

# Proposal for a Regulation on compulsory licensing for crisis management and amending Regulation 816/2006

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## POSITION PAPER September 2023

The European Commission published on 27 April 2023 its proposal for a Regulation on compulsory licensing for crisis management.

The French Association of Large Companies, [AFEP](#), which gathers 117 of the largest companies operating in France, details its position in the position paper below.

### I. Context and preliminary remarks

While **strongly supporting the objective of responding quickly to possible future crises**, AFEP member companies regret that the Commission did not consider, as underlined by stakeholders during its public consultation, that the **existing legal framework regarding compulsory licensing is perfectly established** and does not seem to be a root cause that could have prevented the resolution of situations recently experienced. As pointed out in the synopsis report on the stakeholder consultation, 58% of respondents for example considered that current national laws on compulsory licensing are fit to tackle national crises, 51% for EU-wide crisis and “all business associations and companies considered that compulsory licensing rules are fit to tackle EU-wide crises”<sup>1</sup>.

Furthermore, national legislations have now **taken up international provisions in their internal corpus**, as recalled by the EPO in 2018 in its publication regarding compulsory licensing in Europe<sup>2</sup>. The WTO agreement on trade-related aspects of intellectual property rights (TRIPS Agreement) is the most comprehensive multilateral agreement on intellectual property. In particular, it makes it possible to resolve trade disputes in this area and to provide WTO members with sufficient flexibility to achieve their domestic policy objectives. Compulsory licensing is one of the flexibilities recognised by the TRIPS Agreement.

The 2018 EPO document emphasizes that this type of licence has been intended to be used only when all else fails. In France, article L. 613-16 of the Intellectual Property Code provides for example that if the interest of public health so requires and in the absence of an amicable agreement with the patent holder, the Ministry in charge of intellectual property may, under certain conditions, submit to the ex-officio licencing regime any patent issued for medicinal products, processes for obtaining them or

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<sup>1</sup> Commission’s accompanying staff working document and impact assessment report, Annex II, page 59

<sup>2</sup> Compulsory licensing in Europe, a country-by-country overview, European Patent Office, 2018

diagnostic methods. This system of compulsory licencing in the interest of public health can only be envisaged when these products, or products resulting from these processes, are made available to the public in insufficient quantity or quality or that abnormally high prices, or when the patent is exploited under conditions contrary to the interest of public health or constituting practices declared anti-competitive following a final administrative or judicial decision.

Regarding in particular the COVID-19 crisis, AFEP wishes to recall that the development of vaccines in record time has been welcomed by a large part of the population and European institutions. COVID-19 has, on the other hand, revealed shortcomings downstream of the patent for the implementation of these vaccines. The production sites, the production capacities, the distribution logistics and the distribution of these products were complex due to a lack of suitable infrastructure. The patent has no impact on this downstream part of the crisis; compulsory patent licensing would do nothing to solve production or supply chain problems.

Overall, considering the existing national, European and international framework, AFEP is not sure of the benefits of an additional system. **If it is to be implemented, it should remain compliant with TRIPS, including its flexibilities, and should remain a last resort possibility where a voluntary agreement cannot be reached. Predictability and reliability are key for companies**, and this framework should ensure adequate protection and oversights. AFEP's detailed position on the proposal can be found below.

## II. AFEP Position

### Subject matter and scope (Articles 1 and 2)

The compulsory licensing should **only occur as a last resort and if no prior agreement has been reached** with the patent holder. The proposal moreover covers a scope that does not only include granted patents but also includes patent applications, utility models and supplementary protection certificates in force in one or more Member States. AFEP considers that the scope should be **clearly limited to products necessary for crisis solving**, and not risk including patents that may not be granted in the end or that might be broader than the product subject to compulsory licensing.

Moreover, the notion of intellectual property covered by the compulsory license is not specific enough and could include trade secrets and know-how. These transfers are not explicitly excluded from the scope and their sharing could have further reaching implications for innovative industries, with little to no possible reclaim.

### Definitions (Article 3)

The **definition of “crisis-relevant products” is too vague:**

- it leaves a **wide margin of discretion to the Commission** to determine when and under which conditions a product or process is indispensable for responding to

- a crisis or emergency, or for addressing the impact of a crisis or emergency in the EU;
- it does not specify to whom the commission grants this license, whether it is for example limited to European companies, which is crucial to ensure European strategic autonomy

#### Union compulsory licence (Article 4)

The **nature of the crisis activating the mechanism of compulsory licensing is unclear**. The link to the Single Market Emergency Instrument (SMEI) is moreover premature, as the SMEI Regulation is yet to be adopted and proposes a definition of crisis that is still very much open for interpretation.

It should be better delimited, and the **leeway given to the European Commission to amend the Annex should be limited to cases of force majeure**.

The recently adopted Chips Act is one example of a better-defined relevant product, with a clear notion of what would trigger a crisis, of necessary and mandatory safeguards as well as the duration period. Similar criteria could for example be used in the proposal of regulation.

