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WK 7166/2024 INIT

**LIMITE**

**PI  
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## CONTRIBUTION

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From:	General Secretariat of the Council
To:	Working Party on Intellectual Property (Patents)
N° prev. doc.:	9034/24, WK 5536/2024
N° Cion doc.:	8901/23 + ADD 1-5
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on compulsory licensing for crisis management and amending Regulation (EC) 816/2006 – Member States comments

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Delegations will find attached the drafting suggestions and comments received from delegations in relation to the revised Presidency text (doc. 9034/24) of the above-mentioned proposal.

The working document comprises contributions from the following delegations: DE, DK, ES, FR and HU.

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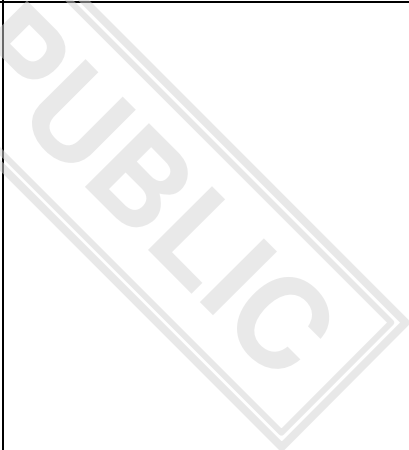
**LIMITE**

**EN**

**Comments from the Germany Federal Government on Article 12 of the proposal for a regulation for a compulsory licensing instrument**

<b>Commission proposal</b>	<b>Presidency Drafting Suggestions</b>	<b>MS Comments</b>
		<p>DEU</p> <p>As a general remark, Germany would like to reiterate that it sees no need for regulatory action for the introduction of an EU-wide compulsory licence.</p> <p>Notwithstanding this fundamental position, we wish to comment on selected substantive aspects in connection with Article 12 – while maintaining our general scrutiny reservation and expressly reserving the right to make further comments:</p>
Article 12		
Customs control		
<p>1. The application of this article is without prejudice to other Union legal acts governing the export of products, in particular Articles 46, 47 and 267 of Regulation (EU) No 952/2013<sup>1</sup>.</p>		
<p>2. Customs authorities shall rely on the Union compulsory</p>	<p>2. Customs authorities shall rely on the Union compulsory</p>	

<sup>1</sup> REGULATION (EU) No 952/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 October 2013 laying down the Union Customs Code.

<b>Commission proposal</b>	<b>Presidency Drafting Suggestions</b>	<b>MS Comments</b>
<p>license and modifications thereof to identify products that may fall under the prohibition laid down in Article 11. For that purpose, risk information as regards each Union compulsory licence and any modification thereof shall be entered in the relevant customs risk management system. Customs authorities shall take such risk information into consideration when they carry out controls on products placed under the customs procedure 'export' in accordance with Articles 46 and 47 of Regulation (EU) No 952/2013.</p>	<p>license and modifications thereof to identify products that may fall under the prohibition laid down in Article 11. For that purpose, <b>the Commission shall enter</b> risk information as regards each Union compulsory licence and any modification thereof <del>shall be entered</del> in the <del>relevant Union-</del>customs risk management system. Customs authorities shall take such risk information into consideration when they carry out controls on products placed under the customs procedure 'export' in accordance with Articles 46 and 47 of Regulation (EU) No 952/2013.</p>	
<p>3. Where customs authorities identify a product that may fall under the prohibition laid down in Article 11, they shall suspend its export. Customs authorities shall immediately notify the Commission of the suspension and provide it with all relevant information to enable it to establish whether the product was manufactured under a Union compulsory licence. To assess whether the suspended products correspond to the Union compulsory licence, the Commission may consult the</p>	<p>Where customs authorities identify a product that may fall under the prohibition laid down in Article 11, they shall suspend its export. Customs authorities shall immediately notify the Commission of the suspension and provide it with all relevant information to enable it to establish whether the product was manufactured under a Union compulsory licence. <b>The Commission shall inform the rights-holder and, where appropriate, the licensee. The Commission may consult the</b></p>	<p>DEU</p> <p>It should be defined which "relevant" information is to be transmitted to the (competent) Commission department in such an event.</p> <p>From our point of view, the relevant information should be specified precisely (e.g. commodity code, type of goods, quantity, country of receipt, photos of the goods/invoices/delivery bills, etc.). Since it is assumed that</p>

<b>Commission proposal</b>	<b>Presidency Drafting Suggestions</b>	<b>MS Comments</b>
relevant rights-holder.	<del>relevant rights-holder</del> To assess whether the suspended products correspond to the Union compulsory license, <del>the Commission may consult the relevant rights holder.</del>	personal information of the consignor/customs declarant or, if applicable, consignee should also be transmitted, it would also be necessary to specify which personal data (e.g. name, address, EORI number, etc.) of which persons (e.g. exporter/consignor, consignee, if applicable, owner) should be transmitted to the (competent) Commission department.
4. Where the export of a product has been suspended in accordance with paragraph 3, the product shall be released for export provided that all the other requirements and formalities under Union or national law relating to such export have been fulfilled, and either of the following conditions is fulfilled:		
(a) the Commission has not requested the customs authorities to maintain the suspension within 10 working days after it was notified thereof;		
(b) the Commission has informed the customs authorities that the product is not manufactured under a Union compulsory licence.		

