discretion of the Commission and potentially open the door to the establishment of unbalanced obligations between the parties.

BUSINESSEUROPE believes that any measures relating to the implementation of the compulsory licence should not be agreed on case-by-case basis, but rather need to be laid down as principles drafted in a clear manner to protect legal certainty.

Article 9 – Remuneration

Article 9 provides that the licencee shall pay an adequate remuneration to the right holder and that the amount of this remuneration shall be determined by the Commission. It also sets out that the remuneration shall not exceed 4 % of total gross revenue generated by the licencee through the relevant activities under the Union compulsory licence.

BUSINESSEUROPE believes that the "adequate remuneration" should still be negotiated and determined by the right holder and the licencee(s). This should remain a prerogative of the parties to the contract. A decision by the Commission would run contrary to the principle of the parties' autonomy in the determination of the essential parts of their contract.

The proposal foresees a remuneration cap of 4% in Article 9(2). However, Article 31(h) of the TRIPS Agreement provides that the "*right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization*". It follows from this that the EU would risk breaching the TRIPS Agreement by setting up a 4% royalty cap. The remuneration cap of 4% should be deleted.

Other jurisdictions do have methodologies to determine the remuneration for compulsory licences (see e.g., the 1998 Japanese Patent Office Royalty Guidelines, the 2001 UNPD Guidelines, 2005 Canadian export guidelines). However, the Commission disregarded these references or failed to provide any calculation methodology. They rather set an arbitrary cap of 4%.

Article 9(3) of the proposal lists the factors that the Commission shall consider when determining the remuneration. These factors are generic and again leaves an unacceptable margin of discretion to the Commission. This approach runs against legal certainty and predictability.

Further, it is not clear from Article 9 how the remuneration should be divided in case there are multiple right holders with variable territorial protections. This would be a very challenging task especially considering that the territorial scope of the compulsory licence is meant to extend to the whole EU territory. This question cannot remain unanswered.

The factor sub (c), i.e., "*the degree to which development costs have been amortized by the rights-holder*" should be removed. It is in fact irrelevant whether the right holder has made money out of his/her invention. This factor would risk to disincentivise businesses from continue innovating and thereby would weaken Europe's ability to tackle future crises.

Articles 13, 14 and 15 – The relation between the right holder and the licencees

Although Article 1 refers to "intellectual property rights", Article 2 states that the proposed Regulation applies to patents, published patent applications, utility models and supplementary protection certificates. For these intellectual property rights, the right owner should not be obliged to assist the licencee, the latter normally being able to understand and implement the patents by itself.

Other provisions of the Compulsory Licencing proposal (e.g., Articles 8(1)(h), 13 and 14(2)) however impose to the right holder an obligation to cooperate in good faith with the licencee(s) to achieve the objectives of the Union compulsory licence. Article 15 adds that, in case the right holder and the licencee fail to cooperate in good faith when performing the rights and obligations under the Union compulsory licence, serious fines may be imposed.

BUSINESSEUROPE considers that such a wide and undefined obligation to cooperate may risk implying that the right holder would also be required to share trade secrets and know-how to comply with the "complementing measures" under Article 8(1)(h) to ensure the exploitation of the invention concerned. This would not be acceptable. The obligation of cooperation in Article 13 should therefore be appropriately limited and explicitly exclude the disclosure of trade secrets within the meaning of Directive (EU) 2016/943 and know-how.

The Compulsory Licencing proposal allows the Commission to impose any obligation to cooperate in the form of "measures complementing the Union compulsory licence" as referred to in Articles 8(1)(h) and 14(2), mentioned in Articles 15(1)(c) and 16(1)(c) of the proposal. However, these measures referred to are not matters which need to be addressed or modulated on a case-by-case basis but need to be laid out as principles in a clear manner promoting legal certainty.

Therefore, the detailed processes related to the implementation of the Union compulsory licence should be paralleled with detailed obligations on the licencee to ensure the confidentiality of the information of the patent holder involved. It should also be ensured that any use of that information by the licencee will not occur in abuse of the right holder.

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