



Council of the  
European Union

Brussels, 15 October 2025  
(OR. en)

10498/25  
ADD 1

---

---

Interinstitutional File:  
2023/0129 (COD)

---

---

PI 126  
PHARM 88  
CODEC 862

## DRAFT STATEMENT OF THE COUNCIL'S REASONS

Subject: Position of the Council at first reading with a view to the adoption of a  
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE  
COUNCIL on compulsory licensing for crisis management and amending  
Regulation (EC) No 816/2006  
- Draft Statement of the Council's reasons

---

## I. INTRODUCTION

1. On 27 April 2023, the Commission published a legislative package intended to modernise and further develop patent law in the EU, building on the Commission's 2020 Intellectual Property Action Plan<sup>1</sup>.
2. The patent package contains six legislative proposals, including the proposal for a Regulation on compulsory licensing for crisis management and amending Regulation 816/2006. The proposal is based on Articles 114 and 207 of the Treaty on the Functioning of the EU.
3. The European Economic and Social Committee adopted an opinion on the proposal on 20 September 2023<sup>2</sup>. The European Data Protection Supervisor provided its opinion on 28 July 2023.
4. The European Parliament adopted its first reading position<sup>3</sup> on the proposal on 13 March 2024, following the adoption of the report on the proposal in the Committee on Legal Affairs (JURI) on 13 February 2024. On 18 November 2024, the European Parliament's JURI Committee re-appointed Mr Adrián Vázquez Lázara (EPP, ES) as rapporteur for the proposal.
5. The Working Party on Intellectual Property started the substantial examination of the proposal in January 2024, under the Belgian Presidency. The examination took place over eight meetings, from January to May 2024.
6. Based on the examination of the text, on 26 June 2024 the Permanent Representatives Committee adopted the Council's mandate<sup>4</sup> for interinstitutional negotiations.

---

<sup>1</sup> 13354/20.  
<sup>2</sup> 13349/23.  
<sup>3</sup> T9-0143/2024.  
<sup>4</sup> 11613/24.

7. The interinstitutional negotiations started with the first trilogue on 10 December 2024, under the Hungarian Presidency. The second and third trilogues took place under the Polish Presidency, on 26 March and 21 May 2025 respectively. In addition, 21 interinstitutional technical meetings were held. A provisional agreement between the co-legislators was reached at the third trilogue on 21 May 2025.
8. On 13 June 2025, the Permanent Representatives Committee analysed the final compromise text of the proposal with a view to agreement and confirmed it.<sup>5</sup>
9. The European Parliament's JURI Committee approved the outcome of the interinstitutional negotiations on 24 June 2025. On 30 June 2025, the Chair of JURI addressed a letter to the Chair of the Permanent Representatives Committee stating that, if the Council adopted its position at first reading in accordance with the agreed overall provisional agreement, he would recommend to the Plenary that the Council's position be accepted without amendment at Parliament's second reading, subject to legal-linguistic verification.

## **II. OBJECTIVE**

10. The objective of the proposed Regulation is to introduce a Union compulsory licensing system that can strengthen the resilience of the EU by addressing certain crises that have a cross-border dimension within the Union. In situations when other means, including voluntary agreements, might not be found or might not be adequate, the Union compulsory licence would facilitate access to crisis-relevant products that are protected by intellectual property rights.

## **III. ANALYSIS OF THE COUNCIL'S POSITION AT FIRST READING**

11. The Council's position at first reading contains the following main elements, on which agreement has been reached between the co-legislators:
  - i. The Regulation does not impose any obligation to disclose trade secrets. However, a clarification was introduced to elaborate that the Regulation does not preclude voluntary conclusion of agreements on trade secrets.

---

<sup>5</sup> 9765/25.

- ii. When it comes to the issues of scope, the Chips Act and the Gas Security of Supply Regulation were removed from the list of crisis instruments that trigger the possibility of granting a Union compulsory licence. An agreement was reached that the remaining crisis instruments would only be listed in the Annex to the Regulation, and defence-related products were explicitly excluded from the scope.
- iii. The implementing acts on the granting, modification and termination of the Union compulsory licence will be adopted using the examination procedure. A non-opinion clause was inserted to ensure that implementing acts cannot be adopted when the comitology committee does not deliver an opinion.
- iv. It was agreed that one of the general conditions for granting a Union compulsory licence would be that a voluntary agreement could not be achieved within a reasonable timeframe. However, a provision was added to clarify that voluntary agreements could be concluded at any time during or after the compulsory licence granting process.
- v. The 4 % cap on remuneration, proposed by the Commission, was removed. The criteria for determining remuneration were adjusted to emphasise the economic value of the relevant activities authorised under the Union compulsory licence and public support received to develop the invention.
- vi. Fines and periodic penalty payments for failure of the licensee to comply with the obligations provided for in the Regulation were adjusted to result in lower payments than proposed by the Commission, as well as to account for SMEs. The Regulation does not envisage fines or periodic penalty payments for the right holders.
- vii. When it comes to amendments to Regulation (EC) 816/2006 for export, the co-legislators decided to limit the introduced changes to those that enable Regulation (EC) 816/2006 and the Regulation on Union compulsory licensing to co-exist in a legally sound way.
- viii. The Commission is obliged to regularly assess the list of crisis instruments in the Annex to the Regulation and to report on the assessment to the co-legislators every five years. As part of the evaluation, the Commission will have to give specific regard to the issue of semiconductors for medical equipment.

#### IV. CONCLUSION

12. The Council's position at first reading fully reflects the compromise reached in the negotiations between the European Parliament and the Council, facilitated by the Commission.
  13. The Council therefore believes that its position at first reading is a balanced representation of the outcome of the negotiations and that, once adopted, the Regulation will introduce a Union compulsory licensing system that will contribute to strengthening the resilience of the EU by addressing crises that have a cross-border dimension within the Union.
-