Commission proposal	Presidency Drafting Suggestions	MS Comments
<p>5. Where the Commission concludes that a product manufactured under a Union compulsory licence does not comply with the prohibition laid down in Article 11, customs authorities shall not authorise its release for export. The Commission shall inform the concerned rights-holder of such non-compliance.</p>		<p>DEU</p> <p>The adequate information of customs authorities is a prerequisite in order to ensure that these authorities can act in accordance with Para 5. Therefore, the text should be amended as follows (cf. in <b><u>bolt underlined</u></b>):</p> <p><i>5. Where the Commission concludes that a product manufactured under a Union compulsory licence does not comply with the prohibition laid down in Article 11, customs authorities shall not authorise its release for export. The Commission shall inform the <b><u>customs authorities and</u></b> concerned rights-holder of such non-compliance.</i></p>
<p>6. Where the release for export of a product has not been authorised:</p>		<p>DEU</p> <p>According to Art. 3 of Regulation (EU) No 952/2013, customs authorities shall be primarily responsible for the supervision of the Union's international trade. Since the goods in question are union goods, they are no longer subject to customs supervision</p>

<b>Commission proposal</b>	<b>Presidency Drafting Suggestions</b>	<b>MS Comments</b>
		<p>after the refusal of release for the export procedure. In addition, the customs authorities are unable to decide which measures are appropriate in the event of a crisis due to a lack of technical expertise. Against this background, the wording of Para. 6 lit. a and b should be amended as follows (cf. in <b><u>bolt underlined</u></b>):</p>
<p>(a) where appropriate in view of the crisis or emergency context, the Commission may require customs authorities to oblige the exporter to take specific actions at their own costs, including supplying them to designated Member States, if need be, after rendering them compliant with Union law.</p>		<p>(a) <i>where appropriate in view of the crisis or emergency context, the Commission may <del>require customs authorities to</del> oblige the exporter to take specific actions at their own costs, including supplying them to designated Member States, if need be, after rendering them compliant with Union law.</i></p>
<p>(b) in all other cases, customs authorities may take any necessary measure to ensure that the product concerned is disposed of in accordance with national law consistent with Union law. Articles 197 and 198 of Regulation (EU) No 952/2013 shall apply accordingly.</p>		<p>(b) <i>in all other cases, <del>customs authorities the</del> <b><u>Commission</u></b> may take any necessary measure to ensure that the product concerned is disposed of in accordance with national law consistent with Union law. Articles 197 and 198 of Regulation (EU) No 952/2013 shall apply accordingly.</i></p>

## ES comments on the Compulsory licensing Proposal

### Comentarios generales:

Nos gustaría trasladar los siguientes comentarios generales antes de comenzar con el articulado, que creemos ayudarían a la mejor comprensión del texto y coherencia del mismo:

1. **Congruencia en uso del singular/plural de rights-holder y licensee** a lo largo del texto.
2. **Referencia al art. 24.2 cuando este apartado ha sido eliminado.** Sería necesario revisar las referencias internas en el Reglamento teniendo en cuenta las modificaciones.
3. **Unificación terminológica al igual que en otros artículos**, como, por ejemplo, art. 2.4 y 3 (a-1). A modo de ejemplo, se citan los dos siguientes artículos:

#### ART. 4(a)

(a) a crisis mode or an emergency mode listed in the Annex to this Regulation has been activated or declared in accordance with the respective Union **legal** Act;

#### ART. 22.1

1. When a national compulsory licence has been granted for the purpose of addressing a national crisis or emergency corresponding in nature to crises or emergencies falling within the scope of the Union **legal** Acts listed in the Annex, the Member State shall notify inform the Commission of the granting of the licence and of the specific conditions modalities attached to it without undue delay. The information provided shall also include the following:

### General comments:

We would like to make the following general comments before starting with the articles, which we believe would help to better understand the text and make it more coherent:

1. Consistency in the use of the singular/plural of rights-holder and licensee throughout the text.
2. Proper references to Art. 24.2 when this paragraph has been eliminated. It would be necessary to review the internal references in the Regulation taking into account the modifications.

3. Unification of terminology as in other articles, such as, for example, Art. 2.4 and 3 (a-1). By way of example, the following two articles are cited:

ART. 4(a)

(a) a crisis mode or an emergency mode listed in the Annex to this Regulation has been activated or declared in accordance with the respective Union **legal** Act;

ART. 22.1

1. When a national compulsory licence has been granted for the purpose of addressing a national crisis or emergency corresponding in nature to crises or emergencies falling within the scope of the Union **legal** Acts listed in the Annex, the Member State shall notify inform the Commission of the granting of the licence and of the specific conditions modalities attached to it without undue delay. The information provided shall also include the following:

Considerando 17:

El **considerando 17** es confuso, porque no sabemos a qué órgano consultivo se está refiriendo. La clave es saber en qué momento empieza a actuar el órgano consultivo para licencias obligatorias, pues podría pasar (será lo más probable), que otro órgano consultivo (sanitario por ej) sea el que determine que es necesaria una LLOO y cuando el órgano consultivo para LLOO entre a actuar sea ya tarde. Habría que conseguir que el órgano consultivo de LLOO se convocara en cuanto se determine que hay una crisis (de cualquiera de los instrumentos de emergencia). Esto debería recogerse en el texto expresamente.

Aunque se explica en los Considerandos, creemos que al igual que antes se recogía en el articulado, este debería explicarse en el propio texto.

**Recital 17:**

Recital 17 is confusing, because we do not know which advisory body is being referred to. The key is to know at what moment the advisory body for compulsory licenses starts to act, because it could happen (most likely), that another advisory body (e.g. health) is the one that determines that a CL is necessary and when the advisory body for CL starts to act it's already too late. It would be necessary to ensure that the CL advisory body is convened as soon as it is determined that there is a crisis (of any of the emergency instruments). This should be expressly stated in the text.

Although it is explained in the Recitals, we believe that just as it was previously included in the articles, it should be explained in the text itself.

