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INFORMATION

From:	Presidency
To:	Working Party on Intellectual Property (Patents)
N° prev. doc.:	9034/24
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

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 23 April 2024.



Compulsory Licensing

Presidency second revised text

overview of topics



Last resort

- Other means, including voluntary agreements, could not adequately, efficiently and swiftly remedy the lack of adequate supply (*Art. 1 & 4 (c)*)
- Encourage voluntary agreements (Advisory body) *Art. 6 (1) (d) and 7 (2) (c)*
- No obligation prior negotiation in crisis (*recital 3, 31 b TRIPS*)
- *Recitals 1, 2, 3 & 5, 15a*

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Patent applications



- Published patent applications and utility model applications
 - TRIPS compliance
 - Most recent technology
 - Practices national laws
 - Rights on (protection for) applications
 - CL on patent applications
 - “Where applicable”
- *Art 2, 5, 8, 9*
- *Recitals 9, 10, 12, 24, 27, 33*
- Legal certainty to licensee to exploit

Trade secrets

Art. 2

- No prejudice Directive 2016/943
 - No obligation to disclose trade secrets
 - Concept of trade secrets is defined by Directive 2016/943, with a reference in *recital (14)* to main categories (undisclosed know-how, business information and technological information) and the key elements of that notion (confidentiality information has a value),
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- *Art. 10 , 13, 19*
 - *Recitals 13, 27a*

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Links with crisis mechanisms

Art. 4 (a), 7 (1) & recitals 15a and 19a

- Initiation of the procedure only if a crisis mode is activated

Art. 2 (4) & recital 13a

- Only for the purpose of carrying out the specific measures of the crisis mechanism
 - e.g. Joint procurement or Commission as a Central purchasing body
 - Scope of the crisis mechanisms

Art. 5 (1) (h)

- Automatic expiry of the CL when the crisis mode has ended

Art. 3 (ea), 6 and 7 (1) & recitals 17, 18, 19a and 19b

- Advisory body set up by crisis mechanism
 - Expertise
 - Early discussions unveiling a lack of adequate supply before the initiation of the CL procedure

Advisory body

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

Advisory body

Art. 3 (ea) and 6 & recitals 18, 19, 19c and 20

- '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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Involvement and protection of the rights-holders



- Objectives of the involvement of the rights-holders →
 - Protection of their rights and interests
 - Gathering of all the relevant information for the assessments (Lack of adequate supply, possibility of voluntary solutions, need of a CL, content of the CL, amount of the remuneration, modifications or termination,...)
- Considering rights and interests of the RH at every step of the procedure (*Art. 6, 7 (2, 8, 9 and 10), 9 (3) and 14 (6) & recitals 3, 16, 19, 19b, 20, 21, 21a, 24, 27 and 27a*)
- Condition to grant a CL (*Art. 4 (d) & recitals 15a and 21a*)
- Publication of the notice on COM's website and in the OJEU (*Art. 7 & recitals 19a, 19b and 21a*)
- Invitation to provide comments (*Art. 9 (2, 8, 9 and 10) & recitals 19, 19a, 19b, 21, 21a*)

Involvement and protection of the rights-holders

- Dissemination of the notice via IP Offices, relevant industry associations, international organisations (*Art. 6 (1) (b) & recital 19*)
- Identification of the RH (*Art. 6, 7, 8, 14 (1) & recitals 19, 20 and 24*)
- Information to the RH when the Commission considers continuing the procedure (*Art. 7 & recitals 21 and 21a*)
- Suppression of the possibility to avoid identification of IPR and RH where it would significantly delay the granting of CL (*Art. 8 (1) (~~a~~ & ~~b~~)*)
- Notification to the addressees of implementing acts (*Art. 297 TFEU, art. 14 (3a) & recitals 24 and 33*)
- Notification to the RH in case of infringing products (*Art. 12 (3) & recital 30*)
- Notification to the addressees of decisions on fines and penalties (*Art. 297 TFEU & recital 35*)

List of the IP rights and the rights-holders



Art. 6 and 7 & recitals 19 and 20

- Identification of the IPR and RH by Commission assisted by the advisory body

Art. 8 (1 and 2)

