



Council of the European Union
General Secretariat

Brussels, 06 February 2024

**Interinstitutional files:
2023/0129 (COD)**

WK 1896/2024 INIT

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CONTRIBUTION

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| From: | General Secretariat of the Council |
| To: | Working Party on Intellectual Property (Patents) |
| 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 |

Delegations will find attached a compilation of drafting suggestions and comments received in response to the request from the Presidency regarding Articles 1-5 and Article 12 of the above-mentioned proposal.

The contributions received so far are from the following delegations: PT - AT - EE - PL - NL - DE - CZ - ES - FI - DK - SE - IT.

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| <p>GENERAL COMMENTS TO THE PROPOSAL</p> | <p>PT (Comments): It is important to ensure that the rules established in the Regulation are completely clear and transparent - avoiding very broadly terms or wording – and defined in a precise manner. They should also be fair to all stakeholders (holders of the right; potential licensees and general public). Therefore the accuracy of the Regulation will determine its efficiency. Regarding this, it is important to mention that there are some points in the proposal that are defined in a general and vague way - which can lead to a lack of clarity -, or that need clarification. Other aspect that should be included,e.g in the recitals, is that priority should always be given to voluntary licenses, and compulsory licenses should be seen as a last resort.</p> <p>NL (Drafting): Considering that we have only covered a portion of the proposal (only articles 1-5 and 11-12_ thus far, it is premature to offer specific drafting recommendations at this point. We plan to provide drafting suggestions at a later stage in the process.</p> <p>NL (Comments): Voluntary cooperation and agreements are and remain the most efficient means of enabling rapid production of patent-protected products, even in crisis situations. However, it cannot be excluded that exceptional cases will arise in the future where such voluntary agreements are not available or appropriate. In such circumstances, compulsory licences could potentially</p> |

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| | <p>offer a solution.</p> <p>The Dutch government therefore welcomes the proposal, which introduces the possibility of compulsory licensing at EU level of products or processes that are indispensable to deal with a cross-border crisis or emergency in the Union. The same goes for expanding the possibilities for exports of medical products to third countries with public health problems. The government is broadly supportive of the measures announced herein, but has a number of concerns as this proposal is further negotiated.</p> <p>Like the Regulatory Review Board (RSB), the government considers that the effects of and consistency with other EU crisis management instruments recently presented or coming into force should be adequately taken into account, more specifically SMEI, serious cross-border health threats, HERA, Chips Act and gas supply security measures. NL is still considering the usefulness and necessity of including all mentioned crisis instruments. NL is also still considering whether the proposal should also apply to other EU crisis instruments, e.g. the Integrated Political Crisis Response (IPCR). This is the Council's central cross-sector EU crisis management instrument where the initiative and coordination lies with the member states, as opposed to the aforementioned sectoral instruments where the initiative and coordination often lies with the Commission.</p> <p>Furthermore, the expected exceptional use of the instrument should remain clear. In addition, the definitions and wording used in the proposal lack sufficient clarity on several points. This concerns, for instance, the wording of the different crises covered and the crisis-related critical products. Also, in the relationship between right holder (e.g. patent holder) and licensee, the extent of the principle of good faith cooperation is insufficiently clear. It is also important to ensure sufficient knowledge, including in the field of intellectual property, in the competent 'advisory bodies'. Furthermore, the</p> |

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| | <p>relationship between the proposal and the requirements of parts of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) should be carefully assessed, for instance with regard to determining the appropriate remuneration under the proposal and further examine whether this takes sufficient account of the economic value of the licence and whether review by a separate higher authority is guaranteed. Finally, it should be kept well in mind that the final instrument should not have a negative impact on the willingness of companies to enter into voluntary collaborations and invest in research and innovation of (crisis) products and processes.</p> <p>Finally, under the current proposal, the advisory procedure is used for the adoption of implementing acts granting, supplementing, amending or terminating a compulsory Union license and for implementing acts determining the fee. In view of the Dutch government, in principle, the examination procedure is preferred as it provides better guarantees for the involvement of the Member States.</p> <p>DE (Comments): The German Federal Government sees no need for regulatory action for the introduction of an EU-wide compulsory licence. Such a licence is neither appropriate nor necessary to ensure effective crisis management within the EU. Compulsory licences are provided for in the legislation of all Member States in line with the TRIPS Agreement. However, the European Commission's statements on transnational aspects do not allow for a fact-based discussion. This applies in particular to the proposed additions to Regulation (EC) No. 816/2006. Confidence in patent protection itself would be disturbed by the proposal.</p> |

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| | <p>In this respect, compulsory licenses are in no way suitable for eliminating acute production and distribution bottlenecks.</p> <p>Notwithstanding this fundamental position, the German Federal Government wishes to comment on selected substantive aspects as follows while maintaining its general scrutiny reservation and expressly reserving the right to make further comments:</p> <p>CZ (Comments):</p> <p>In general, the Czech Republic welcomes the discussion on improving preparedness, coordination and its effectiveness at EU level for emergencies such as those we have recently witnessed on a global scale. The Czech Republic has no experience of compulsory licensing. The body authorised to grant compulsory licences is the Industrial Property Office. The conditions for granting a compulsory licence, which are in line with the TRIPS Agreement, are laid down in the Patent Act. However, no application for a compulsory licence has yet been filed.</p> <p>The draft regulation is seen by the Czech Republic as a last resort in a situation where a licensing agreement cannot be reached on a voluntary basis. It would therefore appreciate it if this fact were explicitly highlighted in the proposal directly in Article 1.</p> <p>Consequently, the Czech Republic could agree that the Regulation should apply to patents, published patent applications, supplementary protection certificates and utility models as set out in Article 2(1) of the draft Regulation.</p> <p>As regards the basic parameters of EU compulsory licensing (non-exclusivity, non-transferability, right of the patent proprietor to adequate</p> |

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| | <p>compensation), the draft Regulation respects the international legal framework for compulsory licensing established by the TRIPS Agreement. These parameters are therefore acceptable to the Czech Republic.</p> <p>The Czech Republic considers that conferring the power to grant compulsory licences on the European Commission is acceptable. If the majority of Member States agree to the introduction of compulsory licensing at EU level, the Czech Republic will not oppose the adoption of the draft Regulation.</p> <p>At this stage we have no textual proposals. We are ready to consider proposals from other member states.</p> <p>DK (Comments):</p> <p>Many thanks for giving us the opportunity to comment on articles 1-5 as well as 11-12, which were covered at the last IP working group meeting. Please note, Denmark is yet to obtain a parliamentary mandate on the file, which is why we are not able to provide drafting suggestions as of yet. Please find below general comments on the mentioned articles.</p> <p>Based on the Commission’s Impact Assessment and lessons learned from the covid-19 pandemic, Denmark questions the need for a compulsory licensing instrument at Union level overall. The pandemic has shown that voluntary agreements were the most effective way to deal with a crisis situation in the EU. We fear that an EU compulsory licensing instrument could lead to legal uncertainty and thereby jeopardise a well-functioning system.</p> |

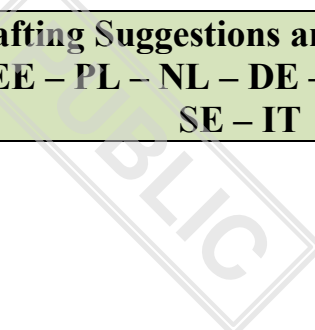
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| | <p>SE (Comments): Intellectual property protection is a prerequisite for the development of products needed to combat crises, and interventionist measures such as compulsory licenses must always be seen as a last resort when other solutions are not possible. Sweden is not immediately convinced that there is a strong need to change the current IP regime on compulsory licensing. It is clear that patent holders and manufacturers in most situations are able to enter into voluntary agreements, and introduction of new instruments risk decreasing the general trust in a solid IP system. Any new regulation in the area must be predictable, clearly defined and provide for adequate legal certainty. The request for this regulation must also be weighed against the international perspective and it needs to be ensured that this is not communicated as opening the doors for less strict IP regulations in general.</p> |
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| Proposal for a | |
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| (Text with EEA relevance) | |
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| <p>THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,</p> | |
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| <p>Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114 and 207 thereof,</p> | |
| | |
| <p>Having regard to the proposal from the European Commission,</p> | |
| | |
| <p>After transmission of the draft legislative act to the national parliaments,</p> | |
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| <p>Having regard to the opinion of the European Economic and Social Committee¹,</p> | |
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| <p>Having regard to the opinion of the Committee of the Regions²,</p> | |
| | |
| <p>Acting in accordance with the ordinary legislative procedure,</p> | |
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| <p>Whereas:</p> | |

¹ OJ C , , p. .

² OJ C , , p. .