Artículo 2.2:

Tal vez, para evitar repeticiones, se podría poner en forma de listado:

*Propuesta de redacción:*

2. This Regulation is without prejudice to the rules laid down by other Union legal acts:

- (i) the copyright and related rights, granted by the Directive 2001/29 and the Directive 2009/24;
- (ii) the sui generis rights granted by Directive 96/9/EC on the legal protection of databases; and
- (iii) the protection of trade secrets as defined in without prejudice to Directive (EU) 2016/943 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure.

**Article 2.2:**

In order to avoid repetitions we propose the following draft:

2. This Regulation is without prejudice to the rules laid down by other Union legal acts:

- (i) the copyright and related rights, granted by the Directive 2001/29 and the Directive 2009/24;
- (ii) the sui generis rights granted by Directive 96/9/EC on the legal protection of databases; and
- (iii) the protection of trade secrets as defined in without prejudice to Directive (EU) 2016/943 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure.

Artículo 4:

En el Considerando 15<sup>a</sup>, así como en el art. 4 (b) (modificado para evitar dar la impresión de que los derechos de PI pueden actuar como un obstáculo en el abastecimiento de productos relevantes para la crisis) se dice directamente que la Comisión ha concluido que los derechos de PI que protegen productos relevantes para la crisis “obstaculizan” el adecuado suministro de dichos productos. Creemos que esto puede producir una contradicción y al final la imagen que parece dar es que la culpa es de los derechos de PI. A fin de evitar contradicciones con la posición de la UE en otras organizaciones internacionales no debería dañarse la imagen de la PI asociándola con un problema.

**Article 4:**

In Recital 15, as well as in Art. 4 (b) (modified to avoid giving the impression that IP rights may act as an obstacle to the supply of products relevant to the crisis) it is directly stated that the Commission has concluded that IP rights protecting products relevant to the crisis “hamper” the adequate supply of such products. We believe that this may produce a contradiction and, in the end, the image it gives is that IP rights are to blame. In order to avoid contradictions with the EU's position in other international organizations, the image of IP should not be damaged by associating it with a problem.

Artículo 6:

**La interacción entre el órgano consultivo sustancial y el órgano consultivo para LLOO no está nada clara en la propuesta.** Debería aclararse, especificar cómo interactuaría el órgano consultivo con el órgano consultivo sustancial, en el que no estamos presentes, y que es el que lleva todo el procedimiento y asume la decisión de las medidas a adoptar en un momento de crisis.

- ✓ ¿Si el órgano consultivo de LLOO y la COM consideraran que no hace falta una LLOO, el órgano consultivo sustantivo estaría vinculado? son preguntas a formular a la COM.
  
- ✓ ¿son procesos totalmente separados?, el dictamen del órgano consultivo para LLOO debería remitirse al órgano consultivo sustantivo, para su consideración. Lo debe decir la propuesta expresamente, parece evidente pero es dejar claro que sobre esto, la opinión del órgano consultivo para LLOO es el competente para decidirlo (a través de la COM).

**Article 6:**

The interaction between the substantial advisory body and the advisory body for CL is not at all clear in the proposal. It should be clarified, specifying how the advisory body would interact with the substantial advisory body, in which we are not present, and which is the one that carries the whole procedure and assumes the decision of the measures to be adopted in a moment of crisis.

If the CL advisory body and the COM were to consider that there is no need for an CL, would the substantive advisory body be bound by that opinion?

Are they totally separate processes? The opinion of the advisory body for CL should be referred to the substantive advisory body, for consideration. The proposal should say it expressly, it seems obvious but it is to make it clear that on this issue, the opinion of the advisory body for CL is the competent to decide it (through the COM).

**Artículo 7:**

En las explicaciones al artículo 4 se indica que el término “ejercicio” de los derechos de PI es confuso y que por eso se elimina dicha referencia. Sin embargo, se mantiene en el art. 7.1, lo cual es incongruente.

Por otro lado, igualmente, por congruencia terminológica, tal vez sería conveniente que se indique, al igual que en el art. 4, que “la Comisión ha concluido”, en lugar de “la comisión considera”.

Se mantiene la **posibilidad de una decisión tomada en solitario por la Comisión Europea, carente de la necesaria seguridad jurídica al conceder la licencia obligatoria**. El desencadenante de la apertura del procedimiento, descrito en el artículo 7, es un proceso interno y desconocido de la Comisión que, en base a informaciones recogidas, considera oportuno abrir el proceso y publica la nota. No se contempla la necesidad de que existan pruebas fehacientes contrastables que justifiquen la solicitud de la Licencia Obligatoria. Se desconoce si debe haber diligencias previas, (y quien las practicaría, en su caso), que órgano de la COM se considera competente, qué conocimientos tiene para serlo o cómo se evitaría la politización de la decisión. Dado que el proceso posterior de opinión técnica no es vinculante, la COM podría conceder o no la LO como le parezca más oportuno. En un momento de alarma social al que la COM tiene que dar una respuesta urgente ante la demanda de la opinión pública, si la respuesta no está jurídicamente

vinculada a una opinión experta de un Órgano Consultivo de carácter técnico, la decisión podría ser arbitraria. Hay muchos peligros de politización con las patentes y las licencias obligatorias que ya vimos durante la pandemia. Con la desaparición del *ad-hoc advisory body* del antiguo artículo 6.2, también desaparece la posibilidad de dotar de contenido técnico al órgano consultivo.

El Órgano Consultivo, tal y como está ahora mismo planteado, no influye en el proceso decisivo, ya que su opinión no es vinculante, lo que no quiere decir que en otras condiciones sí podrían utilizarse datos o referencias para comprobar el cumplimiento de las condiciones. Al final la opinión del órgano consultivo se queda en un mero trámite formal para aparentar que la decisión de la COM cumple los requisitos.

