

## **EuropaBio Response to Public Consultation on the proposal for a Regulation on compulsory licensing for crisis management**

The COVID-19 pandemic has shown the importance for Europe to have the right tools to respond to major health crises. The EU has already adopted several laws to improve its ability to respond to health emergencies and the coordination between the Member States. National and international instruments on compulsory licensing (CL) already exist, questioning the actual need to propose a new framework at EU level that is inconsistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and EU law.

Intellectual property protection is a fundamental pillar to drive innovation and investment in the biotech sector, allowing companies to recoup R&D costs, stimulate further discoveries, and deliver valuable solutions to society. The proposed Regulation, combined with Article 80(4) of proposed revision of Directive 2001/83/EC, runs the risk of further eroding intellectual property protection and set a dangerous precedent about the stability and value of intellectual property rights (IPRs) in Europe.

The experience of the COVID-19 pandemic has shown that IP is not a barrier to access. In fact, thanks to collaboration between all actors of the innovation ecosystem and Member States, sufficient and continuous supply of vaccines and therapeutics to and from Europe were delivered without the need for CL. In strengthening its resilience, the EU must not create an unattractive environment that would lead to medical countermeasures (MCMs) being developed and manufactured outside Europe. It would therefore be more appropriate to build on the lessons learnt from the pandemic to strengthen collaborative networks that can deliver fast responses to emerging health crises as well as reinforce Europe's biomanufacturing capacity to quickly produce and deploy the necessary MCM. Importantly, while the CL rules are intended to apply to the EU only, it will have a ripple effect and could weaken the value of innovation globally as any company with a patent registered in the EU will be impacted.

The proposed Regulation will also significantly impact small and mid-size companies. Although the impact assessment accompanying the proposal is correct that those companies hold a relatively low number of patents, it fails to properly recognise that few or even just one patent is often the key value to the existence of those companies, without which they would not be able to get investments. In addition, large companies regularly in-license from smaller companies as this is where innovation in this sector comes from to a large degree. This means SMEs would be licensors and impacted by the CL.

Therefore, it is essential that CL remains a last resort option, triggered appropriately within the right legal framework, and subject to a continuous, independent, and fair judicial oversight through all phases of the CL process, which is lacking in the current draft proposal. This paper highlights EuropaBio's key concerns as regards compulsory licensing of medicines. We remain committed to work with policymakers and stakeholders to ensure the proposal does not negatively impact Europe's innovative biotech industries.

- The nature of the crisis activating the mechanism is not clearly defined and, for medicinal products, should be limited to public health emergencies pursuant to Regulation (EU) 2022/2371. The crisis framework under Council Regulation (EU) 2022/2372 should not be ground to grant a compulsory licence.
- The proposal does not specify that CL should be a last resort option and only granted if voluntary measures or any other mechanism that would allow the EU to secure MCMs have been unsuccessful. Importantly, the proposal does not include the proper involvement of the right-holder at all steps of the process, including in relevant meetings of the competent advisory body as a CL can be granted without the right-holder(s) having had opportunity to be heard.
- The scope of a CL is not limited to granted patents only and includes patent applications. Encompassing patent applications within the scope of the proposed Regulation provides for a broad CL structure runs the risk of including applications that may not eventually be granted or be granted with claims that do not encompass the product which is the subject of a CL.
- The transfer of know-how, confidential information, or trade secrets – including data submitted to receive a marketing authorisation – is not explicitly excluded from the scope of the proposed Regulation. The legislative requirement to transfer know-how and other confidential information has far reaching implications for innovative industries and cannot be easily reclaimed once a CL ceases to have an effect. This potentially leaves innovative patent filers in a vulnerable position and at a disadvantage with respect to this proposal as compared to those who have not filed for patent protection.
- A CL can be granted by the Commission for an undetermined period without a binding opinion of the competent advisory body. The composition and role of any granting body needs to be clear, transparent, and unbiased.
- Where a CL has been determined to be wrongly awarded by a competent judicial authority, the right-holder shall be entitled to full compensation and damages. This is key to respect fundamental principles of EU law and guarantee more judicial protection than in the ordinary circumstances.
- The provisions on remuneration of the patent holder should be aligned with Article 31(h) of the TRIPS Agreement to establish that remuneration dependent on the circumstances of each CL.

## About EuropaBio

EuropaBio, the European Association for Bioindustries, promotes an innovative and dynamic European biotechnology industry. EuropaBio and its members are committed to the socially responsible use of biotechnology to improve quality of life, to prevent, diagnose, treat and cure diseases, to improve the quality and quantity of food and feedstuffs and to move towards a biobased and zero-waste economy.