

## Consultation response

# Call for evidence: 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 trillion in 2020, directly supports more than 4.8 million jobs in Europe, and generates billions of euros annually in income, trade and research and development.

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, high-risk investments over extended periods of time to bring cross-sectoral and world-wide innovation. Hence, the opportunity to provide suggestions and input for the European Commission's call for evidence on Compulsory Licensing (CL) in the EU is welcomed.

IP plays a key role in advancing scientific research and innovation since patent holders publicly disclose their invention. As the EU 27 Member States have 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'.

IP rights such as patents provide a framework for recuperating research and development (R&D) investments upon success in the marketplace. They provide a foundation for collaboration between companies, research centres, universities and individual entrepreneurs and affect investment decisions across industrial ecosystems. They also drive efficiency in R&D by providing the possibility of in-licensing technology, allowing companies to build on existing innovation and to focus on their area of expertise and secure a license to use the patented technology developed by another innovator.

The TRIPS Agreement provides a process based on specific circumstances and conditions under which national governments can issue a CL on patented technologies. Under article 31, the entity applying for a CL must first try to obtain a voluntary licence from the rights holder on reasonable commercial terms. Should a CL be issued to the applicant, appropriate remuneration must still be paid to the patent holder. Improving the predictability of CL systems in EU countries for patent holders is a worthy objective, but any EU initiative to ameliorate the legal frameworks to use compulsory licensing needs to stay within the current parameters of the TRIPS agreement. To achieve this, it is important that the scope (both geographically and 'the nature of the crisis') of CL and its duration be clearly defined.

CL should remain an option of last resort. It is important for the Commission and European Health Emergency Preparedness and Response Authority (HERA) to draw lessons from the experience with the innovation response to COVID-19. In the face of one of the most urgent crisis in recent history, vaccines and therapeutics were developed in record time (nine months). Manufacturing was rapidly scaled up without the need for CL, and IP played a key enabling role for collaborations and global manufacturing networks. It is the IP system, not CLs, that ensures the flow of intangible assets such as technology and know-how.

To stimulate R&D and accelerate the innovation reaction in the event of a crisis, the Commission could consider measures such as (a) emergency funding and other support measures to de-risk engagement during a crisis, (b) trade facilitation to ensure that equipment and inputs can flow to where they are needed and (c) maintenance of a predictable and legally certain IP regulatory framework. Turning away from these measures and using CLs would only create further uncertainty during a crisis, and in the absence of IP protection for their patents and trade secrets, innovators would be less likely to work with others in a future crisis.

The Commission must ensure that its proposal will not negatively affect EU legislation for incentives, or risk doing so at any point during the legislative process. Aligned with this, CLs should not be used to undermine or get around the regulatory processes - it is important scientific standards are maintained.

Thank you and we appreciate the opportunity to provide input.