En este punto se ha tomado ya la decisión y además se produce la primera aparición del órgano asesor. En este punto nos surgen algunas dudas:

- ¿Cómo llega la Comisión a esta conclusión?
- ¿Qué diligencias previas ha realizado? Por razones de Seguridad jurídica, es necesario realizar una serie de pasos previos que recojan pruebas fehacientes de todo el panorama

#### **Article 7:**

In the Commission's explanations to Article 4, it is indicated that the term "exercise" of IP rights is confusing and that's why that reference is erased. However, it is maintained in Article 7.1, which is incongruous.

On the other hand, for the sake of terminological consistency, it might be appropriate to indicate, as in Art. 4, that "the Commission has concluded", instead of "the Commission considers".

The possibility of a decision taken alone by the Commission, lacking the necessary legal certainty in granting the compulsory license, is maintained. The trigger for the procedure's opening, described in Article 7, is an internal and unknown process in which the Commission, based on gathered information, considers it appropriate to open it and publishes the notice. It is not contemplated that there is a need for reliable and verifiable evidence to justify the request for the Compulsory License. It is not known if there are prior proceedings, (and who would practice them), which body of the COM is considered competent, what knowledge it has to be considered competent or how the politicization of the decision would be avoided. Since the subsequent technical opinion is not binding, the COM could grant or not the CL as it sees fit. At a time of social alarm to which the COM has to give an urgent response to public demand, if the response is not legally linked to an expert opinion of a technical Advisory Body, that decision could be arbitrary. There are a great degree of politicization with patents and compulsory licenses as we already saw during the pandemic. With the disappearance of the ad-hoc advisory body of the former Article 6.2, the possibility of providing the advisory body with technical content also disappears.

The Advisory Body, as it currently stands, has no influence on the decision-making process, since its opinion is not binding, which does not mean that under other conditions, data or references could be used to verify compliance with the conditions. In the end, the opinion of the advisory body remains a mere formality to make it appear that the COM decision meets all the requirements.

At this point the decision has already been taken and the first appearance of the advisory body takes place.

At this point some doubts arise:

- How does the Commission come to this conclusion?
- What preliminary proceedings has it carried out? For reasons of legal certainty, it is necessary to carry out a series of preliminary steps to gather reliable evidence of the whole picture.

#### Artículo 9.3.b):

Nos surge la de duda de ¿cómo se valora en la práctica las ayudas públicas recibidas? de qué ámbito serían, nacional, local, europeo o todos? ¿Y como se calculan?

#### Article 9.3.b):

The question arises as to how is the public aid received valued in practical terms? At what level would it be calculated: at national level, local level, European level or all levels included? And how will it be calculated?

#### Artículo 10:

**Las Obligaciones del Licenciario** (artículo 10 del Reglamento), deberían incluir la capacidad de poder fabricar el producto, en las cantidades y tiempo necesario, con la calidad requerida en cada campo técnico, con el cumplimiento de requisitos industriales, sanitarios, etc. Este requisito está así recogido en la Ley de Patentes española, art 98. 2 que exige que el licenciario debe acreditar que cuenta con los medios y garantías suficientes para llevar a cabo una explotación real y efectiva de la invención patentada acorde con la finalidad de la licencia. Actualmente la propuesta de Reglamento, en relación a los licenciarios, se centra exclusivamente en las cuestiones formales o de requisitos comerciales o legales, pero en ningún caso aparecen sus capacidades, dando la impresión que cualquiera puede fabricar cualquier cosa.

**Article 10:**

The licensee's obligations should include the capacity to manufacture the product, in the necessary quantities in a timely fashion, with the quality required in each technical field, in compliance with all the industrial and sanitary requirements. This requirement is included in the Spanish Patent Law, art 98. 2, which requires that the licensee must prove that it has sufficient means and guarantees to carry out a real and effective exploitation of the patented invention in accordance with the purpose of the license. Currently, the proposed Regulation, in relation to licensees, focuses exclusively on formal issues or commercial or legal requirements, but in no case do their capabilities appear, giving the impression that anyone can manufacture anything.

**Comments of Hungary on the Presidency's second revised text of the Proposal for a Regulation on compulsory licensing for crisis management and amending Regulation (EC) 816/2006**

We thank the Presidency for the new revised text and for taking a number of our comments on board. In order to further improve the text, the Hungarian delegation submits the following drafting proposals for the Presidency's consideration.

### **Article 3**

**(e) Union compulsory licence:** It is not clear for us which type of patents can be the subject of a Union compulsory license, especially whether it is possible to grant such a license for a second (third or further) indication patent of a crisis-relevant product. In order to clarify the wording, we propose the following new definition:

*“Union compulsory licence” means a compulsory licence granted by the Commission to exploit a protected invention in order to carry out any of the relevant activities referred to in Article 3(b) in the territory of the Union concerning a crisis-relevant product.*

### **Articles 4 and 7**

We find it very concerning that the new wording of Article 4(1)(b) refers to IP rights as bottlenecks of the supply of crisis-relevant products (*“intellectual property rights protecting crisis-relevant products are hampering the adequate supply of these products”*). Similarly, we do not agree with the wording of Article 7(1), either, which states that the lack of adequate supply results from the *“exercise of intellectual property rights”*. We point out that a shortage of crisis-relevant products protected by IPRs may occur as a consequence of *the lack of exploitation of IPRs by the right-holder*, not as a result of exercising such rights.

