The Consumer Voice in Europe

REVISED FRAMEWORK FOR COMPULSORY LICENSING OF PATENTS

BEUC's comments on the Commission's proposal for a regulation on compulsory licensing for crisis management

Contact: health@beuc.eu | competition@beuc.eu

BUREAU EUROPÉEN DES UNIONS DE CONSOMMATEURS AISBL | DER EUROPÄISCHE VERBRAUCHERVERBAND
Rue d'Arlon 80, B-1040 Brussels • Tel. +32 (0)2 743 15 90 • www.twitter.com/beuc • www.beuc.eu
EC register for interest representatives: identification number 9505781573-45

Co-funded by the European Union

Ref: BEUC-X-2023-103 - 31/07/2023

Why it matters to consumers

Patients should have access to affordable and innovative medicines. This is all the more important in times of crises. A compulsory licensing system at EU level would guarantee the supply and the free movement of crisis-critical patented products in the Single Market. While the Commission's proposal goes beyond medicines, this contribution focuses on medicines and the importance of enabling alternative production or importation between countries in the Single Market of a generic version of a patented pharmaceutical product without the patentee's prior consent during crisis or emergency situations. The proposed regulation would ensure that patients and consumers have timely access to affordable medicines, vaccines and other medical products. In doing so, compulsory licensing can also help address inequalities in access within the EU.

Summary

Prompted by the COVID-19 pandemic and given the role intellectual property rights can play in a crisis, the European Commission aims to establish an efficient compulsory licensing system at EU level. The Proposal for a regulation on compulsory licensing for crisis management and amending Regulation (EC) 816/2006[1] (the Commission's proposal) would enable a swift and appropriate response to a crisis or emergency by guaranteeing the supply and the free movement of crisis-critical patented products in the Single Market. While the Commission's proposal refers to all crisis-critical products and/or technologies, the focus of our present response is limited to medical products.

Currently, a compulsory licence can be granted for a Member State's own territory only. While this can suffice in purely national crises, it will not be adequate when a crisis has a cross-border dimension. Thus, having a compulsory licensing system at EU level is to be welcomed.

However, the Commission's proposal calls for certain improvements. This position paper sets out the necessary amendments to the Commission's proposal:

1. The Commission's proposal should state in an explicit manner that in a crisis or emergency, while voluntary agreements would be an option, the process of compulsory licensing should not be delayed by imposing a requirement to demonstrate the attempt to secure a voluntary agreement between the prospective licensee(s) and the patent holder.
2. The Commission's proposal should include within the scope of compulsory licensing all aspects that are essential to ensure the swift and effective production of medicines and other medical products, including the complementary know-how.
3. The Commission's proposal should not be limited to the situations described in the Annex, but also include the concept of 'major events' from Regulation (EU) 2022/123 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices.[2]

[1] See: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13357-Intellectual-property-revised-framework-for-compulsory-licensing-of-patents_en.

[2] EU Regulation 2022/123 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R0123.

Contents

---°---

1. Introduction

Currently, each Member State has its own rules and procedures on compulsory licensing of patents applying to its domestic market. However, the COVID-19 pandemic has shown that common tools are needed to tackle cross-border crises more effectively. We therefore welcome the proposed regulation that sets out rules on the conditions and procedures for the granting at EU level of compulsory licences of intellectual property rights and thereby ensures that in a crisis or emergency the EU has access to crisis-relevant products and processes.[3]

While the Commission's proposal allows for the use of compulsory licensing for all crisis-critical products when circumstances call for it, the focus of our present response is limited to medical products. This does not preclude that our comments may be relevant also in other sectors.[4]

Compulsory licensing is a pro-public health tool embedded in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS agreement) that aims to ensure swift access to critical patented products or technologies, even in the absence of voluntary agreements in certain situations. It aims to balance the need to, on the one hand, preserve innovation incentives that create new health products and, on the other hand, the need to ensure their availability and affordability everywhere.

Pursuant to the Charter of Fundamental Rights of the European Union[5] certain limitations in terms of the exercise of intellectual property rights are permitted as long as the proportionality principle is respected. This means, inter alia, that compulsory licensing should always be granted on a non-exclusive basis and for a limited duration.[6]

We welcome the Commission's readiness to make use of the flexibility provided under the TRIPS Agreement. The proposal represents an important step in enhancing the EU's capacity to prepare and respond to future crises by ensuring swift access to critical products in these situations. We welcome that not only patents, but also published patent applications, utility models and supplementary protection certificates are part of the scope

[3] The Commission's proposal complements other EU crisis instruments included in different EU legislation aiming at ensuring the supply of and access to critical products in the Single Market, page 3 of the proposal.
[4] Compulsory licensing may in particular also be relevant in terms of consumer protection related to combatting the negative impact from climate change and natural disasters such as to ensure clean water and sanitation, clean energy supplies, build resilient infrastructures and safe human settlements.
[5] Article 17(2) of the Charter of Fundamental Rights of the European Union.
[6] The Commission's proposal, page 8.

of the proposed compulsory licensing. These are all important elements for the effectiveness of the mechanism.

