



Council of the European Union  
General Secretariat

Brussels, 07 May 2024

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**Interinstitutional files:  
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## INFORMATION

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From:	Presidency
To:	Working Party on Intellectual Property (Patents)
N° prev. doc.:	9034/24, WK 5889/2024
N° Cion doc.:	8901/23 + ADD 1-5
Subject:	Proposal for a Regulation on Compulsory Licensing for crisis management and amending Regulation (EC) 816/2006 – Presentation of the second revised Presidency text

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Delegations will find attached a PowerPoint presentation on the above-mentioned proposal, as presented by the Presidency and used as basis for discussions of the IP Working Party at its meeting on 7 May 2024.



# Compulsory Licensing

*Presidency second revised text*

*overview of topics*



# Article 1 (Objectives and subject matter)

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- Activated crisis mode annex, public interest, last resort, union CL IPR
- Possible deletion of the crisis mechanisms relating to Gas and Chips
- Possible conversion of the Annex into an article
- Possible amendment to emphasize IP approach:
  - *“This Regulation has the objective to lay down rules on the conditions and procedure for the granting, in the public interest and as an exceptional and last resort measure, of a Union compulsory licence of intellectual property rights that are necessary for the supply of crisis-relevant products to the Member States during an activated or declared crisis or emergency mode, pursuant to any of the respective Union legal acts listed in Article XX.”*

# Article 2 (Scope)

## Article 3 (Definitions)

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- Published patent applications and utility model applications

TRIPS compliance	Most recent technology
Practices national laws (Provisional protection & CL on patent applications)	Legal certainty for both the licensee and the rights-holder

- “Where applicable” to be clarified in recitals
- Extension to SPC where it covers the crisis-relevant product
- Exclusion of forced sharing of Trade secrets

## Article 2 (Scope)

## Article 3 (Definitions)

PUBLIC

- Union CL carried out within the framework of the crisis mechanisms
  - Supply and distribution
  - Limitation of the scope (no defence-related products)
- Possible amendment (IMERA art. 2 (2) (g) ):
  - *“This Regulation shall not apply to defence-related products as defined in Article 3 paragraph 1 of Directive 2009/43/EC of the European Parliament and the Council of 6 May 2009 simplifying terms and conditions of transfers of defence-related products within the Community or as defined by national law of Member States in compliance of Union law”*
- Processes removed from the definition of 'crisis-relevant products' and inserted under point (e)

# Article 4 (Conditions for granting) Article 5 (Requirements)

- IP hampering the adequate supply
  - IP is generally not the problem BUT CL only when there is an IP issue
- Art. 4 (b) and (c) evaluated by COM with assistance of Advisory
- Importance of RH's comments
  
- "Requirements"
- Evaluation of the capacity to produce of the licensee
  - Factories
  - Supply chain
  - Expertise
- Automatic expiry of the CL when the crisis mode has ended

## Article 6 (Advisory body) Article 7 (Procedure)

Identification of IPR and RH	Dissemination of the notice
Identification of potential licensees	Gathering of views and participation of RH and potential licensees
Gathering of views of economic operators and other entities (e.g. EPO or WHO)	Involvement of national IP experts and authorities responsible for national CL
Gathering and analysis of data	Facilitation of collaboration with relevant authorities

To provide a non-binding opinion on the need for a CL and its content

# **Article 6 (Advisory body)**

## **Article 7 (Procedure)**

- 'Internal' expertise in the relevant field and in IP
  - Expediency
  - Inputs from relevant actors
- 
- Forum to stimulate and facilitate the conclusion of voluntary agreements
- 
- Consulted for modification and termination of the CL and for additional measures
- 
- Suppression of the Ad hoc advisory body

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# Article 6 (Advisory body) Article 7 (Procedure)

- Suppression of “unless the identification of the RH would cause significant delay” (Art. 7 (8))
  - COM should always identify the rights
- Recitals 17 to 25 partially or completely redrafted to clarify the procedure
- Recital 31 → Explicit review by the CJEU (Article 263 TFEU)

# Article 8 (Content)

## Article 9 (Remuneration)

- Art. 8 (h) → Spoiler alert: possible deletion of the additional measures (see below)
- No cap for remuneration
  - Benchmark of 4% for medicines (to be supported by evidence)
- Relevant criteria:
  - Opinion of the Advisory body & comments of RH and licensee
  - Economic value relevant activities
  - Other relevant factors
- Recital 27 → Clarification of some factors

## Article 10 (Obligations of the licensee)



- Recital 27a → Possible deletion to stay in line with the principle of no disclosure of trade secrets
  - Does not prevent the conclusion of voluntary agreements on trade secrets

# **Article 13 (Good faith)**

## **Article 14 (Modification, termination & additional measures)**

- Good faith in the relationship between RH and the licensee, and throughout the procedure, taking into account each other's interests
- Clarification of the meaning of good faith
  - Provide information (about IPR, RH, capacity of the licensee,...)
  - Refrain from undermining or delaying behaviour
  - Take appropriate measures to preserve confidentiality of voluntarily disclosed trade secrets and know-how
- Commission's role as facilitator
  - Meetings and exchanges
  - Sharing of crisis-relevant information

# Article 13 (Good faith)

## Article 14 (Modification, termination & additional measures)

- Possible amendment of Article 13:
  - *"In order to ensure effective implementation of the Union compulsory licence, the rights-holder and the licensee shall act in good faith, taking into account each other's interests, when performing rights and obligations under this Regulation."*
  - Suppression of the points (a), (b) and (c)
  
- Possible suppression of fines related to Article 13

# Article 13 (Good faith)

## Article 14 (Modification, termination & additional measures)

- Modification of the content of the CL where necessary
  - Update of the list of IPR and RH (↗ or ↘)
  - Modification of the remuneration (↗ or ↘)
  - Modification of the duration (↗ or ↘)
- Possible suppression of Article 14 (2) on additional measures
  - Addition of a provision on how to tackle the issue of partially manufactured products in the event of expiry of the Union CL

## Articles 15 to 21 (Fines & periodic penalty payments)

- Caps → 300K and 50K (SME) for fines and 1,5% and 0,5% (SME) daily turnover for periodic penalty payments
- Principle of proportionality
- Safeguard of the rights and interests
- Efficient implementation
- Gradation of sanctions, permitting scalability
- Fine & periodic could be cumulative
- Titles Articles 19 and 20 clarified

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