### **Article 6**

We welcome that it is clear from the new text that a Union compulsory license cannot be granted without identifying the rights and right-holders, affected by such license. Nonetheless, we are concerned that the Advisory Body would not properly complete its task to identify the IP rights protecting the crisis-relevant product. Instead of the Advisory Body, we think that it should be the potential licensee who identifies the IP rights protecting the crisis-relevant product as they are in a better position to do so. Therefore, we are of the view that the procedure of granting a compulsory licence should be initiated upon the request of the potential licensee who identifies the IP rights after the Advisory Body identifies the crisis-relevant products and the Commission publishes its notification.

### **Article 8**

We support the plan of the Presidency to delete references to *“additional measures complementing the compulsory licence”* throughout the text.

### **Article 9**

We welcome that the cap of 4% of total gross revenue in paragraph (2) has been removed from the operative text. We are of the view that the factors listed in paragraph (3)(aa) and (ab) should be considered in terms of economic value, and should be treated as a mandatory aspect to consider

when determining the adequate remuneration. Therefore points (aa) and (ab) should be inserted in the chapeau of paragraph (3).

#### **Article 10**

We believe that paragraph (1) should be supplemented with further obligations imposed on the licensee to ensure that the Union compulsory license reaches its goals: e.g. the licensee should provide credible information on its capacities to manufacture the crisis-relevant product, including on its expertise, security of supply chains, in order to ensure a safe and secure supply.

#### **Article 14**

We do not agree with the concept of the modification of the compulsory licence to update the list of rights and right-holders covered by the compulsory license with retroactive effect. We do not see how this would be feasible in practice and how it would affect the issue of remuneration. Instead of the modification of the compulsory licence, a new procedure for granting a new compulsory licence should be launched.

#### **Article 22**

We point out that the information obligation in paragraph (1) is imposed on the Member States, thus, Member States are free to decide which authority is going to fulfil such obligation; it is not necessarily the same authority granting the national compulsory license. According to paragraph (2), Member States shall inform the Commission of the national authority entrusted with the information obligation and a list of those national authorities will be published on the Commission's website. We do not see the added value of publishing a list of national authorities, which simply has the task of providing information to the Commission.

**Commentaires FR Licences obligatoires****Proposition d'amendement de l'Article 1 :**

*“This Regulation has the objective to authorize the use of the subject matter of industrial property rights required for the production and supply of crisis relevant products without the consent of the right holder to the extent necessary to complete the measures of the Union Acts listed in the Annex guaranteeing the supply of crisis-relevant products in the event of an activated or declared crisis or emergency mode. To this end, this Regulation lays down rules on conditions and procedure for the granting, in the public interest and as an exceptional and last resort measure, when no voluntary agreement could be reached, of a Union compulsory licence of industrial property rights that are necessary for the supply of crisis-relevant products to the Member States during such crisis or emergency mode”.*

**Proposition d'amendement du Considérant 1 :**

*“In such cases, compulsory licensing can provide a solution of last resort, where no voluntary agreements could be reached, to allow access to patented products, in particular products necessary to tackle the consequences of a crisis”.*

**Proposition d'amendement du Considérant 2 :**

*“As a last resort, where adequate, efficient and swift access to crisis-relevant products and processes protected by an industrial property right cannot be achieved through other means, including voluntary cooperation, compulsory licensing can allow for the use of subject matter of industrial property rights in the public interest for production and supply of crisis-relevant products”.*

**Proposition d'amendement du Considérant 5 :**

*“This suboptimal compulsory licensing framework prevents the Union from relying on an additional instrument when facing crises, in particular namely when means other than a Union compulsory licence, including voluntary agreements, could not adequately, efficiently and swiftly ensure access to crisis-relevant products and processes protected by an industrial property right”.*

**Proposition d'amendement du Considérant 6 :**

*“Therefore, it is necessary to establish a compulsory licence for crisis or emergency management at Union level. Under this system, the Commission, after considering the opinion of the advisory body, should be empowered to grant, in the public interest and as an exceptional measure, a compulsory licence that is valid throughout the Union and that allows the use of subject matter of intellectual property rights, in the public interest, for the production and supply of crisis-relevant products necessary to address a crisis or emergency in the Union”.*

**Proposition d'amendement du Considérant 15a) :**

*“In addition, a Union compulsory licence should only be used to authorize, without the consent of the right holders, the use of the subject matter of intellectual property rights for the production and supply of crisis-relevant products in the territory of the Union”. As a further condition, a Union compulsory licence should*

*only be granted as a measure of last resort in the sense that it should only be granted where voluntary agreements could not be reached to access to crisis-relevant products and processes protected by an industrial property right”.*

**Proposition d’amendement à l’article 3 a) et e) :**

*a) ‘crisis-relevant products’ means products or processes or, including processes required to manufacture these products, that are indispensable and produced in insufficient quantity for responding to a temporary crisis or emergency or for addressing the direct impacts of a crisis or emergency in the Union and for which the grant of a compulsory license is the only means of ensuring the sufficient and timely availability and supply of such products or processes as determined by the Commission through the guidance of the advisory body in accordance with Article 6”.*

*e) “Union compulsory licence’ means a compulsory licence granted by the Commission as a last resort , which allows, without the consent of the right holders, the use of subject matter of industrial property rights, in the public interest, for the production and supply of crisis-relevant products in the territory of the Union”.*

**Proposition d’amendement de l’article 4 b) et c) et ajout d’un e) :**

*(b) “the Commission has concluded, in accordance with Article 6 and 7, that use of subject matter of industrial property rights protecting crisis-relevant products is necessary to produce and supply these products in the territory of the Union territory”.*

*(c) “the Commission has concluded, in accordance with Article 6 and 7, that means other than a Union compulsory licence, including voluntary agreements, could not be reached to use subject matter of industrial property rights protecting crisis-relevant products (‘measure of last resort’)”.*

*e) “A Union compulsory license should not be applied to matters related to national security and defence”.*