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| | <p>EE (Drafting): The explanatory memorandum of the proposal reiterates, in the very first passage, that patent rights play a key role in supporting EU innovation and creating the right environment for investment. However, the regulation itself contains no <i>expressis verbis</i> references to innovation. Perhaps wording, referring <i>expressis verbis</i> to the importance of innovation in the EU, could be added to the recitals of the regulation. We fully trust you to find the appropriate place for this in the recitals.</p> |
| <p>(1) Crises require the setting-up of exceptional, swift, and adequate measures able to provide means to address the consequences of the crisis. In this context, the use of patented products or processes could prove indispensable to address the consequences of a crisis. Voluntary licensing agreements usually suffice to licence the patent rights on these products and allow their supply in the Union territory. Voluntary agreements are the most adequate, quick, and efficient solution to allow the use of patented products, including in crises. Nevertheless, voluntary agreements may not always be available or only under inadequate conditions such as lengthy delivery times. In such cases, compulsory licensing can provide a solution to allow access to patented products, in particular products necessary to tackle the consequences of a crisis.</p> | |
| <p>(2) In the context of the Union crisis or emergency mechanisms, the Union should therefore have the possibility to</p> | |

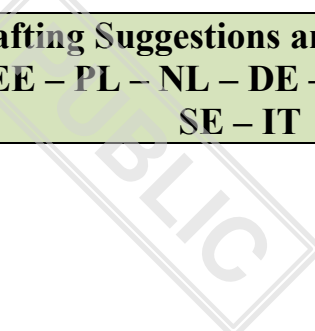
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| <p>rely on compulsory licensing. The activation of a crisis or an emergency mode or the declaration of a crisis or a state of emergency addresses obstacles to free movement of goods, services, and persons in crises and shortages of crisis-relevant goods and services. In cases where access to crisis-relevant products and processes protected by a patent cannot be achieved through voluntary cooperation, compulsory licensing can help in lifting any patent-related barriers and thus ensure the supply of products or services needed to confront an ongoing crisis or emergency. It is therefore important that, in the context of said crisis mechanisms, the Union can rely on an efficient and effective compulsory licensing scheme at Union level, which is uniformly applicable within the Union. This would guarantee a functioning internal market, ensuring the supply and the free movement of crisis-critical products subject to compulsory licencing in the internal market.</p> |  |
| <p>(3) The possibility of using compulsory licences in situations of national emergency or other circumstances of extreme urgency is explicitly envisaged under the Agreement on Trade-Related Aspects of Intellectual Property Rights ('TRIPS Agreement')³.</p> | |
| <p>(4) All Member States have implemented compulsory licensing frameworks for patents in their national law. National</p> | |

³ *OJL 336, 23.12.1994, p. 214*

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| <p>laws usually allow compulsory licensing on the ground of public interest or in the event of an emergency. However, divergences exist across Member States, as regards the grounds, conditions, and procedures under which a compulsory licence can be granted. This results in a fragmented, suboptimal, and uncoordinated system preventing the Union from effectively relying on compulsory licensing when addressing a cross-border crisis.</p> | <p>IT (Drafting): (4) All Member States have implemented compulsory licensing frameworks for patents in their national law. National laws usually allow compulsory licensing on the ground of public interest or in the event of crisis or an emergency. However, divergences exist across Member States, as regards the grounds, conditions, and procedures under which a compulsory licence can be granted. This results in a fragmented, suboptimal, and uncoordinated system preventing the Union from effectively relying on compulsory licensing when addressing a cross-border crisis.</p> <p>IT (Comments): clarify the definition of “state of crisis and/or emergency” (recitals 4, 5, 9, 16). If crisis and emergency refer to potentially different situations it is more correct to always mention both. Now sometimes they are quoted both and sometimes they are not. This is confusing.</p> |
| <p>(5) National compulsory licensing systems only operate within the national territory. They are designed to meet the needs of the population of the issuing Member State and to satisfy the public interest of that Member State. This limited territorial reach of a national compulsory licensing system is reinforced by the fact that there is no exhaustion of the patent right regarding products manufactured under a compulsory</p> | <p>IT (Drafting): (5) National compulsory licensing systems only operate within the national territory. They are designed to meet the needs of the population of the issuing Member State and to satisfy the public interest of that Member State. This limited territorial reach of a national compulsory licensing system is reinforced by the fact that there is no exhaustion of the</p> |

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| <p>licence. Consequently, compulsory licensing schemes do not provide an adequate solution for cross-border manufacturing processes, and therefore there is no functioning internal market for product manufactured under a compulsory licence. Apart from the fact that the issuance of multiple national compulsory licences is a high hurdle for cross-border supply within the single market, it also bears the risk of contradicting and incoherent decisions among Member States. 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 when voluntary agreements 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.</p> | <p>patent right regarding products manufactured under a compulsory licence. Consequently, compulsory licensing schemes do not provide an adequate solution for cross-border manufacturing processes, and therefore there is no functioning internal market for product manufactured under a compulsory licence. Apart from the fact that the issuance of multiple national compulsory licences is a high hurdle for cross-border supply within the single market, it also bears the risk of contradicting and incoherent decisions among Member States. 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 when voluntary agreements are unavailable or inadequate. At a time where the Union and its Member States are striving to improve their resilience to crises <u>or emergency</u>, it is necessary to provide for an optimal compulsory licensing system for crisis <u>or emergency</u> management that takes the full advantage of the internal market and allows Member States to support one another in crises <u>or emergency</u>.</p> <p>IT (Comments): See comments on recital 4</p> |
| <p>(6) Therefore, it is necessary to establish a compulsory licence for crisis or emergency management at Union level. Under this system, the Commission should be empowered to grant a compulsory licence that is valid throughout the Union</p> | |

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| <p>and that allows the manufacturing and distribution of products necessary to address a crisis or emergency in the Union ('Union compulsory licence').</p> | |
| <p>(7) In recent years, the European Union has adopted several crisis mechanisms to improve its resilience to crises or emergencies affecting the Union. The recent mechanisms include the Single Market Emergency Instrument (SMEI) established under Regulation (EU) No XXX/XX [COM(2022) 459] and Regulation (EU) No 2022/2371 under which the Commission may recognise a public health emergency at Union level. In the event of a public health emergency at Union level a framework of measures for ensuring the supply of crisis-relevant medical countermeasures might be activated under Regulation (EU) No 2022/2372. Furthermore, in case of a significant shortage of semiconductors due to serious disruptions in their supply, the Commission may activate a crisis stage by means of implementing acts under Regulation (EU) No XXX/XX (Chips Act) [COM(2022) 46].</p> | |
| <p>(8) These mechanisms provide for the activation of an emergency or crisis mode and aim at providing the means to address Union emergencies. By allowing the Commission to grant a compulsory licence when a crisis or emergency mode has been activated by a Union legal act, the necessary synergy between the existing crisis mechanisms and a Union wide compulsory licencing scheme is achieved. In such a case, the</p> | |

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| <p>determination of the existence of a crisis or emergency depends solely on the Union legal act underlying the crisis mechanism and the crisis definition included therein. For the sake of legal certainty, the crisis mechanisms that qualify as Union emergency or extreme urgency measures and that can trigger a Union compulsory licence should be listed in an Annex to this Regulation.</p> |  |
| <p>(9) To ensure optimal efficiency of the Union compulsory licence as a tool to address crises, it should be made available in respect of a granted patent or utility model, of a published patent application or a supplementary protection certificate. The Union compulsory licence should equally apply to a national patents, European patents and European patents with unitary effect.</p> | <p>PT (Comments): The scope of the compulsory license is defined as including patents, published patent applications, supplementary protection certificates and utility models. In this Article, the granted patents were included, as well as its published applications. However, regarding utility models - another way to protect inventions - only the granted utility models were included. This seems somehow inconsistent. Therefore, for the sake of harmonisation and coherence, we consider that the options regarding patents and utility models should be the same.</p> <p>IT (Drafting): (9) To ensure optimal efficiency of the Union compulsory licence as a tool to address crises <u>or emergency</u>, it should be made available in respect of a granted patent or utility model, of a published patent application or a supplementary protection certificate. The Union compulsory licence should equally apply to a national patents, European patents and European patents with unitary effect.</p> |

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| | IT (Comments): See comments on recital 4 |
| <p>(10) Utility model systems protect new technical inventions that do not fulfil the patentability requirements through the granting of an exclusive right to prevent others, for a limited period of time, from commercially exploiting the protected inventions without consent of the right holders. The definition of utility models varies from one country to another, and not all Member States provide for utility model systems. In general, utility models are suited for protecting inventions that make small improvements to, or adaptations of, existing products, or that have a short commercial life. However, similarly to patents, utility models can protect inventions that could prove necessary to address a crisis and should therefore be included in the scope of the Union compulsory licence.</p> | <p>PT (Comments): In Portugal, utility models have the same patentability requirements as patents, and there is an alternative way to assess the inventive step. Therefore, the recital should be worded in such a way as not to conflict with the various national laws.</p> <p>ES (Drafting): <i>..whose patentability requirements are less stringent than for patents.</i></p> <p>ES (Comments): It is inaccurate to draft that Utility Models do not fulfil patentability requirements, as they are always required to meet the novelty and industrial applicability requirements, although regarding inventive step, in some jurisdictions, these may be lower requirements. It would be more appropriate to say that their patentability requirements are less stringent than those required for patents. The wording should approach to a more impartial definition, and not include definitions that implicitly discredit this industrial property right. For example, from the WIPO Guide "Understanding Industrial Property": "<i>The requirements for acquiring a utility model are less stringent than for patents</i>"</p> |

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| <p>(11) A Union compulsory licence for a patent should extend to the supplementary protection certificate where such protection is granted when the patent expires during the duration period of that compulsory licence. This would allow a compulsory licence on a patent to produce its effect should the crisis-relevant products no longer be protected by a patent while being protected through a supplementary protection certificate after the expiration of the patent. It should also apply to a supplementary protection certificate in isolation where the licence is granted after the expiry of the patent.</p> | |
| <p>(12) The Union compulsory licence should also apply to published patent applications for national patents and for European patents. 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 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. In order to ensure that a Union compulsory licence on a published patent application continues to keep its effects once the patent is granted, the Union compulsory licence for published patent applications</p> | |

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| should extend to the patent once granted to the extent that the crisis-relevant product still falls within the scope of the patent claims. | |
| (13) It should be clarified that this Regulation is without prejudice to Union law on copyright and related rights, including Directives 96/9 ⁴ , 2009/24 ⁵ Directives 2001/29/EC ⁶ , 2004/48/EC ⁷ and (EU) 2019/790 ⁸ of the European Parliament and of the Council, which establish specific rules and procedures that should remain unaffected. | |
| (14) When a compulsory licence has been granted, regulatory data protection may, if still in force, prevent the effective use of the compulsory licence as it impedes the authorisation of generic medicinal products. This would result in serious negative consequences for Union compulsory licences granted to tackle a crisis, as this could hamper access to the medicinal products needed to address the crisis. For this | <p>ES (Drafting): Delete paragraph crossed out</p> <p>ES (Comments): This Regulation proposal for a compulsory licensing cannot be linked to the Pharmaceutical Directive that is still under discussion, has not been</p> |

⁴ Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases (*OJ L 77, 27.3.1996, p. 20*)

⁵ Directive 2009/24/EC of the European Parliament and of the Council of 23 April 2009 on the legal protection of computer programs (*OJ L 111, 5.5.2009, p. 16*)

⁶ Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the information society (*OJ L 167, 22.6.2001, p. 10*).

