

Health Action International (HAI) response to the European Commission public consultation on Intellectual property – revised framework for compulsory licensing of patents

The European Commission proposal as contained in [COM \(2023\)224](#)¹ and accompanying documents is an overdue step forward towards a more nuanced balanced between innovation and access as it aims to streamline and facilitate the use of Compulsory Licenses.

It has been a longstanding position of Health Action International (HAI) that Compulsory Licenses are not only a legitimate legal instrument to manage the Intellectual Property (IP) rights but also a critical component of public interventions to achieve health policy objectives regarding access to health technologies and economic sustainability of public health systems².

Covid-19 pandemic and the difficulties associated with access to health goods have highlighted the trouble faced by EU governments to expedite access to life-saving health technologies, while we welcome that the new regulation will address some of the obstacles and hurdles currently hindering the use of Compulsory Licenses such as national disparities and the lack of an effective Single Market for licensed products.

We must voice our concern regarding the fact that the measure would only be invocable as a last resource in an emergency context. As we have repeatedly stated, we believe reasons to make use of a Compulsory Licence are to be determined by national authorities and can include excessive high pricing, anti-competitive practice or failure to exploit a patent among other instances; such approach has been endorsed by the Doha Declaration (2001) and has not been challenged at the World Trade Organisation dispute settlement mechanisms.

This proposal, framed within an IP-package that also addresses essential patents and Supplementary Protection Certificates (SPC), is being considered at the same time as other initiatives like the update of the European Pharmaceutical Strategy or interventions by the European Health Emergency Preparedness and Response Authority (HERA). It is critical that the legislative coherence is upheld and that the removal of obstacles for CL (like Data Exclusivity) is not impeded by new incentives for specific products such as antibiotics or drugs for rare diseases.

Beyond the scope of this proposal, but of interest for EU lawmakers as regards coherence with external EU actions in the field of global health, is whether products manufactured under a EU-wide CL could be exported to fulfil eventual demand in Low and Middle Income Countries (LMIC) with no or insufficient pharmaceutical manufacturing capabilities as stated in Regulation (EC) No. 816/2016;

¹ See EUROPEAN COMMISSION (EC) COM(2023)224 - Proposal for a regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) 816/2006 23 April 2023 Accessible at https://single-market-economy.ec.europa.eu/publications/com2023224-proposal-regulation-compulsory-licensing-crisis-management_en consulted 28 July 2023

² See HEALTH ACTION INTERNATIONAL (HAI) TRIPS flexibilities and access to medicines. An European approach. May 2018 Available at <https://haiweb.org/wp-content/uploads/2019/06/HAI-TRIPS-Brochure.pdf> consulted 28 July 2023 and HAI Response to European Consultation on Compulsory Licensing 22 May 2022 Available at <https://haiweb.org/publication/response-to-european-consultation-on-compulsory-licensing/> Consulted on 28 July 2023

currently this would not be possible as Article 11 prohibits exports of licensed products, we ask the European Commission and EU lawmakers to reconsider.

As part of HAI's work towards greater use of CL as a policy tool to improve and secure access to medicines and other health technologies, a specific tool was designed and set up; the TRIPS flexibilities navigator aims to provide policymakers, academics, advocates and other relevant stakeholders with the necessary legal and administrative information in each EU jurisdiction to make use of CL³. This mechanism is going to be scaled up to widen its scope to cater to the needs of generic medicines manufacturers and include other official EU languages, the community being built by access and use of the platform will be guiding next steps.

We remain at the disposal of EU institutions and concerned parties to engage in this and other important discussions regarding access to innovation and a balanced approach to IP and health.

³ See LAWRENCE, A and VIDAL, J Introducing the TRIPS Flexibilities Navigator HAI 9 May 2022 Available at <https://haiweb.org/introducing-the-trips-flexibilities-navigator/> Consulted on 28 July 2023 and TRIPS flexibilities navigator available at <https://www.flexibilitiesnavigator.org/> Consulted 28 July 2023