**Proposition d’amendement du Considérant 15a) :**

*“In addition, a Union compulsory licence should only be used to authorize, without the consent of the right holders, the use of the subject matter of industrial property rights for the production and supply of crisis-relevant products in the territory of the Union”.*

**Proposition d’amendement de l’article 5, 1 :**

*(d) “only be granted against payment of an adequate remuneration to the rights-holder, in the circumstances of each case, taking into account the economic value of the authorization in accordance with Article 9”.*

**Proposition d’amendements de l’Article 6.1 :**

*“For the purposes of the present Regulation, the competent advisory body shall assist and advise the Commission by in the following tasks :*

- a) Establishment of whether there is a need to grant a Union compulsory licence*
- b) The determination of crisis relevant products*

- c) the identification of the intellectual property rights protecting the crisis-relevant product and the rights-holders;
- d) the dissemination of the published notice referred to in Article 7(1) through the appropriate channels;
- e) the identification of potential licensees and assessment of whether they have the capacity to efficiently and swiftly exploit the protected invention in a manner that permits the effective and proper carrying out of the relevant activities relating to the crisis-relevant product, in accordance with the obligations referred to in Article 10;
- f) the gathering of the views of the rights-holders and potential licensees, including on the possibility of voluntary licensing agreements, and, where relevant, through their participation in the discussions of the competent advisory body as well as the analysis of the comments received in accordance with Article 7(2)(c);
- g) the gathering of the views, where relevant, of economic operators of the sectors concerned, and of other relevant entities;
- h) the gathering of the views of experts from national intellectual property offices and representatives of national authorities responsible for granting national compulsory licences, including by ensuring their participation in the discussions of the competent advisory body where discussions relate to intellectual property;
- i) The gathering and analysis of the crisis-relevant information and market intelligence available, notably in order to take account of the, nature, characteristics and scope of the crisis or emergency and how it is expected to evolve and the shortage of crisis relevant products and existence of other means than Union compulsory licence to remedy such shortage ;
- j) the facilitation of the collaboration, cooperation, exchanges and sharing of information with other relevant bodies and other crisis-relevant bodies at Union and national level, as well as relevant authorities at international level, where appropriate”.

**Proposition d’amendement de l’Article 7.1**

“When the Commission, in the context of crisis or emergency mode, and on the basis of preliminary information gathered in that framework, concludes that use of subject matter of industrial property rights protecting crisis-relevant products is necessary to produce and supply such products in the territory of the Union, it may initiate the procedure for the granting of a Union compulsory license by publishing a notice on the website of the Commission”.

## Comments and drafting suggestions from Denmark on the proposal for a regulation for a compulsory licensing instrument – second reading of the revised Presidency text

*Changes proposed by Denmark are marked in red. Overall, there is a lot of repetition in the recitals, so it is suggested to delete duplications.*

- **Recital 1:**

Suggest changing text to make it clear that voluntary agreements should always be sought:

*(...) Voluntary agreements are the most adequate, quick, and efficient solution to allow the use of patented products, including in crises. ~~Nevertheless, However, there might be situations in which it has not be possible to reach~~ voluntary agreements ~~may~~ ~~might not~~ ~~always be available~~ or only under inadequate conditions such as lengthy delivery times. In such cases, compulsory licensing can provide a solution of last resort, where voluntary agreements could not be reached would not be available or where they would not prove adequate, to allow access to patented products, in particular products necessary to tackle the consequences of a crisis.*

- **Recital 3:**

The wording around 'reasonable period of time' remains unclear. Suggest adding wording that this refers to a given crisis situation. Suggest to delete the sentences that follow as it should always be a prerequisite that voluntary agreements are sought. The mentioning of 'waiving' rights is not ideal in the context of TRIPS as it would undermine the EU's legitimacy and international reputation in light of the TRIPS waiver discussions at WTO level:

*(...) To this end, the present Regulation should establish a compulsory licensing scheme at Union level for crisis management. In accordance with the international obligations laid down in the TRIPS Agreement, as a condition for making use of compulsory licensing, efforts should have been made to obtain prior authorisation from the rights-holder on reasonable commercial terms and conditions and such efforts should have not been successful within a reasonable period of time to address the crisis. ~~However, this~~*

*requirement may be waived in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. To allow for effectiveness of compulsory licensing systems in crises, where time is of the essence, this Regulation should therefore not include any obligation of prior negotiations. At the same time, The granting process of a Union compulsory licence should be tailored in a way that it ensures the participation of the rights-holders throughout the procedure, with a view to enable and stimulate voluntary agreements.*

- **Recital 5:**

Suggest deleting sentences to avoid unnecessary wording and duplications:

(...) Consequently, the current compulsory licensing framework appears inadequate to address the realities of the internal market and its inherent cross-border supply chains. ~~This suboptimal compulsory licensing framework prevents the Union from relying on an additional instrument when facing crises, in particular namely when means other than a Union compulsory licence, including voluntary agreements, could not adequately, efficiently and swiftly remedy the lack of adequate supply are unavailable or inadequate.~~ At a time where the Union and its Member States are striving to improve their resilience to crises, it is necessary to provide for an optimal compulsory licensing system for crisis management that takes the full advantage of the internal market and allows Member States to support one another in crises.

- **Recital 9:**

A grammatical change and suggest deleting reference to published patent applications and published utility model applications.

(...) To ensure optimal efficiency of the Union compulsory licence as a tool ~~to address to in addressing~~ crises or emergencies, it should be made available in respect of a granted patent or utility model, ~~of a published patent application~~ or a supplementary protection certificate. Where applicable, it should also be available in respect of a published patent application or a published utility model application.

- **Recital 12:**

As per comment above, suggest deleting any reference to patent applications or utility model applications.

