Questions and Answers on Compulsory Licensing

Brussels, 27 April 2023

Why is intellectual property important and why is the Commission proposing a new initiative on patents today?

Europe has a long tradition of encouraging creativity and innovation. Intellectual property (IP) rights help companies, inventors and creators protect and valorise their intangible assets. The Commission continues to deliver on the Action Plan on Intellectual Property of November 2020 to improve the IP legal framework, notably in three patent-related fields where legislative action is required: supplementary protection certificates, compulsory licensing and standard-essential patents. Despite the strategic importance of patents, EU patent law remains fragmented. EU patent law therefore needs to be modernised to boost the resilience of our patent system, support the EU's green and digital transition and strengthen the EU's technological sovereignty, in particular in emerging technologies. With the set of proposals for a Regulation adopted today the EU shows its willingness to further reinforce the harmonisation of EU patent law and complement the Unitary Patent System, whose launch will take place in June 2023. In today's world of globalised markets and the knowledge economy, it is vital to ensure that the EU IP system is effective, transparent and future proof, setting global standards.

What is the objective of the initiative on compulsory licensing for crises management?

This initiative aims to create, at EU level, an efficient compulsory licensing framework to address EU-relevant crises. Voluntary licensing agreement are most effective in ramping up production, but should voluntary agreements not be available or adequate, compulsory licensing can help provide access to key crisis-relevant products and technologies in emergencies.

An effective EU compulsory licensing mechanism will:

- Serve as an effective tool in crisis times as a last resort when voluntary agreements do not work.
- Ensure an appropriate territorial reach of compulsory licensing to cover cross-border supply chains.
- Build on EU crisis mechanisms.

Currently, legislation on compulsory licensing of patents in the EU is fragmented: EU countries regulate their own national compulsory licensing schemes, subject to different conditions, scopes, and procedures. In addition, national compulsory licensing schemes are designed to meet the needs of the population of the issuing Member State and to satisfy the public interest of that Member State only. These purely national systems are unable to rely on cross-border value chains and therefore unfit to tackle EU crises. At a time where the EU is aiming to build up its resilience to crises, it is necessary for the EU to be able to rely on a Union IP crisis tool.

Today’s initiative will allow the EU to rely on an efficient compulsory licensing framework for crisis management that would be applicable to the whole EU territory. Currently, a compulsory licence to export pharmaceutical products to non-EU countries is only possible at national level and for the national territory, making it impossible to rely on cross-border supply chains. This initiative would allow the granting at EU level of a Union level compulsory licence applicable in the whole Union territory and therefore able to rely on the internal market.

What would trigger a Union compulsory licence?

The initiative aims at providing the EU with an efficient compulsory licensing system to tackle EU-wide crises. To this end, this initiative is closely linked to EU crisis instruments. Recent crisis instruments include the Single Market Emergency Instrument (SMEI) proposal, the Chips Act proposal, the Regulation on cross-border health threats (EU) No 2022/2371 under which the Commission may recognise a public health emergency at Union level, and HERA's framework of measures for ensuring the supply of crisis-relevant medical countermeasures under Regulation (EU) No 2022/2372. A Union compulsory licence can only be granted in the context of an EU crisis.
More specifically, a Union compulsory licence can only be granted after the activation of an emergency or crisis mode at EU level. The determination of the existence of a crisis or emergency is therefore not defined by the Regulation on compulsory licensing but rather by the relevant EU crisis instrument. For the sake of legal certainty, the EU crisis instruments that can trigger a Union compulsory licence are listed in an Annex to the proposed Regulation.

**Will compulsory licensing apply for products export to non-EU Countries?**

Compulsory licensing for export of medicines to non-EU countries with public health problems is already harmonised at EU level, although the procedures remain national. Compulsory licensing is therefore already available to certain non-EU countries to ensure access to pharmaceutical products but not to other products. This initiative will ensure that a Union-level compulsory licence can also be granted for export purpose for pharmaceutical products. Therefore, for export purposes, the scope is limited to such products.

The proposal allows a Union compulsory licence to be granted at Union level for the Union territory, taking therefore full advantage of the Single Market. The initiative amends Regulation (EC) No 816/2006 in order to add the possibility, in the context of a cross-border manufacturing process, to rely on a Union compulsory license. This is a strong signal that the EU is further improving its tools to support access to critical health-related products by certain third countries.

**Does this initiative replace compulsory licensing frameworks at national level?**

No, it does not. Member States have implemented different compulsory licensing schemes in national legislation, only applicable to their national territory. The proposal leaves these national compulsory licensing systems untouched. The Union compulsory licensing system introduced by this proposal does not aim at addressing purely national crises or emergencies. The proposal instead aims to address crises or emergencies at EU level, which do not fall in their entirety within the scope of national compulsory licensing schemes. Therefore, the proposal establishes a Union compulsory licensing scheme with its own triggers, procedure and conditions ensuring at the same time coherence with other crisis and emergency instruments at EU level.

**Will patent holders subject to compulsory licensing be compensated?**

Yes, patent holders will receive an adequate remuneration. In addition, safeguards will be established along the whole compulsory licensing "lifecycle", reaching from the pre-granting to the post-granting phase of the Union compulsory licence. First, the trigger (activation or declaration of an EU emergency/crisis mode under an EU legal act) is already a high threshold for the initiation of the granting process. Furthermore, when considering the need to issue a Union compulsory licence and the conditions thereof, including an adequate remuneration, the Commission will be assisted by an advisory body, involving Member States and relevant stakeholders. Finally, the Commission is given the competences to review, complement and terminate the compulsory licence granted and, if necessary, to impose coercive measures (such as fines and periodic penalty payments) in case of infringement of the licence. Finally, the Union level compulsory licence will be subject to judicial review.

**For More Information**

[Proposal](#) for a Regulation on Compulsory Licensing of Patents

[Press Release](#)

[ Factsheet on Compulsory Licensing](#)

QANDA/23/2456

**Press contacts:**

Sonya GOSPODINOVA (+32 2 296 69 53)
Federica MICCOLI (+32 2 295 83 00)

General public inquiries: Europe Direct by phone 00 800 67 89 10 11 or by email