- List of the IPR and RH in the CL
 - Suppression of the possibility to avoid identification of IPR and RH where it would significantly delay the granting of CL (*Art. 8 (1) (a & b)*)

Art. 14 (1) & recital 33

- Update of the list by means of an implementing act
 - Consultation of the advisory body
 - With retroactive effect if justified
 - To ensure proportionality between public interest and the rights and interests of the RH
 - To add or remove IPR

Review by the CJEU

- General principle: *Article 263 TFEU*:

“The Court of Justice of the European Union shall review the legality of legislative acts, of acts of the Council, of the Commission and of the European Central Bank, other than recommendations and opinions, and of acts of the European Parliament and of the European Council intended to produce legal effects vis-à-vis third parties.”

- => (*recital 31*) the validity of implementing acts granting or modifying the Union compulsory license and the adequate remuneration provided therein, is subject to judicial review by the Court of Justice of the European Union
- Article *261 TFEU*:

“Regulations adopted jointly by the European Parliament and the Council, and by the Council, pursuant to the provisions of the Treaties, may give the Court of Justice of the European Union unlimited jurisdiction with regard to the penalties provided for in such regulations.”

- *Article 21* : In accordance with Article 261 TFEU, the CJEU has unlimited jurisdiction to review decisions by which the Commission has imposed fines or periodic penalty payments

Adequate remuneration

Art. 9

- No cap
- Relevant criteria:
 - Opinion AB + comments
 - Economic value relevant activities
 - Other relevant factors
- *Recital 27*: 4% total gross revenue of act under licence = benchmark for medicines
- *Art. 5, 7, 8, 9, 22*

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Good faith

Art. 13 & recitals 27a and 32

- 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

Modification, termination & additional measures



Art. 14 & recitals 24 and 33

- 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 ↘)

Art. 14 & recitals 24 and 33

- Termination of the CL
 - No more lack of supply
 - Voluntary agreement

Modification, termination & additional measures



Art. 14 (2) & recital 32

- Additional measures where necessary
 - To obtain further information
 - To ensure balance between public interest and rights and interests of the RH and the licensee
 - To ensure balance between the rights and interests of RH and the rights and interests of the licensee

- Possible additional measures →
 - Requirement to obtain, within a specified period of time, documents enabling the licensee's capacity to be assessed
 - Determination of the fate of the partially manufactured products or leftover stock when the crisis mode has ended, and the CL expired
 - Setting precise IT specifications necessary for the licensee to effectively protect the confidential information or the trade secrets voluntarily shared by the RH

Fines & periodic penalty payments

Art 15

- Cap 6% turnover business year removed, only 300 K and 50K cap remaining

Art 16

- 1,5% of 0,5% (SME) daily turnover
- *Recital 34, 35*: Principle of proportionality
- Titles Articles 19 and 20 clarified

Reporting of national CL

Art. 22 & recital 36

- Information when a national CL is granted
 - Only national CL for crisis similar in nature to the EU crisis mechanisms (e.g. no product related to national defense)
 - To improve preparedness at EU level
 - To facilitate the assessments made by the advisory body and the Commission on the need to grant a Union CL

- Flexible procedure to take account of differences between MS
 - National authority responsible for providing information to be determined by MS
 - List of these authorities on the website of the Commission
 - 'Without undue delay'

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Involvement of Member States



Art. 2 (4), and 4 (a) & recitals 8, 13a, 15a a

- CL only granted when a crisis mode has been activated and to complement specific measures taken under the relevant crisis mechanism
 - Involvement of MS regarding activation of the crisis mode
 - Involvement of MS regarding specific measures (e.g. joint procurement)

Art. 6 and 7 (3, 5, 7, 8, 9 and 11) & recitals 7, 8, 17, 18, 19, 19a, 19c, 20 and 21

- Opinion of the advisory body requested to grant a CL
 - Representatives of MS in accordance with the relevant crisis mechanism
 - Experts from national IP offices
 - Representatives of authorities responsible for the granting of national CL

Art. 7 (g)

- Justification when the decision to grant is not aligned with the opinion of the advisory body

Involvement of Member States

Art. 7 (9a), and 24 (4 and 5)

- Examination procedure
 - 'Non opinion clause'

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