#### General conditions of a Union compulsory licence (Article 5)

The licence shall be (a) non-exclusive, and non-assignable, (b) have a scope and a duration that is limited to the scope and duration of the crisis, (c) be strictly limited to the relevant activities of crisis relevant product in the Union, (d) only be granted against payment of adequate remuneration, (e) be limited to the territory of the Union and (f) only be granted to a person deemed to be in a position to exploit the protected invention in a manner that permits the proper carrying out of the relevant activities.

Such general conditions could **prove difficult to implement** in some areas, especially regarding condition (e) limiting the licence to the Union territory. For example, it is unclear how the condition would apply to **products distributed and/or finished outside of the Union, but holding components that are covered by the licensing**.

#### Advisory body (Article 6)

The Commission shall consult an advisory body when considering the granting of a Union compulsory licence. The composition and workings of the advisory body should be clear, transparent and unbiased.

Thus, companies propose to replace the item “may invite” (Article 6.4b) with “shall” and to **include the relevant stakeholders**, including businesses and right holders, including in the ad hoc advisory body set up by the Commission in the absence of any existing competent body.

## Procedure for granting a Union compulsory licence (Article 7) and content of the Union compulsory licence (Article 8)

It should again be made clearer that the Union compulsory licence shall only be granted in a last-resort situation.

Moreover, companies find unclear the scope of the following provisions:

- the necessity for the Commission assessing whether a Union compulsory licence is to be granted to consider notably “the rights and interests of the rights-holder and the licensee” (Article 7.6b) - which could in practice be contradictory ;
- **measures complementing the compulsory licence**, which are necessary to achieve the objective of the compulsory licence (Article 8.1h), which should clearly exclude know-how.

## Remuneration (Article 9)

The proposal states that adequate remuneration shall be determined by the Commission and shall not exceed 4% of total gross revenue.

AFEP considers that **contractual freedom should be respected** and that the parties should still be allowed to negotiate the remuneration. In the absence of an amicable agreement on the price, the amount could be fixed by a court. The **criteria to be considered to determine the remuneration also raises unclarity concerns**, especially the ones related to “humanitarian circumstances relating to the granting of the Union compulsory licence” and to amortization of the development costs by the rights holders, which go too far and could harm innovation incentives.

Moreover, the 4% cap goes against the TRIPS Agreements, which details that “the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization”, but does not define such adequate remuneration or economic value.

Companies also suggest adding “subject to national law “ in Article 9.4. In fact, in the French intellectual property code, the rights-holder shall not refund the remuneration paid to the licensee if the published patent application for which a compulsory licence has been granted does not subsequently lead to the granting of a patent.

## Prohibition of exports (Article 11)

The proposal states that the export of products manufactured under a Union compulsory licence is prohibited. However, Article 31-f of the TRIPS Agreement mentions that “any such use shall be authorised primarily for supplying the domestic market of the Member which authorises such use”. It does not **explicitly exclude exports outside of the domestic market**. This has been taken over in national legislations and its concrete application would moreover be **difficult in complex products partly covered by licensing** (see also our comments on Article 5).

## Relations between right holders and licensee (Article 13)

**More detailed obligations for the licensee** could be laid out, for example regarding the confidentiality of the information and the use of the licence with no abuse.

AFEP member companies support Article 13's provisions which specify that in compliance with the **good faith obligation**, the rights-holder and the licensee shall make their best efforts to fulfil the objective of the Union compulsory licence, considering each other's interests. At the same time, they wish to underline how subjective this good faith is, with national jurisprudence in various Member States providing numerous interpretations on this concept which should be clarified, especially regarding to Articles 15.1b) and 16.b) provisions.

## Fines (Article 15)

The Commission proposes that fines imposed shall not exceed 6% of a company respective total turnover.

In Article 15.2, the Commission reproduces criteria of competition law by asserting that in fixing the amount of the fine, regard shall be had to the gravity, to the recurrence of the infringement and to the duration of the infringement.

The violations found here do not have the same economic impact as an anti-competitive practice. The amount of this sanction therefore appears disproportionate and must be revised downwards accordingly (**maximum of 2% social turnover**).

Moreover, it should be specified in this Article that the targeted turnover is the social total turnover, similar to Article 16.

## ABOUT AFEP

Since 1982, AFEP brings together large companies operating in France. The Association, based in Paris and Brussels, aims to foster a business-friendly environment and to present the company members' vision to French public authorities, European institutions and international organisations. Restoring business competitiveness to achieve growth and sustainable employment in Europe and tackle the challenges of globalisation is AFEP's core priority. AFEP has 117 members. More than 8 million people are employed by AFEP companies and their annual combined turnover amounts to €2,600 billion. AFEP is involved in drafting cross-sectoral legislation, at French and European levels, in the following areas: economy, taxation, company law and corporate governance, corporate finance and financial markets, competition, intellectual property, digital and consumer affairs, labour law and social protection, environment and energy, corporate social responsibility and trade.

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