We also support the proposal's reference to the necessary suspension of regulatory data and market protection where the compulsory licence has been granted for a patent relating to a medicinal product in order to address a public health emergency, covered by the proposed reform of the pharmaceutical legislation. This is important as the rules on regulatory data and market protection can impede the effective use of compulsory licensing.[7]

But other parts of the proposal require further improvement as set out below.

2. Areas for improvement

2.1. Voluntary agreements

The text of the Commission's proposal is not clear on whether there must be an attempt to secure a voluntary agreement with the patentee before granting a compulsory licence.[8] The proposal should state in an explicit manner that in a crisis or emergency, while voluntary agreements would be an option, the process of compulsory licensing should not be delayed by imposing a requirement to attempt to secure a voluntary agreement between the prospective licensee(s) and the patent holder. A different interpretation would be contrary to and incompatible with the TRIPS Agreement, which notes that the requirement of demonstrating a voluntary licensing failure may be waived in the case of a national emergency or in other circumstances of extreme urgency.[9]

2.2. Scope of the compulsory licensing

The Commission's proposal should include within the scope of compulsory licensing all aspects that are necessary to ensure the swift and effective production of medicines and other health products, including complementary know-how and technological solutions, ring-fenced to precise circumstances where such a waiver is essential for enforcing compulsory licensing in an effective way. While overriding patents alone may be sufficient to enable other producers to swiftly manufacture small molecule medicines, in cases of more complex pharmaceutical products (e.g., vaccines in a pandemic) this will often not be the case. Here, the alternative producer will also need immediate access to other intellectual property protected assets in order to be able to make use of compulsory licencing in an effective manner.[10]

---

[7] The Commission's proposal, page 3, 4, para. 14. See also Max Planck Institute for Innovation and Competition Research Paper No. 23-07, Lamping (et al.): Revisiting the Framework for Compulsory Licensing of Patents in the European Union, Reflections on the European Commission's Initiative, para. 45.

[8] See for example paras. 1, 21, 22 of the Commission's proposal. See also Article 7(3) of the Commission's proposal which states that "before the granting of a Union compulsory licence, the Commission shall give the rights-holder and the licensee an opportunity to comment on the following: a) the possibility to reach a voluntary licensing agreement with manufacturers on intellectual property rights for the purpose of manufacturing, using and distributing the crisis-relevant products; […]".

[9] Article 31(b) states that "such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use."

[10] "For these products to be expeditiously made available in the shortest timeline, producers need to be able to access confidential information and trade-secret protected knowledge, data, manufacturing, quality control know-how, regulatory data, and even cell lines and other biologic resources.", page 9, https://msfaccess.org/sites/default/files/2021-05/COVID_TechBrief_MSF_AC_IP_CompulsoryLicensesTRIPSWaiver_ENG_21May2021_0.pdf. See also European Parliament resolution of 12 July 2023 on the COVID-19 pandemic: lessons learned and recommendations for the future (2022/2076(INI)), in particular points 509, 525 on the importance of sharing

2.3. Grounds for compulsory licensing

The Doha Declaration on the TRIPS Agreement and Public Health stipulates that countries have the right to use compulsory licences and other flexibilities to safeguard health and have a discretion to define the grounds for compulsory licences.[11] The regulation should not be limited to the situations described in the Annex, but also include the concept of 'major events' as defined in the new regulation expanding the European Medicines Agency's mandate in crisis preparedness and management. This is essential to ensure that compulsory licensing can also be triggered to respond to an event which is likely to have a serious impact on public health in relation to a medicinal product in more than one Member State, and which would ultimately lead to shortages and require an urgent and coordinated response at EU level. For example, a major incident outside the EU affecting the production of a patented vaccine or priority antimicrobial that cannot be resolved promptly by the marketing authorisation holder, and for which insufficient supply results in serious harm or risk of serious harm to EU patients, denoting thereby a public health threat, should also be covered by the proposal.[12]

Finally, it is important to ensure that the EU has a robust framework in place not only to manage existing crisis situations, but also to prevent their occurrence in the first place and as much as possible.

IP and know-how within the legal framework to ensure large-scale production and global availability of medical countermeasures during pandemics, epidemics and endemics.

[11] Paragraph 5(b) of the Doha Declaration on the TRIPS agreement and public health:https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

[12] Major event is defined in the Regulation reinforcing the EMA mandate as "an event which is likely to pose a serious risk to public health in relation to medicinal products in more than one Member State, which concerns a deadly threat or otherwise serious threat to health of biological, chemical, environmental or other origin, or a serious incident that can affect the supply of or demand for medicinal products, or quality, safety or efficacy of medicinal products, which may lead to shortages of medicinal products in more than one Member State and necessitates urgent coordination at Union level in order to ensure a high level of human health protection." It is distinct from the definition of 'public health emergency'.

Co-funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or EISMEA. Neither the European Union nor the granting authority can be held responsible for them.