⁷ Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (*OJ L 157, 30.4.2004, p. 45*).

⁸ Directive (EU) 2019/790 of the European Parliament and of the Council of 17 April 2019 on copyright and related rights in the Digital Single Market and amending Directives 96/9/EC and 2001/29/EC (*OJ L 130, 17.5.2019, p. 92*).

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| <p>reason, Union pharmaceutical legislation (cf. Art. 80 para. 4 of Directive (EU) No XXX/XX [COM(2023)192]) provides for the suspension of data exclusivity and market protection when a compulsory licence has been issued to tackle a public health emergency. Such suspension is allowed only in relation to the compulsory licence granted and its beneficiary and must comply with the objectives, the territorial scope, the duration, and the subject-matter of the granted compulsory licence. The suspension means that the data exclusivity and market protection produce no effect in relation to the licensee of the compulsory licence while that licence is in effect. When the compulsory licence ends, the data exclusivity and market protection resume their effect. The suspension should not result in an extension of the original duration of the regulatory data protection.</p> | <p>adopted and the final wording is unknown. The suspension of data exclusivity is not a trivial issue. Many pharmaceutical companies are not based in the EU and clinical data protection legislation may be subject to international laws and face a legal conflict between jurisdictions.</p> |
| <p>(15) 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 general in order to cover products related to different kinds of crises or emergencies.</p> | |
| <p>(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</p> | <p>PL (Drafting): Therefore, it must only be granted exceptionally and under conditions that</p> |

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| <p>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 framework, the duration of the licence shall not extend beyond the duration of the activated or declared crisis or emergency mode. 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.</p> | <p>take into account the interests of the rights-holder when other measures that have been taken failed.</p> <p>PL (Comments): It seems important to highlight the need for a precise definition of the conditions under which it is necessary to resort to a Union compulsory license.</p> <p>IT (Drafting): (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 <u>or emergency</u> 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 framework, the duration of the licence shall not extend beyond the duration of the activated or declared crisis or emergency mode. 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 <u>person entity</u> able to manufacture the crisis-relevant product and to pay a reasonable remuneration to the rights-holder.</p> |

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| | IT (Comments): See comments on recital 4 instead of referring to "qualified person capable of manufacturing the product" it would be better to refer to "qualified entity" which is more neutral and can also include e.g. companies |
| <p>(17) When considering the granting of a Union compulsory licence, the Commission should, in order to be able to take a well-informed decision, be assisted by an advisory body. The consultation of the advisory body should arise early in the discussions on the need to issue a compulsory licence under the relevant instrument. Discussions on whether there is a need for a Union compulsory licence will often start already in the context of the work of the advisory body involved in the context of the relevant Union crisis or emergency mechanisms. In such case, there is no need for the Commission to convene the advisory body but rather to swiftly indicate that that body also has the competence to assess the need for compulsory licensing at Union level, and the conditions thereof. Clarification as regards the competence of the advisory body should be given early in the process, as soon as concrete consideration of using compulsory licensing at Union level is expressed by the Commission.</p> | |
| <p>(18) The participation of an advisory body aims at</p> | |

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| <p>guaranteeing a comprehensive, thorough, and concrete assessment of the situation, taking into consideration the individual merits of each situation. It is therefore important that the advisory body has the right composition, expertise, and procedures to support the Commission when deciding on whether to grant a Union compulsory licence and under what conditions. Union crisis mechanisms usually include the setting-up of an advisory body ensuring coordination of action of the Commission and relevant bodies and agencies, the Council and the Member States. In this respect, an advisory group is set up under SMEI. Regulation (EU) No 2022/2371 provides for a Health Crisis Board and under Regulation (EU) No XXX/XX (Chips Act) [COM/2022) 46], the Commission relies on the Semiconductor Board. 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. The competent advisory bodies shall be listed, together with the corresponding crisis mechanisms, in an Annex to this Regulation. In case the Union crisis mechanism does not provide for an advisory body, the Commission should set up an ad hoc advisory body for the granting of the Union (the ‘ad hoc advisory body’).</p> | <p align="center">PUBLIC</p> |
| | |

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| <p>(19) The role of the advisory body is to advise the Commission when discussions arise on the need to rely on compulsory licensing at Union level. It should provide the Commission with a non-binding opinion. Its main tasks include assisting of the Commission in the determination of the necessity to rely on compulsory licensing at Union level, and in the determination of the conditions for such licensing. When the advisory body is already set up, its existing rules of procedure should apply. As regards ad hoc advisory bodies, they should be composed of one representative of each Member State in order to provide the Commission with information and input concerning the situation on the national level, including information on manufacturing capacities, potential licensees and, if applicable, proposals for voluntary solutions. In addition, the advisory body should have the function of collecting and analysing relevant data, as well as ensuring coherence and cooperation with other crisis relevant bodies at Union and national level in order to ensure an adequate, coordinated and coherent crisis reply at Union level.</p> | <p style="text-align: center; opacity: 0.5; font-size: 48px; transform: rotate(-15deg);">PUBLIC</p> |
| <p>(20) The Commission should grant the Union compulsory licence in the light of the non-binding opinion of the advisory body. Persons, in particular the licensee and the rights-holder, whose interests may be affected by the Union compulsory licence should be given the opportunity to submit their comments. These elements should enable the Commission to consider the individual merits of the situation and determine,</p> | <p>IT (Drafting): (20) The Commission should grant the Union compulsory licence in the light of the non-binding opinion of the advisory body. Persons, in particular the licensee and the rights-holder, whose interests may be affected by the Union compulsory licence should be given the opportunity to submit their comment after being provided with the case file and</p> |

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| <p>on that basis, the adequate conditions of the licence, including an adequate remuneration to be paid by the licensee to the rights-holder. To avoid overproduction of products manufactured under a Union compulsory licence, the Commission should also consider any existing compulsory licences at national level.</p> | <p><u>analyses submitted to or carried out by the advisory body, and with all other relevant information necessary for them to assess the impact of a proposed Union compulsory license on their intellectual property rights.</u> These elements should enable the Commission to consider the individual merits of the situation and determine, on that basis, the adequate conditions of the licence, including an adequate remuneration to be paid by the licensee to the rights-holder. To avoid overproduction of products manufactured under a Union compulsory licence, the Commission should also consider any existing compulsory licences at national level <i>within the internal market.</i></p> <p>IT (Comments): In order to safeguard their rights, including under Article 17 (right to property), Article 41 (right of access to the file and right to be heard) and Article 52 of the Charter (proportionality), rights-holders should be provided with access to the file, and to all relevant information before they provide comments to the proposed Union compulsory licence.</p> |
| <p>(21) The Commission should guarantee that the rights-holder has the right to be heard before the adoption of the Union compulsory licence. Therefore, the Commission should inform the concerned rights-holder, where possible individually, without undue delay that a Union compulsory licence might be granted. The involvement of the rights-holder should be possible once there are ongoing advanced discussions in the relevant advisory body as regards the</p> | |

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| granting of a Union compulsory licence. | |
| <p>(22) When informed of advanced discussions as regards the granting of a Union compulsory licence, the rights-holder should have the possibility to propose a voluntary agreement, should the circumstances of the Union crisis or emergency, including the urgency of the situation, allow it. The rights-holder should also be given the opportunity to comment on the need for a Union compulsory licence and on the conditions of the licence, including remuneration, should it be granted. To this end, the rights-holder should be allowed to provide the Commission with written or oral comments and any information the rights-holder considers useful to allow the Commission to make a fair, comprehensive, and thorough assessment of the situation. The Commission should allow the rights-holder a reasonable period of time to provide comments and information, considering the situation of the rights-holder and the urgency of the situation. The comments of the rights-holder should, where relevant, be transmitted by the Commission to the competent advisory body. In order for confidential information to be shared with the Commission, the Commission shall ensure a safe environment for the sharing of this information and should take measures to preserve the confidentiality of the documents provided by the rights-holder in the context of that procedure. Once a Union compulsory licence has been granted, the Commission should notify the rights-holder as soon as reasonably practicable.</p> | <p>PT (Comments): “(…) the Commission should notify the rights-holder as soon as reasonably practicable.” This is not clear, a time limit should be established.</p> <p>IT (Comments): At present, only this recital is indicating that the system proposed by the regulation will only be used when voluntary cooperation between MS has failed. This concept is not reproduced in any article. Therefore, it would be useful to clarify also in the articles that this is an instrument of last instance, an exceptional one.</p> |