~~(...) *The Union compulsory licence should also apply to published patent applications for national patents and for European patents, as well as to published utility model applications, where applicable. As the grant of a patent after the publishing of the patent application can take years, targeting only inventions protected by a granted patent could prevent an effective and timely crisis response. In crises, solutions can derive from the latest state-of-the-art technology. Moreover, certain national patent legislations, as well as the European Patent Convention, provide for provisional protection of patent applicants with regard to unconsented use of their inventions and the corresponding possibility for such applicants to licence the use of their patent application rights. For similar reasons, it should be ensured that a Union compulsory licence also applies to published utility model applications. In order to ensure that a Union compulsory licence on a published patent application or utility model application continues to keep its effects once the patent or utility model is granted, the Union compulsory licence for published patent applications or utility model applications should extend to the patent or utility model once granted to the extent that the crisis-relevant product still falls within the final scope of the patent claims protection of these intellectual property rights as granted.*~~

- **Recital 13:**

Suggest amending the wording, to make it clear that trade secrets must (rather than shall) be protected. Suggest deleting last sentence that references ‘additional measures’. Denmark is in favour of deleting any reference to ‘additional measures’, including in the articles.

~~(...) *It should also be clarified that this Regulation is without prejudice to Directive (EU) 2016/94310. In addition, no provision of this Regulation **are to should** be interpreted as imposing any obligation to disclose undisclosed know-how, business information or technological information protected by trade secrets as defined by Directive (EU) 2016/943. **This exclusion of forced sharing of trade secrets should also apply to additional measures taken by the Commission under this Regulation.***~~

- **Recital 15:**

This recital remains unclear, especially the wording ‘sufficiently general’. Suggest to delete the whole recital:

*(...) ~~In order to ensure as much coherence as possible with existing crisis mechanisms and with other Union legislation, the definition of a ‘crisis-relevant product’ should be based on the definition adopted in the Single Market Emergency Instrument (SMEI) but should be more sufficiently general in order so as to cover products related to different kinds of crises or emergencies emergency modes under the respective Union legal acts listed in the Annex.~~*

- **Recital 15a:**

This recital is somewhat unclear and given the setting out of the role of the advisory body in recital 17, it is proposed to delete most of the recital and make some amendments, also to reflect that the regulations that can trigger a crisis are in the articles and not in the annex:

*(...) ~~A Union compulsory licence should only be granted when specific conditions are fulfilled. In particular, given the fact that the Union compulsory licensing framework complements the Union crisis or emergency mechanisms, A Union compulsory licence should only be granted where a crisis or emergency mode listed in the Annex has been activated or declared, and where it has not been possible to reach voluntary agreements between rights holders and potential licensees for the production and supply of crisis relevant products. In addition, a Union compulsory licence should only be relied upon in situations in which intellectual property rights or their exercise are hampering the adequate supply of crisis-relevant products in the territory of the Union. As a further condition, A Union compulsory licence should only be granted as a measure of last resort in the sense that it should only be granted where voluntary agreements could not adequately, efficiently and swiftly remedy the lack of adequate supply of crisis relevant products. The second and third conditions should be evaluated and assessed by the Commission, with the assistance and advice of the competent advisory body, in accordance with the procedure under this Regulation. Finally, It is of utmost importance that rights-holders are given the opportunity to provide their comments in order to safeguard their rights, as well as to enable the advisory body to obtain all information necessary.~~*

- **Recital 17:**

It is important that IP rights and the rights holder are identified:

*(...) These early discussions should already provide the Commission with information on the lack of supply of crisis-relevant products, as well as, ~~when possible, initial~~ information on the intellectual property rights concerned and the rights-holders. As part of the early discussions within the advisory body, the Commission should also assess whether the specific measures taken under the relevant crisis or emergency mechanism are sufficient to address the lack of supply of crisis-relevant products. If this is not the case and a Union compulsory licence seems, a priori, necessary, the advisory body should provide the Commission with a clear~~er~~ idea of how products manufactured under ~~a potential the~~ Union compulsory licence could be adequately delivered via these measures.*

- **Recital 18:**

There appears to be a lot of duplication in recitals 17, 18 and 19, so it is suggested to cut it down and simplify the language. Wording around the listing of the crisis mechanisms in the annex should also be deleted:

*(...) Those advisory bodies have the right composition, expertise, and procedures to address the crises and emergencies for which they have been set-up. ~~When compulsory licensing is being discussed in the context of such crisis instrument, relying on the advisory body set-up for the specific instrument allows the Commission to be adequately advised and avoid duplication of advisory bodies, leading to incoherences between processes. However, considering the specific role of the advisory body, it should be ensured that the said body draws on additional expertise in intellectual property rights, in particular patents, and in the granting of compulsory licenses.~~The competent advisory bodies shall be listed, together with the corresponding crisis mechanisms, in an Annex to this Regulation.*

- **Recital 19:**

Suggest simplifying the language and making it mandatory for the advisory body to consult national IP offices etc. The last sentence should be deleted as right holders should be

contacted individually as previously suggested by the Presidency (please see comments on article 6).

(19) *The role of the advisory body is to assist and advise the Commission when discussions arise on the need ~~for to rely on~~ a Union compulsory licence ~~in ge and its content at Union level.~~*

*~~To achieve this, The advisory body should support the Commission in taking the necessary steps to identify the intellectual property rights concerned and the rightsholders. To allow for the widest dissemination of information on the initiation of the procedure for granting a Union compulsory licence, the advisory body **must should** contact ~~the~~ national intellectual property offices, ~~the~~ relevant businesses and industry associations as well as international organisations. ~~The advisory body should draw the attention of these entities to the notice published by the Commission on the initiation of the procedure for granting a Union compulsory licence, containing the relevant information, and should encourage its further distribution by any means appropriate.~~~~*

#### Article 1 – subject matter

- DK would be in favour of including wording around voluntary agreements as indicated previously.
- DK supports deletion of crisis mechanisms related to gas and microchips, and moving them from the annex to the articles.
- DK is in favour of changing the wording, to move to an IP centric approach rather than product centric approach.

