



Introduction

Intellectual Property Owners Association (IPO) appreciates the opportunity to comment on the “Proposal for a Regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) 816/2006.”

IPO is an international trade association representing a “big tent” of diverse companies, law firms, service providers and individuals in all industries and fields of technology that own, or are interested in, intellectual property rights. IPO membership includes over 125 companies and spans over 30 countries. IPO advocates for effective and affordable IP ownership rights and offers a wide array of services, including supporting member interests relating to legislative and international issues; analyzing current IP issues; providing information and educational services; supporting and advocating for diversity, equity, and inclusion in IP and innovation; and disseminating information to the public on the importance of IP rights.

IPO’s vision is the global acceleration of innovation, creativity, and investment necessary to improve lives. The Board of Directors has adopted a strategic objective to foster diverse engagement in the innovation ecosystem and to integrate diversity, equity, and inclusion in all its work to complement IPO’s mission of promoting high quality and enforceable IP rights and predictable legal systems for all industries and technologies.

Comments on Proposal

A clear and predictable legal framework for the protection of intellectual property enables innovation; inventors are encouraged to devote time and creative spirit, and investors are encouraged to dedicate resources, to take on the world’s toughest problems. The current IP framework fosters innovation, collaboration, and partnerships among inventors, investors, manufacturers, and suppliers in order to improve the lives of end users.

The unprecedented development of innovative technology and solutions to tackle the COVID-19 pandemic, for example, provides an emphatic demonstration of the value that an effective IP protection framework brings to society. The full attention to, and speed in, developing and providing solutions to tackle the pandemic can be traced directly to the guarantees offered by IP protections. During the COVID-19 crisis, the innovative industry collaborated at an unprecedented scale, including through voluntary licensing and other partnerships, to manufacture and supply countermeasures to patients and consumers globally. The expectation that the creative output resulting from costly research & development (R&D) initiatives will be protected is vital to encouraging R&D and to encouraging collaborations and partnerships, and must be preserved.

Innovation spurred by intellectual property is not a barrier to addressing global challenges. Rather, intellectual property is essential to the solutions to these challenges, and these challenges can only be met with investment in research and technology, and through creative thinking about solutions.

IPO is concerned that the proposed Regulation envisions a new framework that would establish an EU-wide compulsory licensing instrument where a crisis or emergency is declared (*i.e.*, a Union compulsory licence or “Union CL”). The 27 Member States that make up the European Union represent a significant market for IPO Members, many with substantial R&D and manufacturing sites based in the EU, and the home for several IPO members. The threat of eroding the market’s potential based on the unfounded belief that IP impedes access to innovative solutions sends a negative message that may serve to position the EU as a less attractive environment for competitiveness and investments in innovation and manufacturing.

Further, there is no clear evidence to support the need for a Union CL. Continuing efforts to weaken IP protections, without clear and compelling evidence, will set a dangerous precedent for the innovative community. The resulting unpredictability can be expected to adversely impact the innovation system globally, at a time when we need to encourage innovation to address our global challenges.

IPO suggests that the European Union should address the crucial and real issues that impact access to innovative solutions, such as health system readiness. This proposed administrative and legal instrument, by instead focusing on intellectual property, will undoubtedly undermine the global response to a future crisis by diverting attention from resolving the known challenges. Further, IPO’s concerns about the proposed Regulation include, for example, the following (in no specific order):

- There is no clear definition of a crisis or how it is triggered. Leaving such a vital aspect of the Regulation vague and unclear would prevent a rights-holder (or potential rights-holder) from understanding the scope of their rights.
- There is ambiguity as to when a rights-holder will be notified of a compulsory licence (CL) or the potential thereof.
- The proposed Regulation covers not just granted patents, but patent applications as well, bringing into question its compliance with the TRIPS Agreement. This will also create complexity around appropriate notification of rights holders and adequate compensation; for example, how can it be predetermined if a licence will be required or what the appropriate level of compensation would be *before* the final claim scope has been determined?
- The role and constitution of the Advisory Board is unclear. Although Article 6 indicates that the “opinion of the advisory board shall not be binding on the Commission,” more clarity is needed in relation to the specific role, responsibilities, and constitution of this Board. In terms of its constitution, members from the innovative industry should be represented and advisers should have appropriate expertise.
- The proposal overall is opaque on process and lacks independent judicial oversight. The processes described throughout the proposal do not seem to be subject to any independent scrutiny, and although Recital 31 addresses the judicial review of the Commission’s decision to grant a Union CL, the Articles of the draft regulation do not address it.
- The “adequate” remuneration is capped at a level that may be materially insufficient for all situations.

- The Commission is provided with the power to impose severe and disproportionate financial penalties for the breach of vague obligations such as the principle of “good faith and cooperation” or failing to comply with “any obligation” that results from “additional measures complementing” the Union CL. Such additional measures potentially include the transfer of trade secrets and/or know-how to help effectuate the success of the CL. A requirement that would demand the disclosure of highly valuable, sensitive and confidential business information – without appropriate compensation, and with the threat of significant penalties – sets a dangerous precedent towards quelling innovation and would run contrary to the TRIPS Agreement. By penalizing rights-holders, it would place the rights-holders in an arguably worse position than had they not sought patents in the first place. In addition, under the TRIPS Agreement, a CL restricts a government-granted right (*i.e.*, the patent), but it does not compel the rights-holder to affirmatively act. A CL does not come with a duty to transfer trade secrets or technical know-how to others. In other words, there is no duty to provide technical information to others, other than that which must be disclosed in the patent itself. A system that includes the risk of imposing such far reaching, indefinite duties has the potential for discouraging investment in those markets, as innovators have reasonable concerns about being forced to transfer their technologies and confidential information.

Such a broad reaching, vague, ambiguous, and unclear Regulation will have negative effects on investments and advancement in innovation across all industries and across the globe, not just in Europe. It would undermine the IP protections afforded to inventions simply because such inventions serve the public good. The well-known benefits of protecting IP rights have led to countless innovations that have improved human existence and solved some of the most significant challenges facing humankind. Consequently, policy measures designed to limit such protection must be evaluated with exceptional care. This is particularly the case where there is no evidence that IP has impeded the EU’s ability to respond to a crisis, and many European countries already provide for limited exceptions to patent protection through their national compulsory licensing frameworks. Although IPO recognizes that compulsory licenses of IP rights may be legally permissible in limited and rare situations, IPO believes that licensing of IP rights is best accomplished through voluntary efforts.

IPO strongly supports equitable, widespread, and successful distribution of innovative solutions that are necessary to meet a global crisis; however, it must be reiterated and emphasized that it was the IP protection underpinning innovation that allowed the world to benefit from effective solutions, enable rapid development and manufacturing, and address one of the most challenging global crises of the modern world. Innovation will continue to benefit and be sustained by the IP protections that pave the way for future innovations and solutions to global challenges.