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| <p>(23) The initiation of the compulsory licensing procedure should be publicised, by means of a notice published in the Official Journal of the European Union. This notice should include information on the discussions about the granting of a Union compulsory licence in the context of a Union crisis or emergency mechanism. This notice should also help the Commission in identifying the intellectual property rights concerned, the rights-holders concerned as well as potential licensees.</p> | <p>IT (Drafting): (23) The initiation of the compulsory licensing procedure should be publicised, by means of a notice published in the Official Journal of the European Union. This notice should include information on the discussions about the granting of a Union compulsory licence in the context of a Union crisis or emergency mechanism <u>and the identification of crisis-relevant products</u>. This notice should also help the Commission in identifying the intellectual property rights concerned, the rights-holders concerned as well as potential licensees.</p> <p>IT (Comments): If the prerequisite for CL is the activation of the emergency/crisis mechanism and the absence of voluntary agreements, at the commencement of CL proceedings Commission should report in any case the identification of the crisis-relevant products needed in relation to which the evaluations of appropriateness for granting or not a CL will be carried out so that the rights holders can actively participate in the proceedings, reporting their rights during the proceeding. See also recital (25)</p> |
| <p>(24) The Commission should, assisted by the advisory body, make its best efforts to identify in its decision the patent, patent application, supplementary protection certificate and utility model related to the crisis-relevant products, and the rights-</p> | <p>EE (Drafting): Article 2(1)(a) of the regulation refers to not <i>unpublished</i> but only <i>published</i> patent applications. In view of this and for the sake of clarity,</p> |

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| <p>holders of those intellectual property rights. In certain circumstances, the identification of intellectual property rights and of their respective rights-holders may require lengthy and complex investigations. In such cases, a complete identification of all intellectual property rights and of their rights-holders may seriously undermine the efficient use of the Union compulsory licence to swiftly tackle the crisis or the emergency. Therefore, where the identification of all those intellectual property rights or rights-holders would significantly delay the granting of the Union compulsory licence, the Commission should be able to initially only indicate in the licence the non-proprietary name of the product for which it is sought. The Commission should nevertheless identify all applicable and relevant intellectual property rights and their rights-holder as soon as possible and amend the implementing act accordingly. The amended implementing act should also identify any necessary safeguards and remuneration to be paid to each identified rights-holder.</p> | <p>could the same reference to not simply <i>applications</i> but <i>published applications</i> also be included in article 8(1)(a) and likewise in recital 24 of the regulation?</p> <p>IT (Drafting): (24) The Commission should, assisted by the advisory body, make its best efforts to identify in its decision the patent, patent application, supplementary protection certificate and utility model related to the crisis-relevant products, and the rights-holders of those intellectual property rights. In certain circumstances, the identification of intellectual property rights and of their respective rights-holders may require lengthy and complex investigations. In such cases, a complete identification of all intellectual property rights and of their rights-holders may seriously undermine the efficient use of the Union compulsory licence to swiftly tackle the crisis or the emergency. Therefore, where the identification of all those intellectual property rights or rights-holders would significantly delay the granting of the Union compulsory licence, the Commission should be able to initially only indicate in the licence the non-proprietary name of the product for which it is sought. The Commission should nevertheless identify all applicable and relevant intellectual property rights and their rights-holder as soon as possible and amend the implementing act accordingly. The amended implementing act should also identify any necessary safeguards and remuneration to be paid to each identified rights-holder.</p> |
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| (25) Where the rights-holder or not all the rights-holders | |

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| <p>could be identified in a reasonable period of time, the Commission should exceptionally be entitled to grant the Union compulsory licence by referring only to the non-proprietary name of the crisis-relevant product where it is absolutely necessary considering the urgency of the situation. Nevertheless, after the granting of the Union compulsory licence, the Commission should identify, notify and consult the concerned rights-holders as quickly as possible, including by relying on publication measures and on national Intellectual Property Offices.</p> | <p>PT (Comments): In such cases, where the rights-holder is identified after the grant of the license, may he/she still file observations? If so, can the license be declared annulled due to the holders' observations? This situation should be provided for.</p> |
| <p>(26) The Union compulsory licence should also include information allowing the identification of the crisis-relevant product for which it is granted, as well as details on the licensee to whom the Union compulsory licence is granted, including details about the description, name or brand of the product; the commodity codes under which the crisis-relevant products are classified, as defined in Council Regulation (EEC) No 2658/87; details on the licensees (and, where applicable, the manufacturers) to whom the compulsory licence is granted, including their name, trade name or registered trade mark, their contact details, their unique identification number in the country where they are established and, where available, their Economic Operators Registration and Identification (EORI) number. Where required under Union legislation, other information should be included, such as a type, reference, model, batch or serial number, or unique identifier of a product</p> | |

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| passport. | |
| <p>(27) The licensee should pay an adequate remuneration to the rights-holder as determined by the Commission. The amount of the remuneration should be determined considering the economic value of the exploitation authorised under the licence to the licensee and to the Member States concerned by the crisis, any public support received by the rights-holder to develop the invention, the degree to which development costs have been amortized as well as humanitarian circumstances relating to the granting of the Union compulsory licence. In addition, the Commission should consider the comments made by the rights-holder and the assessment made by the advisory body with regard to the amount of the remuneration. In any case, the remuneration should not exceed 4 % of the total gross revenue generated by the licensee through the acts under the Union compulsory licence. This percentage is the same as the one provided for under Regulation 816/2006. In the event of a compulsory licence granted on the basis of a published patent application that ultimately does not lead to the granting of a patent, the rights-holder would have no ground to receive remuneration under the compulsory licence, as the subject matter for the receipt of the remuneration has not materialised. In such circumstances, the rights-holder should refund the remuneration it received under the compulsory licence.</p> | <p>IT (Drafting): In any case, the remuneration should not exceed 4 % of the total gross revenue generated by the licensee through the acts under the Union compulsory licence. This percentage is the same as the one provided for under Regulation 816/2006.</p> <p>IT (Comments): We do not think that the adoption of the 4% threshold as a general principle is sufficiently justified in this framework. The 4 percent limit, provided for in paragraph 9 of Article 10 of Regulation (EC) No. 816/2006, - applies only in cases of exports to non-EU countries of the <u>total price paid</u> by or on behalf of the importing country and <u>only in certain situations</u>, it is not the general rule to be applied; <u>in all other cases</u>, no limits applies and the remuneration shall be determined by considering the <u>economic value</u> of the use authorized to the importing country or countries concerned under the license as well as any humanitarian or extra-commercial circumstances related to the granting of the license." We would like to know so far how many times the 4% criterion has been applied under the EU Reg. 816/2006 and if any case in this framework was submitted to judicial review. We prefer a case by case evaluation of the value of the patent concerned, in line with the TRIPs.</p> |

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| <p>(28) It is imperative that products manufactured under a Union compulsory licence reach only the internal market. The Union compulsory licence should therefore impose clear conditions upon the licensee as regards the activities authorised under the licence, including the territorial reach of those activities. The rights-holder should be able to challenge actions and uses of the rights concerned by the Union compulsory licence that do not comply with the conditions of the licence, as infringement of its intellectual property rights in accordance with Directive 2004/48/EC of the European Parliament and of the Council⁹. In order to facilitate monitoring of the distribution of products manufactured under a Union compulsory licence, including controls by customs authorities, the licensee should ensure that such products have special characteristics that make them easily identifiable and distinguishable from the products marketed by the rights-holder.</p> | |
| <p>(29) A Union compulsory licence in the context of a Union crisis or emergency mechanism should only be granted to supply the internal market with crisis-relevant products. Therefore, it should be prohibited to export products manufactured under a Union compulsory licence.</p> | |

⁹ Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (OJ L 157 30.4.2004, p. 45).

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| <p>(30) Customs authorities should ensure, through a risk analysis approach, that products manufactured under a Union compulsory license are not exported. To identify such products, the main source of information to feed such customs risk-analysis should be the Union compulsory license itself. Information on each implementing act granting or modifying a Union compulsory license should thus be entered in the Electronic Customs Risk Management System (CRMS) referred to in Article 36 of Commission Implementing Regulation (EU) 2015/2447¹⁰. When customs authorities identify a product that is suspected not to comply with the export prohibition, they should suspend the export of that product and notify the Commission immediately. The Commission should reach a conclusion on the compliance with the export prohibition within 10 working days, but should have the possibility of requiring the customs authorities to maintain the suspension where necessary. To help its assessment the Commission may consult the relevant rights-holder. Where the Commission concludes that a product does not comply with the export prohibition, customs authorities should refuse its export.</p> | <p>IT (Drafting): Where the Commission concludes that a product does not comply with the export prohibition, customs authorities should refuse its export.</p> <p>IT (Comments): Logically speaking, it seems that if an export prohibition occurs, then customs authorities should refuse its export.</p> |
| <p>(31) The legal validity of the implementing act granting the Union compulsory license, or any subsequent implementing</p> | |

¹⁰ Commission Implementing Regulation (EU) 2015/2447 of 24 November 2015 laying down detailed rules for implementing certain provisions of Regulation (EU) No 952/2013 of the European Parliament and of the Council laying down the Union Customs Code (OJ L 343, 29.12.2015, p. 558).