#### Article 2 – Scope

- DK does not see the need to include patent applications or utility models applications, so suggests for the reference to these to be deleted.
- DK is in favour of deleting reference to forced sharing of trade secrets as this can lead to confusion.
- DK supports the exclusion of defence related products.

#### Article 3 – Definitions

- DK supports the proposal to move away from a product centred approach for CL to a IP rights centred approach.

#### Article 4 – General conditions for granting a Union compulsory licence

- New wording which says "...IP rights protecting crisis-relevant products **are hampering** the adequate supply..." (rather than 'preventing') is not ideal. It makes it sound as if IP

rights are an issues. DK proposes for this to be reworded, e.g. to state that the rights holder is not able to produce a sufficient amount of crisis-relevant products to meet demands.

#### **Article 5 – General terms of a Union compulsory licence**

- As per previous comments, article 1a remains unclear. DK has previously proposed:
  - o (a) be non-exclusive and non-assignable, ~~except with that part of the enterprise or goodwill which enjoys such compulsory licence;~~

#### **Article 6 – Advisory Body**

- DK is not in favour of the latest changes in article 6.1.b, which now reads that the Advisory Board shall assist the Commission in “the dissemination of the published notice referred to in Article 7(1) through the appropriate channels.” DK proposed to revert back to the previous text that was introduced by the Presidency, which stated that right holders are contacted individually. If there a rights holder may be subject to a CL it is essential that the rights holder is aware of it, which requires an individual notification.
- Welcome changes in article 6.1.d in which now reads that the advisory body shall assist with “the gathering of the views and the rights-holders and potential licenses, including on the possibility of voluntary agreements...” Language could be tightened up, to say “gathering of views of rights-holders and potential licensees, including on the option to enter into a voluntary agreement...”.

#### **Article 7 – Procedure of granting a Union compulsory licence**

- Welcome article 7.9. which required the Commission to reason if its decision differs from that of the advisory body. However, DK would still prefer if a CL would have to be recommended by the advisory body.

#### **Article 8 – Content of the Union compulsory licence**

- DK is in favour of deleting published patent applications and utility model applications in 8.1.a.
- DK is in favour of deleting references to ‘additional measures’.

#### **Article 9 – Remuneration**

- Welcome that the advisory body is heard on remuneration. Important that IP experts are included, too, so suggest wording to be added.
- It remains unclear how COM will factor in the various aspects incl. humanitarian circumstances (8.3.d) and determine adequate remuneration to the rights holder, so suggest for this to be clarified.

#### **Article 10 – Obligations to be fulfilled by the licensee**

- No comments.

#### **Article 11 – Prohibition of exports**

- No comments.

#### **Article 12 - Customs control**

- Wording agreed in relation to 12.6.b at meeting with DG Taxud on Friday 17<sup>th</sup> May.

#### **Article 13 – Good faith cooperation and conduct**

- DK finds that the wording leaves room for interpretation and suggest for it to be deleted.
- As a fallback option, it could be rephrased so that it explicitly explains the Commission's role as a facilitator e.g. calling parties for meetings.

#### **Article 14 – review and termination of the Union compulsory licence**

- DK would like references to 'retroactive effect' to be deleted as rights holders should always be identified before a CL is issued.
- As previously stated, DK is in favour of deleting reference to 'additional measures' as in article 14.2.

#### **Article 15 – Fines**

- It remains inconsistent that fines can be issued in relation to EU CL, while this is not the case for a CL related to the export to third countries with public health issues.

#### **Article 16 – Periodic penalty payments**

- DK would be in favour of having a monetary cap, similar to that of fines.
- As per comment on fines, it remains inconsistent that fines and period penalty payments can be issued in relation to EU CLs, while there are no fines or periodic penalty payments for CLs related to export to third countries with public health issues.
- It is also somewhat unclear how the calculations will be made and where the figures to calculate periodic penalty payments will be taken from.

#### **Article 17 – Limitation period for the imposition of fines and periodic penalty payments**

- DK remains of the view that the wording in this article remains unclear, incl. when the various periods begin. DK suggests for the language in this article to be tightened up.

#### **Article 18 – Limitation period for the enforcement of fines and periodic penalty payments**

- Same as for article 17, DK finds the wording in this article to be unclear.

#### **Article 19 – Right to be heard and access to the files**

- No comments.

#### **Article 20 – Publication of decisions**

- No comments.

#### **Article 21 – Review of the fines or period penalty payments by the Court of Justice of the EU**

- No comments.

**Article 22 – Reporting on national compulsory licences**

- No comments.

**Article 23 – Amendments to Regulation (EC) No 816/2006**

- As per previous comments, DK finds it inconsistent that EU CL can be subject to fines and periodic penalty payments, while this is not the case for CL for exports under 816/2006, noting that amendments to 816/2006 only can be made after a review of the regulation as previously pointed out by the Commission.
- As for article 18a.2, Denmark suggest for wording to be added around ‘a legal entity with commercial interests’ or something along those lines, rather than ‘a person’.
- DK in favour of adding wording that implementing acts can only be adopted if an opinion has been issued by the committee, similar to that of a Union CL.

**Article 24 – Committee procedure**

- No comments.

**Article 25 – Evaluation**

- No comments.

**Article 26 – Entry into force**

- No comments.