

Compulsory licensing of patents

In 2023, the Commission submitted six patent-related legislative initiatives aimed at helping companies, in particular SMEs, make the most of their inventions and of new technologies, and contribute to the EU's competitiveness and technological sovereignty. In March, Parliament is due to adopt its first-reading position on one of these initiatives, a new regulation on the compulsory licensing of patents for crisis management.

Background

A <u>compulsory licence</u> is the possibility for a third party to use a patent under certain conditions, without the authorisation of the rights-holder. There are currently no EU-wide rules on compulsory licensing, including on European <u>patents with a unitary effect</u>, and national rules and procedures as regards both vary across the Member States. In its 2020 <u>intellectual property action plan</u>, the Commission highlighted 'the need to ensure that effective systems for issuing compulsory licences are in place'. After exploring the creation of an emergency coordination mechanism for compulsory licensing, the Commission decided to include a proposal for clear rules for the compulsory licensing of patents in its <u>2023 work programme</u>.

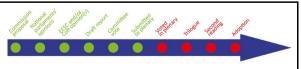
European Commission proposal

The <u>proposal</u> would enable the Commission to grant licences for national, European and unitary patents, where a crisis or emergency mode has been activated or declared. It would also cover utility models and supplementary protection certificates. It aims to create an efficient compulsory licensing scheme for crisis management and to ensure that critical products and components swiftly reach those in need during crises.

European Parliament position

The rapporteur for the Committee on Legal Affairs, Adrián Vázquez Lázara (Renew, Spain), presented his draft report on 16 October 2023, to which 98 amendments were tabled. The report was adopted on 13 February 2024, and proposes a number of key changes. For instance, voluntary agreements would have greater priority than compulsory licensing, and parties would have 4 weeks to reach an agreement. The licensee would be responsible for any liability or warranties arising from the production or distribution of the product, and the rights-holder would not incur any product liability. The Commission would have to 'take utmost account' of the advisory body's opinion and justify any decision not to follow this opinion. The rule allowing the Commission to refrain from identifying all rights-holders if this would delay the procedure, would be deleted, meaning that the Commission would have to identify all rights-holders. The rights-holder $would \, receive \, remuneration \, for the \, use of \, a \, compulsory \, licence \, within \, a \, pre-established \, time frame \, agreed \, agre$ with the Commission. The remuneration cap (no more than 4% of total gross revenue generated by the licensee through the relevant activities) would, in principle, be deleted, though it would still apply, under some conditions, to the compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems, in a situation of national emergency, other circumstances of extreme urgency or in cases of public non-commercial use. The Commission could compel rights-holders to disclose trade secrets and know-how if these are strictly necessary to achieve the purpose of the compulsory licence, and there would be remuneration for the disclosure of trade secrets.

First-reading report: <u>2023/0129 (COD)</u>; Committee responsible: JURI; Rapporteur: Adrián Vázquez Lázara (Renew, Spain). For further information, see our 'EU Legislation in progress' <u>briefing</u>.



EPRS | European Parliamentary Research Service

Author: Rafal Manko with Hugo Carmona Bas, Members' Research Service PE 760.346 – March 2024