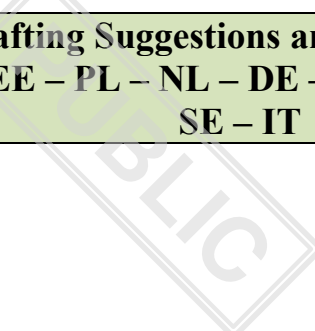
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| act, should be subject to judicial review. | <p>AT (Comments): This is of paramount importance; however, it does not become evident from the text of the proposed regulation how exactly the judicial review would be guaranteed. This needs to be clearer.</p> <p>IT (Drafting): <i>(31) The present Regulation provides the legal basis for a Union compulsory licence which permits potentially serious interferences with intellectual property rights within the meaning of Article 17(2) of the Charter of Fundamental Rights of the European Union. Therefore, in accordance with Article 52 of the Charter and the caselaw of the Court of Justice, the present Regulation must itself define the scope of the limitations on the exercise of those fundamental rights, and must also provide for minimum safeguards so that rightsholders have sufficient guarantees to protect their rights effectively against the risk of interferences that are disproportionate or otherwise non compliant with Union law, and to ensure that the essence of their rights is protected. Therefore, as a minimum guarantee, the legal validity of the implementing act granting the Union compulsory license, or any subsequent implementing act, should be subject to judicial review.</i></p> |
| (32) The relation between the rights-holder and the licensee should be governed by the principle of good faith. The rights-holder and licensee should work towards the success of the Union compulsory licence and collaborate, where necessary, to | <p>IT (Comments): It is unclear what kind of ‘complementary measures’ should be taken by the Commission and whether this would extend to the mandatory</p> |

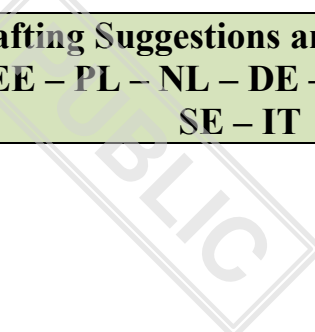
| <p align="center">Commission proposal 2023/0129 (COD)</p> | <p align="center">Drafting Suggestions and Comments PT – AT – EE – PL – NL – DE – CZ – ES – FI – DK – SE – IT</p> |
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| <p>ensure that the Union compulsory licence effectively and efficiently fulfils its objective. The Commission may act as an enabler in achieving the good-faith cooperation between the rights-holder and the licensee, taking into account interests of all parties. In that respect, the Commission should also be entitled to take additional measures in line with Union law to ensure that the compulsory licence meets its objective and ensure that necessary crisis-relevant goods can be made available in the Union. Such additional measures may include requesting further information which is deemed indispensable to achieve the objective of the compulsory licence. These measures should always include adequate safeguards to ensure the protection of the legitimate interests of all parties.</p> | <p>disclosure of confidential information, know-how or other trade secrets. In this case, doubts remain on compatibility of this measure with TRIPS Art. 31 and 39:</p> <ul style="list-style-type: none"> • Art 31 Only refers to “patents”, • Art 39 In the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967), Members shall protect undisclosed information. <p>Moreover, any additional measure should foresee a compensation for the patent owner. No information is provided in this regard in the present proposal.</p> |
| <p>(33) In order to respond appropriately to the crisis situations, the Commission should be authorised to review the conditions of the Union compulsory licence and adapt them to changed circumstances. This should include the modification of the compulsory licence to indicate the complete list of rights and rights-holders covered by the compulsory licence, where this complete identification had not be done initially. This should also include the termination of the licence if the circumstances which led to it cease to exist and are unlikely to recur. When deciding on the revision of the Union compulsory licence, the Commission may decide to consult the competent advisory body for that purpose. If the Commission intends to change essential components of the Union compulsory licence, such as</p> | |

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| <p>its duration or remuneration or if the change itself could be the subject of a separate compulsory licence, it should be required to consult the advisory body.</p> | |
| <p>(34) To prevent and stop any misuse of the Union compulsory licence, specific safeguards should be in place to allow the Commission to take action. In addition to the possibility to terminate the Union compulsory licence, the Commission should be authorised to impose fines and periodic penalty payments on the rights-holder and the licensee in order to enforce the obligations under this Regulation. The penalties should be effective, proportionate and dissuasive.</p> | |
| <p>(35) Compliance with the relevant obligations imposed under this Regulation should be enforceable by means of fines and periodic penalty payments. To that end, appropriate levels of fines and periodic penalty payments should be laid down and the imposition of fines and periodic penalty payments should be subject to appropriate limitation periods in accordance with the principles of proportionality and <i>ne bis in idem</i>. All decisions taken by the Commission under this Regulation are subject to review by the Court of Justice of the European Union in accordance with the TFEU. The Court of Justice of the European Union should have unlimited jurisdiction in respect of fines and penalty payments in accordance with Article 261 TFEU.</p> | |
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| <p>(36) When a national compulsory licence has been granted for the purpose of addressing a crisis, the Member State or its competent authority should be required to notify the Commission of the granting of the licence, and of the specific conditions attached to it, since it allows the Commission to get an overview of national compulsory licences in the Member States and to take those compulsory licences into account when considering a Union compulsory licence, and in particular when setting the conditions for such licence.</p> | |
| <p>(37) The possibility of a compulsory licence at Union level should not only be available for the supply of the Union market but also under certain conditions for export purposes concerning countries with public health problems, already regulated by Regulation (EC) No 816/2006 of the European Parliament and of the Council¹¹. Under that Regulation, the granting of such compulsory licences is decided and performed nationally by the competent authorities of the Member States that have received a corresponding application from a person that intends to manufacture and sell pharmaceutical products covered by a patent or a supplementary protection for export to eligible third countries. Regulation (EC) No 816/2006 only allows compulsory licensing covering the manufacturing of products across several Member States through national</p> | |

¹¹ Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems (OJ L 157, 9.6.2006, p. 1).

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| <p>procedures. In the context of a cross-border manufacturing process different national compulsory licences would be needed. This can lead to a burdensome and lengthy process as this would require the launch of different national procedures with possibly different scope and conditions. In order to achieve the synergies and efficient process as for the Union crisis mechanisms, a Union compulsory licence should also be available, in the context of Regulation (EC) No 816/2006. This will facilitate manufacturing of the relevant products across several Member States and provide Union-level solution in order to avoid a situation where several compulsory licences for the same product in more than one Member States would be required for licensees to manufacture and export the products as planned. Any person considering to apply for a compulsory licence under, for the purposes and within the scope of Regulation (EC) No 816/2006 should have the possibility to request, with a single application, a compulsory licence under that Regulation that is valid throughout the Union, if that person, when relying on national compulsory licencing schemes of the Member States, would otherwise need to apply for multiple compulsory licences for the same crisis-relevant product in more than one Member State in order to realise its intended activities of manufacture and sale for export under Regulation (EC) No 816/2006. Therefore, Regulation (EC) No 816/2006 should be amended accordingly.</p> |  |
| | |
| (38) In order to ensure uniform conditions for the | |

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| <p>implementation of this Regulation, implementing powers should be conferred on the Commission as regards the granting, complementing, modification or termination of a Union compulsory license, the determination of the remuneration to be paid to the rights-holder, the procedural rules for the ad hoc advisory body and the characteristics allowing the identification of products produced under a Union compulsory licence. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council¹². The advisory procedure should be used for the adoption of implementing acts granting, complementing, modifying or terminating a Union compulsory licence, and implementing acts determining the remuneration. The choice of the advisory procedure is justified given that those implementing acts would be adopted in the context of a procedure with considerable participation of the Member States through the consultation of the advisory body. The examination procedure should be used for the adoption of implementing acts establishing procedural rules for the ad hoc advisory body and implementing acts establishing the characteristics allowing the identification of products produced under a Union compulsory licence.</p> |  |
| <p>(39) The Commission should adopt immediately applicable</p> | |

¹² Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

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| <p>implementing acts where, in duly justified cases relating to the granting, modification or termination of a Union compulsory licence or the determination of the remuneration, imperative grounds of urgency so require.</p> | |
| <p>(40) Union compulsory licensing for crisis management is a tool that is only used in exceptional circumstances. The evaluation should therefore be conducted only where a Union compulsory licence has been granted by the Commission. The evaluation report should be submitted by the last day of the third year following the granting of the Union compulsory licence, to allow an adequate and substantiated assessment of this Regulation.</p> | |
| <p>(41) Since a period of time is required to ensure that the framework for the proper functioning of the system for Union compulsory licencing is in place, the application of this Regulation should be deferred.</p> | <p>IT (Comments): There is no indication in the articles that follow that the implementation of the Regulation should be postponed. Article 26 does not provide for a postponement of the entry into force of the regulation. We would be in favour of a longer time for the application of the regulation, given its far reaching implications in many different fields.</p> |
| | |
| <p>HAVE ADOPTED THIS REGULATION:</p> | |
| | |
| <p>Article 1</p> | |

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| | <p>PL (Comments): It is necessary to define the concept of a ‘crisis’ more precisely. The specific nature of the Regulation requires a detailed definition of what situations may trigger the initiation of proceedings for the grant of a Union compulsory licence.</p> |
| | |
| Subject matter | |
| <p>This Regulation has the objective to ensure that in crises the Union has access to crisis-relevant products. To this end, this Regulation lays down rules on the procedure and conditions for the granting of a Union compulsory licence of intellectual property rights that are necessary for the supply of crisis-relevant products to the Member States in the context of a Union crisis or emergency mechanism.</p> | <p>NL (Comments): Wording should be included to clarify that this new instrument would only be used during major crisis affecting the EU, as a <u>measure of last resort</u>.</p> <p>DE (Drafting): This Regulation has the objective to ensure that in crises the Union has access to crisis-relevant products during an activated or declared crisis or emergency mode pursuant to one of the Union Acts listed in the Annex to this Regulation. To this end, this Regulation lays down rules on the procedure and conditions for the granting of a Union compulsory licence of intellectual property rights that are necessary for the supply of crisis-relevant products to the Member States affected by the underlying crisis or emergency in the context of a Union crisis or emergency mechanism. The granting of a Union compulsory licence serves as a measure of last resort and shall only be considered if no prior</p> |

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| | <p>voluntary agreement could be reached between the rights-holder and a potential licensee.</p> <p>DE (Comments): Compulsory licences constitute a limitation of the fundamental right to property and must therefore always be kept to an absolute minimum. This must also be made clear with regard to the temporal and territorial scope of application. In particular, it needs to be clarified, that the granting and duration of a Union compulsory licence is inextricably linked to the activation or declaration of a crisis or emergency mode on the basis of one of the EU-crisis instruments listed in the Annex. The granting of an EU-wide compulsory licence can only ever be considered as a last resort and under clearly defined conditions. Against this background, it must be clarified that serious efforts must first be made to reach a voluntary licensing agreement</p> <p>ES (Comments): The first article raises several doubts that have to do with the precision and scope of the terms used in it. First, it would be necessary to establish a definition of “crisis” and to set up a prior evaluation aimed at determining whether the situation fits into one of the situations contained in the Annex or in the body of the Regulation. We understand that the proposal refers to the definitions contained in other instruments, that’s why it should make an express reference to the definitions of those instruments to give more clarity. It should be clarified whether the crisis that triggers this Regulation needs</p> |

