AmCham EU
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

Consultation response

Public consultation:
Intellectual property - revised framework for compulsory licensing of patents

AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled more than €3.7 trillion in 2022, directly supports more than 4.9 million jobs in Europe, and generates billions of euros annually in income, trade and research and development.

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Executive summary

A predictable and reliable intellectual property system is necessary for companies to innovate. The existing systems of national compulsory licensing already create an appropriate IP environment, and an EU-wide Compulsory License would create unnecessary burdens for businesses. Thus, it is crucial that – if implemented – this legal framework is established with adequate judicial oversight, with a clear definition for what triggers the CL procedures and what constitutes as 'crisis' and in compliance with the TRIPS Agreement.

Consultation response

Innovative companies of all sizes rely on a predictable and reliable system of intellectual property (IP) protection. This support is essential to engage in resource-intensive and high-risk investments over extended periods of time to bring cross-sectoral and world-wide innovation.

Based on the experience of the pandemic and other geopolitical crises impacting health, tech and other critical sectors, we have not seen evidence that justifies the introduction of a Compulsory Licensing (CL) system at EU-level, on top of the existing system of national CLs. Voluntary licencing and other forms of collaboration in manufacturing reached unprecedented levels during the pandemic in Europe and globally, and it is hard to envisage a CL based system that would replicate these benefits.

We are concerned with the overall message this proposal sends on the importance of IP and EU competitiveness in attracting investment in innovative sectors. As the EU Member States stated in the Council conclusions on IP Policy, 'the IP system has proven to be, and should remain, a driver for innovation, competitiveness, economic growth and sustainable development, as well as a key enabling framework for cooperation and transfer of knowledge and technology'. The EU has publicly acknowledged that IP has not been a barrier to access and pandemic response, and that it has facilitated voluntary partnerships and licensing allowing interventions to get to the citizens that need them faster in times of crisis. However, this proposal may accelerate weakening of Europe's IP environment in a multilateral context.

Considering the existing system of national CLs, an EU-wide Compulsory License would hardly be beneficial on top of existing system of national CLs. Additionally, since the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) contemplates that patent CL's may be granted at a national level, it is not clear that an EU-wide CL framework would be compliant with TRIPS. Nonetheless, if such a system was to be in place, this tool should be aligned with existing TRIPS flexibilities, and it should remain as a last resort to be considered in well-defined EU-wide crisis situations where a voluntary agreement cannot be reached in a reasonable timeframe. Moreover, it should feature necessary guardrails for it to be exercised within the right policy and judicial framework. The current proposal is inconsistent with the EU and Member States' commitments to the TRIPS Agreement, notably in relation to the need for a CL 'on its individual merits' (article 31a), the immediate involvement of the rights holder before the start of the procedure (article 31b), the protection of trade secrets and regulatory data protection (article 39) and proper the need for judicial review of CL decisions (article 31(i)/(j)). Overall, we have a number of concerns arising from the Commission's proposal.

Firstly, to safeguard the robustness of the EU IP protection system, any CL should be granted within the right legal framework with adequate judicial oversight. Priority and sufficient time should be given to finding a voluntary agreement with the rights-holder. Currently, the proposals are vague on process and lack independent judicial oversight through all stages of CL (pre, during and post grant). While the Commission has proposed that the rights-holder has a right to be heard before the granting of a CL, the proposed Regulation should include a distinct, clear and accelerated process for right-holders to request independent merits and judicial reviews of the CL granted. In the extraordinary situation where a CL is granted, the Commission would be immediately and irrevocably depriving a company of their IP rights, which this EU institution did not grant in the first place. Therefore, more independent judicial protection through all stages of the CL (pre, during and post grant) would be required than in the ordinary circumstances to respect fundamental principles of EU law.

In addition, we also have concerns on some of the terms and definitions used in the proposal which are vague and unclear. In this context, the EU Chips Act provides a good example of what can be done conceptually to define a crisis, crisis-relevant product, as well as how the crisis stage is triggered, with relevant safeguards and including a predetermined duration period of maximum 12 months. Furthermore, the composition and workings of the proposed advisory body, which will play a key governance role, are too open-ended. There is also significant ambiguity around the actual trigger for the CL procedure and the circumstances when a rights-holder would be notified of a CL being considered by the previously mentioned advisory body. Clarity and precision are needed to ensure predictability and to ensure that the rights-holder has time to engage in the processes as well as the right to appeal a CL before a court that may review the CL fully (including with the optionality of invoking summary proceedings). This is missing from the proposal.

To avoid discouraging innovators from investing in research in crisis-relevant products, CLs must be proportionate and apply only to the patents that are required for the crisis and not be overly broad as to cover any patent linked to a named product. Also, CL should not hinder the patent application processes.

The proposal inappropriately allows the Commission to impose complementary measures to support a CL without defining them. Without a clear definition of complementary measures, this will create confusion for the rights-holder and the parties involved, and it will likely slow down the processes. A more significant concern, based on the Impact Assessment, is that complementary measures may encompass obligations to share sensitive know-how, alongside onerous financial penalties. This risks bringing a form of forced tech transfer into the scope of the proposal, which would send a negative signal at the global level and would run afoul of the limited flexibilities contemplated under TRIPS.

We ultimately call on the EU Council and Parliament to ensure that the proposal will not negatively affect EU legislation for incentives and that it is consistent with the EU and Member States' commitments to the World Trade Organisation's TRIPS Agreement.