Council of the European Union
General Secretariat

Interinstitutional files:
2023/0129 (COD)

Brussels, 08 April 2025

WK 4653/2025 INIT

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NOTE

From:	Presidency
To:	Working Party on Intellectual Property (Patents)
N° prev. doc.:	11273/1/24 REV 1, 16058/24, WK 1024/2025, WK 1663/2025, WK 2614/2025, WK 3176/2025
N° Cion doc.:	8907 2023 + ADD 1-5
Subject:	Proposal for a Regulation on Compulsory Licensing for crisis management and amending Regulation (EC) 816/2006 – Presidency note

At the IP Working Party meeting on 10 April 2025, the Presidency will inform delegations about the progress made in the negotiations with the EP on the above-mentioned proposal at the technical meetings held on 7 and 8 April 2025.

At the Working Party meeting, delegations will also be invited to express their views on the open issues set out in the Annex to this note.

Annex to WK 4653/2025

During the latest two informal technical meetings, which were held on 7 and 8 April 2025, the Commission presented drafting proposals on the following issues: inclusion of representatives of the academia and the civil society, clarification on the inclusion of the Chips Act in the scope, ad hoc advisory body, evaluation and trade secrets/good-faith cooperation.

The Presidency would like to present the drafting proposals made by the Commission below:

1. <u>Inclusion of EP proposal from Article 6(2) (f) row 89 (EP mandate) in recital 19</u>

"(19) Alongside the rights-holders and licensees, it may be useful to invite contributions from other actors, in particular economic operators of the sectors concerned and other relevant entities such as representatives of the academia and of the civil society, social partners, and representatives of international bodies such as the European Patent Office or the World Health Organization."

The Presidency hopes that the abovementioned drafting proposal (point 1) is acceptable to the Member States.

2. <u>Inclusion of the clarification on the Chips Act in the scope (taking into account the limitation arising from the TRIPS Agreement)</u>

a) Article 5

"General conditions of a Union compulsory licence

1. The Union compulsory licence shall
(a) be non-exclusive and non-assignable, except with that part of the enterprise or goodwill which enjoys such compulsory licence;
(b) have a scope and duration that is limited to the purpose for which the compulsory licence is granted and limited to the scope and duration of the crisis or emergency mode in the framework of which it is granted;
(c) be strictly limited to the relevant activities of crisis-relevant products in the Union;
(d) in the case of semi-conductor technology, only be for public non-commercial use;
~~(d)~~ (e) only be granted against payment of an adequate remuneration to the rights-holder;
~~(e)~~ (f) be limited to the territory of the Union;
~~(f)~~ (g)only be granted to a person deemed to be in a position to exploit the protected invention in a manner that permits the proper carry out of the relevant activities of the crisis-relevant products and in accordance with the obligations referred to in Article 10.

2. A Union compulsory licence for an invention protected by a published patent application shall cover a patent granted based on that application, provided that the granting of that patent takes place while the Union compulsory licence is valid.
3. A Union compulsory licence for an invention protected by a patent shall cover a supplementary protection certificate issued with reference to that patent, provided that the transition from patent protection to protection conferred by a supplementary protection certificate takes place while the Union compulsory licence is valid."

b) Recital 16

"Recital 16: A Union compulsory licence authorises the use of a protected invention without the consent of the rights-holder. Therefore, it must only be granted exceptionally and under conditions that take into account the interests of the rights-holder. This includes a clear determination of the scope, duration, and territorial coverage of the licence. In the context of a Union-level crisis mechanism, the crisis mode or emergency mode is activated or declared for a limited period of time. Where a Union compulsory licence is granted within such a framework, the duration of the licence shall not extend beyond the duration of the activated or declared crisis or emergency mode. In strict compliance with the TRIPS Agreement, any Union compulsory licence on semi-conductor technology should only be for public non-commercial use. In order to ensure that the compulsory licence fulfils its objective as well as its conditions, the use of the invention should only be authorised to a qualified person able to manufacture the crisis-relevant product and to pay a reasonable remuneration to the rights-holder."

3. <u>New Article 6 (2) – Clarification on the "ad hoc" advisory body</u>

"2. The Commission shall set up an ad hoc advisory body to perform the tasks referred to in paragraphs 1, 1a and 1b in the following cases: ~~2~~

a) The Union crisis or emergency mechanism referred to in [Article 2/the Annex] of this Regulation no longer provides for a competent advisory body.
b) A new Union crisis or emergency mechanism is included in [Article 2/the Annex] of this Regulation, which does not provide for a competent advisory body.

The Commission shall chair the ad hoc advisory body and ensure its secretariat. Each Member State shall have the right to be represented in the ad hoc advisory body."

4. Article 25 – Evaluation (proposed on the basis of the EP text)

"1.a ~~By ... [two years after the date of entry into force of this Regulation] and every two years thereafter,~~ The Commission shall regularly, and for the first time by 31 December 2027, assess the need to include new crisis instruments providing for an emergency or crisis mode ~~whether the list~~ in the Annex of this Regulation and submit proposals to amend the said Annex, where appropriate. Every five years after the date of entry into force of this Regulation, the Commission shall ~~is up-to-date in light of the adoption of future legislative acts in relation to an emergency or crisis mode. If the list of the Annex is no longer up-to-date, the Commission shall assess its consequences. The Commission shall~~ report on the assessments carried out to the European Parliament and the Council~~, accompanied, where appropriate, by legislative proposals to amend the Annex~~.

1.b ~~In case of exceptional threats to public safety or to national security, the Commission shall carry out the assessment pursuant to paragraph 1a without undue delay.~~"

5. Trade secrets/Good-faith cooperation

a) Article 2 – Scope

The Commission proposes to retain the Council's addition in article 2(3) and in recital 23:

"3. This Regulation does not impose any obligation to disclose trade secrets."

b) Article 13 – Relations between the rights-holder and licensee:

1. When performing rights and obligations under this Regulation, ~~The relations between~~ the rights-holder and the licensee who has been granted a Union compulsory license shall act and cooperate with each other in good faith ~~when performing rights and obligations under this Regulation~~.

~~2. 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, taking into account each other's interests.~~

c) Article 14 (2) – Additional measures:

"2. Where necessary, the Commission shall, upon reasoned request by the rights-holder or the licensee or on its own initiative facilitate the cooperation between the rights-holder and the licensee, including by encouraging the rights-holder to provide the licensee with the necessary information and know-how to support the purpose of the Union compulsory licence, without prejudice to article 2(3).

2bis. Where information and know-how are shared in accordance with paragraph 2, the licensee shall implement all appropriate measures that the rights-holder

identifies as necessary to preserve the confidentiality of trade secrets. The licensee shall provide the Commission and the rights-holder with all the necessary information on the implementation of these measures. In case of failure by the licensee to implement these measures, the Commission may impose fines or periodic penalties on the licensee in accordance with Articles 15 and 16."

d) Article 15 – Fines

"1. The Commission may by decision impose fines if the licensee fails to comply with its obligations under Article 9(1), Article 10(1), Article 11 or Article 13.

2. The Commission may by decision impose fines if the rights-holder fails to comply with its obligations under Article 13."

While the Presidency will continue to defend the Council mandate, with the view of exploring the possibility of compromise the Member States are invited to share their views on the abovementioned drafting propositions (points 2 to 5) and indicate any possible flexibilities.