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| | <p>to occur throughout the Union, in a substantive part, or if it only takes place in one State, as well as the temporal scope and effects of the licenses in case the crisis subsides in a tiered manner in different countries.</p> <p>FI (Comments): FI is in favor of voluntary agreements' priority to be explicitly mentioned in the text of the Regulation.</p> <p>SE (Comments): In general, it needs to be made even clearer in the regulation that a compulsory license always is a measure of last resort when voluntary agreements are refused.</p> <p>IT (Drafting): This Regulation has the objective to ensure that in crisis <i>a temporary and non-exclusive Union compulsory license may be granted to protect the public interest in the context of cross-border crisis or emergency situations</i> in the Union has access to crisis-relevant products. To this end, this Regulation lays down rules on the procedure and conditions for the granting of a Union compulsory licence of intellectual property rights that are necessary for the supply of crisis-relevant products to the Member States in the context of a Union crisis or emergency mechanism. the Commission may grant a Union compulsory license.</p> |

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| | IT (Comments): Emergency should be included as it is part of the mechanism in annex. |
| Article 2 | PL (Comments): The proposal envisages the possibility of granting a Union compulsory licence across various IPR, such as patents (including published patent applications), utility models, and SPCs. It may be prudent to consider expanding this scope to include industrial designs, given that a “crisis-relevant product” as defined in the Proposal could also be protected as an industrial design. Moreover, as the proposal includes patent applications, in the category mentioned above, it would be sensible to consider analogous approach in the case of utility models. |
| Scope | |
| 1. This Regulation establishes Union compulsory licensing of the following intellectual property rights in force in one or more Member States: | ES (Comments): Article 2 raises doubts regarding the possibility of subjecting patent applications to a compulsory license. Given that the claims presented in the application can be modified during the procedure, it would not be pertinent for the compulsory license to automatically extend to the granted patent, whose object could have been altered. Although a patent application has effects (provisional protection), this is |

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| | conditional on the patent being finally granted. Furthermore, the scope of protection will be determined retroactively depending on how it was finally granted. |
| (a) patents, including published patent applications; | <p>PT (Comments): The scope of the compulsory license is defined in this Article as including patents, published patent applications, supplementary protection certificates and utility models. In this Article, the granted patents were included, as well as its published applications. However, regarding utility models, another way to protect inventions, only the granted utility models were included. This seems somehow inconsistent. Therefore, for the sake of harmonisation and coherence, we consider that the options regarding patents and utility models should be the same.</p> <p>NL (Comments): Reservations about inclusion of patent applications. (1) Article 31 TRIPS only refers to subject matter <i>of a patent</i>, not to applications and (2) scope of protection can change (significantly) in process from patent application to granted patent.</p> <p>DE (Drafting): (a) patents, including published patent applications;</p> |

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| | <p>DE (Comments): Please delete – here and elsewhere in the text – references to published patent applications. The German Federal Government rejects EU-wide compulsory licences for published patent applications. There is no evidence-based justification for such a broad scope of application.</p> <p>FI (Comments): FI has some reservations on the inclusion of patent applications under the scope of the Regulation</p> <p>SE (Comments): Inclusion of patent applications needs to be discussed from a TRIPS perspective.</p> |
| | |
| (b) utility models; or | <p>ES (Comments): Although we do not consider that patent applications should be subject to compulsory licenses, we do not understand why, in that case, the utility model applications are not mentioned.</p> |
| | |
| (c) supplementary protection certificates; | |
| | |
| 2. This Regulation is without prejudice to the rules laid down by other Union legal acts regulating copyright and | |

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| <p>related rights, including Directive 2001/29, Directive 2009/24 and the <i>sui generis</i> rights granted by Directive 96/9/EC on the legal protection of databases.</p> | <p>NL (Comments): What stands out in the article 2 on scope is that trade secrets are not mentioned. Directive 2001/29, 2009/24 and 96/9 are all mentioned, but relation to Trade Secrets Directive (EU) 2016/943 is unclear. This proposal deals with (theoretical) patent barriers only. Trade secrets are not and should not be in scope. Wording should be included to clarify that this (proposed) regulation is without prejudice to the rules on the protection of undisclosed know-how and business information as laid down in Directive 2016/943.</p> <p>DE (Drafting): 2. This Regulation is without prejudice to the rules laid down by other Union and national legal acts regulating copyright and related rights, including Directive 2001/29, Directive 2009/24, and the <i>sui generis</i> rights granted by Directive 96/9/EC on the legal protection of databases and the protection of trade secrets as defined in Directive (EU) 2016/943.</p> <p>DE (Comments): Please clarify that rights-holders are not obliged to disclose trade secrets under this regulation. In light of the non-specific power of the European Commission to adopt “<i>complementary measures</i>” (Article 8(1)(h) and Article 14(2) of the proposal) as well as the obligation of the rights-holder and licensee to cooperate “<i>in good faith</i>” (Article 13 of the proposal) such clarification seems necessary, as the disclosure of trade secrets is</p> |

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| | <p>irreversible.</p> <p>FI (Comments): It should be ensured that trade secrets remain outside of the scope of application of the CL regulation.</p> <p>DK (Comments): As mentioned at the last working group meeting, Denmark considers the protection of trade secrets to be essential. Trade secrets may have value way beyond the actual patent, and once they are handed over their value is zero. Therefore, trade secrets <u>must</u> always be protected.</p> <p>SE (Comments): Should be discussed to exclude trade secrets and know how or to at least make clear definitions of what is included, given the provisions on additional measures in article 8 and 14.</p> |
| Article 3 | <p>DE (Comments): As stated above, Germany explicitly reserves the right to make further comments – also on Art. 3. In particular, the Commission has not provided a convincing explanation on the definition of “crisis-relevant products” so far. Nature and scope remain unclear. Against this background, we welcome the Commission’s intention to provide concrete examples during the next session of the WG.</p> |

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| Definitions | <p>NL (Comments): The definitions and wording used in the proposal seem to lack sufficient clarity on several points. This concerns, for instance, the wording of the different crises covered and the crisis-related critical products. Consistency has to be verified for all crisis-instruments mentioned in the Annex.</p> |
| For the purposes of this Regulation, the following definitions shall apply: | <p>DE (Drafting): For the purposes of this Regulation, the following definitions shall apply: (aa) "crisis or emergency" refers to a crisis or emergency mode which has been activated or declared pursuant to one of the Union Acts listed under Article 4;</p> <p>DE (Comments): The meaning of the term “crisis or emergency” should be clarified.</p> <p>ES (Comments): In general, the definitions are very broad. In particular, as in the case of Article 1, the imprecision of the concept of “crisis-relevant products” combined with the vagueness of the concept “crisis” does not promote legal certainty, since it extends the scope to practically anything. In relation to products, throughout the text it is mentioned “critical product” and “crisis-relevant product”, although in Art. 3 there’s a definition, it is a very subjective concept in which different interests, can</p> |

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| | <p>come into play. Each country may consider different products as indispensable. These differences should be assessed by the advisory body formed by experts in different fields.</p> <p>SE (Comments): Crucial to make all definitions as precise as possible. The terms crisis and emergency should preferably be defined in this instrument and not only in regulations in the annex.</p> |
| | <p>IT (Drafting): <i>(-a new) ‘crisis mode or emergency mode’ means a crisis mode or an emergency mode, as applicable, listed in the Annex to this Regulation, which has been activated or declared in the context of a Union crisis or emergency mechanism listed in that Annex in accordance with one of the Union acts listed therein</i></p> <p>IT (Comments): Crisis should be defined in the legislation to ensure consistency with the intent of the legislation. The definition should comply with:</p> <ul style="list-style-type: none"> • Art. 3 SMEI (draft) [COM(2022) 459] • Art. 3 SCBTH Reg. 2022/2371 • Art. 2 Reg 2022/2372 - framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level • Art. 2 Reg. 2017/1938 - concerning measures to safeguard the |

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| | security of gas supply Chips act Reg. 2023/1781 |
| (a) ‘crisis-relevant products’ means products or processes that are indispensable for responding to a crisis or emergency or for addressing the impacts of a crisis or emergency in the Union; | <p>EE (Drafting): The proposal doesn’t very specifically clarify which goods qualify as “important in a crisis”. Article 1 of the regulation as well as recitals 2 and 32 speak of crisis-relevant products. The explanatory memorandum, under the heading “Reasons for and objectives of the proposal” also refers to health products, vaccines and therapeutics in the context of COVID-19 lessons. Article 3 gives some guidance in this regard, but not very specifically. We thus <i>consider it necessary that the goods or products</i> encompassed by the proposal <i>be more precisely defined</i> in either the regulation text (possibly here under Article 3) or in the recitals. At the same time we also acknowledge that giving any highly exhaustive definitions in a totally foreseeable manner may be difficult. However, this’d be an important point of clarity for stakeholders.</p> <p>EE (Comments): In addition to giving clearer definitions of the crisis-relevant products to be covered, we’d appreciate a broader overview of the products covered based on the annex regulations (giving examples under each regulation of possible products covered).</p> <p>PL (Comments): Terms “products” and “processes” are used without really defining them.</p> |

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| | <p>It would be a good idea to clear up what these terms mean the Regulation.</p> <p>NL (Comments): Consistency with all relevant crisis-instruments should be thoroughly assessed and definition should be made more precise / clearer based on findings of that assessment.</p> <p>DE (Drafting): (a) ‘crisis-relevant products’ means products or processes that are indispensable for responding to a crisis or emergency or for addressing the impacts of a crisis or emergency in the Union;</p> <p>DE (Comments): Please delete the second half sentence since a reference to “impacts” seems rather vague and too broad – also in light of the already pretty far-reaching definition of “crisis-relevant products”.</p> <p>FI (Comments): FI has concerns about the word ‘processes’ here. It’s significance is broader than that of ‘products’. ‘Processes’ might be understood to include know-how, or even trade secrets. It may be confusing if ‘crisis relevant product’ can be a process, as the significance of ‘process’ is different from that of ‘product’. Some examples of crisis relevant products could be mentioned here.</p> |

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| | <p>DK (Comments): Denmark finds this definition confusing. A process is not a product.</p> <p>SE (Comments): This definition need to be better defined as to create legal certainty of what products are within the scope.</p> <p>IT (Drafting): (a) ‘crisis-relevant products’ means products or processes that are indispensable for responding to a crisis or emergency or for addressing the impacts of a crisis or emergency in the Union <i>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;</i></p> |
| | |
| (b) ‘relevant activities’ means the acts of making, using, offering for sale, selling or importing. | |
| | |
| (c) ‘rights-holder’ means a holder of any of the intellectual property rights referred to in Article 2(1); | |
| | |
| (d) ‘protected invention’ means any invention protected by any of the intellectual property rights referred to in Article | |

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| 2(1); | <p>PL (Comments): Generally, inventions are protected by patents. However, other exclusive rights such as utility models, are protected by protection rights, and medicinal products and plant protection products are protected by SPCs. Thus, it does not seem appropriate to categorize all industrial property items under an umbrella term “protected invention”.</p> |
| <p>(e) ‘Union compulsory licence’ means a compulsory licence granted by the Commission to exploit a protected invention of crisis-relevant products for any of the relevant activities in the Union;</p> | <p>DE (Drafting): (e) ‘Union compulsory licence’ means a compulsory licence granted by the Commission as a measure of last resort and subject to the conditions set out in this Regulation, in order to exploit a protected invention of crisis-relevant products for any of the relevant activities in the Union Member States affected by the underlying crisis or emergency;</p> <p>DE (Comments): (cf. comment under Art. 1)</p> <p>FI (Comments): What does ‘for any of the relevant activities in the Union’ mean here? This seems all-encompassing, a clearer framing is needed here. ‘In the Union’ could be understood imply activities by other bodies of the Union than the COM. Is this intended? If so, it should be clarified.</p> |

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| | <p>DK (Comments): Denmark has strong reservations about granting the Commission exclusive competencies to issue compulsory licenses. What does the Commission refer to in relation to ‘relevant activities’?</p> |
| (f) ‘customs authorities’ means customs authorities as defined in Article 5, point (1), of Regulation (EU) No 952/2013 of the European Parliament and of the Council ¹³ ; | |
| Article 4 | <p>DE (Comments): As stated above, Germany explicitly reserves the right to make further comments – also on Art. 4 and the Annex. The discussions in the WG have shown so far, that a better understanding of the reasons for the selection and the functioning of the EU-crisis instruments listed in the Annex is particularly necessary before dealing with concrete textual amendments. In any case, the reference to a broad list of EU crisis instruments is not convincing. The character of compulsory licenses as a last resort requires at least further explanations. The selection of the instruments will have to be reconsidered in light of the additional explanations by the Commission during the next WG.</p> |

¹³ Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (OJ L 269, 10.10.2013, p. 1).

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| Union compulsory licence | |
| <p>The Commission may grant a Union compulsory licence where a crisis mode or an emergency mode listed in the Annex to this Regulation has been activated or declared in accordance with one of the Union acts listed in that Annex.</p> | <p>PT (Comments): Specific and practical examples of crisis and its triggering factors should be included in the annex as well, in order to better understand the situations where this Regulation will be applied.</p> <p>AT (Drafting): The Commission may, <u>as a last resort and with the approval of the Council</u>, grant a Union compulsory licence where a crisis mode or an emergency mode listed in the Annex to this Regulation has been activated or declared in accordance with one of the Union acts listed in that Annex <u>and where voluntary agreements were unsuccessful or would not prove efficient</u>.</p> <p>AT (Comments): Adding “as a last resort” makes the nature of the instrument more clear. The Council should be involved in the decision-making. One way to ensure Council participation would be to use the examination procedure as opposed to the advisory procedure in the comitology for the implementing act. Alternatively, it should be considered to use an EU court for the granting of the CL.</p> |

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| | <p>EE (Comments): We support that the regulation should provide a clear a definition as possible regarding the triggers of the EU compulsory licensing scheme. The whole procedure to be followed and powers granted via it should be as clear as possible for both the public as well as patent holders. I.e. it would be preferable if the triggers would be better set out in the text of this regulation, instead extensive reference be made to the annexed regulations.</p> <p>NL (Comments): Wording should be included to clarify that this new instrument would only be used during major crisis affecting the EU, as a <u>measure of last resort</u> / it must only be granted <u>exceptionally</u> taking into account <u>public interest</u> and under conditions that <u>take into account the interests of the rights-holder</u>.</p> <p>With regard to choice of crisis-instruments/annex: (1) We kindly ask the Commission to substantiate the usefulness and necessity of including for each crisis instrument mentioned. And provide some clear examples. What is the relevance of patents in the various areas and which crisis relevant products are intended to be covered; As indicated during the council working parties, the Dutch government is not convinced about the usefulness and necessity of including all mentioned crisis instruments (more specifically SMEI , serious cross-border health threats , HERA , Chips Act and gas supply security measures). In neither the proposal or the impact assessment</p> |

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| | <p>we were able to find substantiation. For example: why is the Chips Act included? And with regard to for example the gas supply regulation, what is the relevance of patents in that area? We look forward to the examples and substantiation for each instrument.</p> <p>We would also like to understand the rationale to not include other EU crisis instruments, e.g. the Integrated Political Crisis Response (IPCR). This is the Council's central cross-sector EU crisis management instrument.</p> <p>DE (Drafting):</p> <p>1. The Commission may grant, as a measure of last resort and subject to the conditions set out in Paragraph 2, a Union compulsory licence only in case and for the duration of one of the following crises or emergencies pursuant to the relevant Union Acts: where a crisis mode or an emergency mode listed in the Annex to this Regulation has been activated or declared in accordance with one of the Union acts listed in that Annex:</p> <p>(a) a public health emergency at Union level formally recognized by means of a Commission implementing act according to Article 23 of Regulation (EU) 2022/2371;</p> <p>(b) an emergency framework activated by the adoption of a Council Regulation according to Article 3 of Regulation (EU) 2022/2372;</p> <p>2. Without prejudice to Article 7, a Union compulsory licence shall only be granted under the following preconditions:</p> <p>(a) the rights-holder was provided with a reasonable opportunity to negotiate a voluntary licence with potential licencees over the</p> |

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| | <p>permission to exploit a protected invention of crisis-relevant products for any of the relevant activities in the affected MS prior to the granting of a Union compulsory licence;</p> <p>(b) crisis-relevant products are produced in insufficient quantity which results from the exercise of the intellectual property rights referred to in Article 2 (1), in particular a failure to provide a licence;</p> <p>(c) the crisis or emergency causes a public interest which calls for the grant of a Union compulsory licence and outweighs the rights and interests of the rights-holder.</p> <p>DE (Comments): For the sake of legal clarity, the relevant EU-crisis instruments should be (exhaustively) listed within the Regulation. The selection of the instruments will have to be reconsidered in light of the additional explanations by the Commission during the next WG. The current listing is not convincing and therefore only of preliminary nature. Please add a new Para. 2 to clarify certain conditions for the granting of a compulsory license in order to limit the Commission’s room for maneuver to a certain extent.</p> <p>FI (Comments): The different Union acts/instruments listed in the Annex have different delegated powers. We are not fully convinced of the adequacy of COM issuing the CL. The inter-references between the CL Regulation and the other crisis instruments are potentially confusing and should be clarified. Also, unpredicted crises may fall outside the scope of this Regulation.</p> |

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| | <p>DK (Comments): As per the comment above, Demark has strong reservations about granting the Commission exclusive competencies over the issuing of compulsory licenses. Furthermore, Denmark has reservations about making decisions on compulsory licensing till SMEI has been adopted given its link to the crisis instrument. In case SMEI is not adopted, it will put the need for a compulsory licensing instrument further into question.</p> <p>SE (Comments): Legally abigious to definer the actual scope and the triggers of the regulation in other regulations. Could for example be made clear that products related to national defence is outside of the scope (due to being outside of reguations in the annex). Should be further discussed if the Commission is the right instance to issues a CL, or if the decision making right should be joint.</p> |
| Article 5 | <p>PL (Comments): Given the unique nature of a Union compulsory licence, it is crucial to precisely delineate the conditions for granting such a licence. The scope, duration, and territorial extent of the licence should be clearly defined, ensuring that the relevant provisions are worded with maximum precision. A Union compulsory licence constitutes a limitation of exclusive rights,</p> |

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| | <p>and thus, it is necessary to balance the purpose behind granting it with the rights of the rights-holder. It is essential to clarify whether the scope of information conveyed during the compulsory licence process will also cover the necessary “know-how” for technology transfer especially for the solution seen as a “crisis-relevant product”.</p> <p>DK (Comments): Denmark generally finds that the language in this article is very unclear.</p> |
| General conditions of a Union compulsory licence | <p>AT (Comments): In Austria’s view, the conditions in this article should be more clear; furthermore, there are additional conditions listed in subsequent articles of the proposal; it could be clarified further how they interact and that they all must be fulfilled.</p> <p>ES (Comments): This article raises two questions. First, although the Regulation mentions non-exclusive licenses, the general conditions and the procedure established for granting them represent an alteration of the usual system of granting licenses since it will be the Commission that initiates and determines who will be the recipient of the licenses. In the Spanish procedure, it is the future licensee who must initiate the procedure. An open licensing framework should be established for other operators to participate.</p> |

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| | <p>Secondly, we have doubts about the way in which the European system of compulsory licenses will be structured in the event that the invention subject to the compulsory licensing regime is protected in some Member States, but not in others, thus its manufacture in the latter would be free. Questions also arise regarding the duplication of licenses in case of licensing both in a Member State and in the EU. Therefore, a product manufactured under the protection of a CL could circulate freely within the EU, even in those states not affected by the crisis.</p> <p>Finally, doubts are raised about the term of the compulsory license, as well as the territorial scope.</p> <p>SE (Comments): Conditions should be properly defined in relation to the full proposal and contain clear definitions.</p> |
| 1. The Union compulsory licence shall | <p>IT (Drafting): The Union compulsory <i>license that may be granted by the Commission in accordance with Article 4 shall, notwithstanding the obligations to be fulfilled by the licensee in accordance with Article 10:</i></p> |
| (a) be non-exclusive and non-assignable, except with that part of the enterprise or goodwill which enjoys such compulsory licence; | <p>FI (Comments): What does ‘except with that part of the enterprise or goodwill which enjoys such compulsory licence’ mean here?</p> |

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| | <p>DK (Comments): Denmark does not understand the wording of “enterprise or goodwill which enjoys such compulsory licence”. It is unclear what ‘goodwill’ refers to and what is meant by ‘enjoys’.</p> |
| <p>(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;</p> | <p>PT (Comments): Considering the extraordinary nature of the compulsory licenses, it is crucial to define their scope, duration and territorial coverage clearly and precisely.</p> <p>NL (Comments): Clarify that scope includes volume/number of crisis-relevant-products. Consider including a maximum period (which can be extended). With regard to the Chips-act (if included in the Annex), it should be clarified that the scope is limited to non-commercial government use and legal remedies for anti-competitive practices as required by article 31(c) TRIPS.</p> <p>DE (Drafting): (b) have a material and territorial scope and duration that is strictly limited to the purpose and necessities for which the Union compulsory licence is granted and be strictly limited to the scope and duration of the crisis or emergency mode in the framework of which it is granted;</p> |

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| | <p>DE (Comments): Amendments shall reflect that a Union compulsory licence only serves as a last resort mechanism and needs to be strictly limited to what is necessary.</p> <p>DK (Comments): Denmark finds the wording to be quite unclear. Reference to the relevant article that covers the timeframe is also missing.</p> <p>IT (Drafting): (b) have a <i>strict limitation concerning</i> scope, <i>field of use, necessary quantities</i>, and <i>a</i> duration that is is limited to the <i>fully in line with the specific</i> purpose for which the compulsory licence granted and limited is issued, as well as strictly linked to the scope and duration of the crisis or emergency mode in the framework of under which it is granted <i>within the Union</i></p> |
| (c) be strictly limited to the relevant activities of crisis-relevant products in the Union; | <p>DE (Drafting): (c) be strictly limited to the relevant activities that are necessary for the supply of crisis-relevant products in the Union Member States affected by the underlying crisis or emergency;</p> |

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| | <p>DE (Comments): (cf. comment under Art. 1)</p> <p>IT (Drafting): (c) be strictly limited to the relevant <i>and properly justified</i> activities of crisis-relevant products in the Union;</p> |
| (d) only be granted against payment of an adequate remuneration to the rights-holder; | <p>PT (Comments): The expression ‘adequate remuneration’ is not clear <i>per se</i>.</p> <p>NL (Comments): Article 31(h) TRIPS non-compliance shall be addressed in more detail after discussion of Article 9 of the proposal.</p> <p>FI (Comments): Reference could be made to Art. 9 on remuneration.</p> <p>DK (Comments): As per comment above, the reference to the relevant article is missing.</p> <p>IT (Drafting): (d) only be granted against payment of an adequate remuneration to the</p> |

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| | rights-holder <i>determined in accordance with article 9</i> ; |
| (e) be limited to the territory of the Union; | <p>DE (Drafting): (e) be strictly limited to the territory of the Union;</p> <p>DE (Comments): Clarification in light of the underlying objective.</p> <p>IT (Drafting): (e) be <i>strictly</i> limited to the <i>precisely defined</i> territory of the Union</p> |
| (f) 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. | <p>PT (Comments): What are the criteria used to decide whether a person is deemed to be in a position to exploit the protected invention and how is that assessment made? Minimum acceptance requirements should be established for a person to be deemed to be in a position to exploit the protected invention</p> <p>PL (Comments): It is worth contemplating whether the definition specifying the entity eligible for the grant of a Union compulsory licence is sufficiently precise, i.e. will advisory bodies be able to discern and effectively assess the capability of the respective entity to fulfil the purpose of the compulsory license grant.</p> |

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| | <p>DE (Drafting): (f) only be granted to a person deemed to be that is 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.</p> <p>DE (Comments): Question: does “person” entail also companies and other entities? It seems rather unlikely, that a compulsory licence would be granted to a natural person, isn’t it? In any case, the wording should be more concrete in order to ensure, that a potential licensee is able to cope with obligations under this Regulation.</p> <p>FI (Comments): A ‘person’ should perhaps be ‘legal entity’ instead.</p> <p>DK (Comments): Denmark worders about the reference to ‘a person’ rather than a company.</p> |
| 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. | <p>NL (Comments): Reservations about inclusion of patent applications. (1) Article 31 TRIPS only refers to subject matter <i>of a patent</i>, not to applications and (2) scope</p> |

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| | <p>of protection can change (significantly) in process from patent application to granted patent.</p> <p>DE (Drafting): 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.</p> <p>DE (Comments): (cf. comment under Art. 2)</p> |
| <p>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.</p> | |
| Article 6 | |
| Advisory body | <p>ES (Drafting): Advisory Body Expert and Independent.</p> |

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| | <p>ES (Comments): This "Advisory body" as drafted in the regulations is undefined. While its functions are listed, neither its composition nor its mode of operation is specified. Given the stereotypes about patents, which are present in all media debates, or the political biases associated with the questioning of the patent system, an advisory body constituted without the requirements of quality, professionalism and independence of its members or its rules of operation, may tend to give distorted or flawed results and diagnoses. It can only be constituted by patent experts from the respective national offices, absolutely independent and with previous competences in the analysis and granting of national compulsory licenses. It is suggested that the name be changed to "Advisory Body Expert and Independent".</p> |
| <p>1. When the Commission considers the granting of a Union compulsory licence, it shall without undue delay consult an advisory body.</p> | <p>PT (Comments): The expression ‘without undue delay’ is not sufficiently clear. A time limit should be established.</p> |
| <p>2. The advisory body referred to in paragraph 1 shall be the advisory body competent for the Union crisis or emergency mechanism as listed in Annex I to this Regulation (the ‘competent advisory body’). For the purposes of the present Regulation, the competent advisory body shall assist and advise the Commission as regards the following tasks:</p> | <p>PT (Comments): Regarding the advisory body, it is necessary to ensure IP competences</p> <p>ES (Comments): It would be necessary to include within the tasks of the advisory body the mandatory evaluation of the qualifications and capabilities of the</p> |

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| | licensees in order to guarantee that they can carry out the production tasks of the “crisis-relevant products”. Spanish law establishes the need for the applicant of a compulsory license “to have the means to carry out real and effective exploitation of the patented invention”. |
| (a) the gathering of crisis-relevant information, market intelligence and the analysis of those data; | |
| (b) the analysis of the crisis-relevant information gathered by Member States or the Commission and aggregated data received by other crisis-relevant bodies at Union and international level; | |
| (c) the facilitation of exchanges and sharing of information with other relevant bodies and other crisis-relevant bodies at Union and national level, as well as at international level, where appropriate; | |
| (d) the identification of the rights protecting the crisis-relevant product; | |
| (e) the establishment of whether there is a need to grant a Union compulsory licence; | |
| (f) the identification and consultation of the representatives of right holders or their representatives as well as potential | |

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| licensees and consulting other economic operators, and the industry; | PT (Comments): How is the identification and consultation of potential licensees carried out? |
| (g) the establishment, if relevant, of whether the criteria for termination or modification of the Union compulsory licence set out in Article 15 have been fulfilled. | |
| 3. The advisory body shall cooperate and coordinate closely, where appropriate, with other relevant crisis-related bodies and with intellectual property offices at Union and national level. | |
| 4. For the purpose of the present Regulation, the Commission: | |
| (a) shall ensure participation and invite representatives of other crisis-relevant bodies at Union level as observers to the relevant meetings of the advisory body in order to ensure coherence with the measures implemented through other Union mechanisms; and | |
| (b) may invite representatives of the European Parliament, representatives of economic operators, right holders, potential licensees, stakeholder organisations, social partners and experts | ES (Comments): Section 4 b) indicates the possibility of inviting experts to the meetings of |

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| to attend meetings of the advisory body as observers. | the advisory body. We stress that technical experts should not be invited, they should rather be members of the ad hoc advisory body. |
| <p>5. In the absence of any existing competent advisory body, the tasks referred to in paragraph 2 shall be performed by an ad hoc advisory body set up by the Commission (the ‘ad hoc 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.</p> | <p>PT (Comments): It is necessary to ensure IP competences of the ad hoc advisory body.</p> <p>ES (Comments): With regard to the ad hoc advisory body provided for in this Regulation, the following clarifications should be made: In order to guarantee the impartiality and rigor of the decisions of both the advisory body and the Commission, it should be composed of representatives of the organizations of the Member States that are in charge of studying and granting national compulsory licenses. The participation of national experts in the field of industrial property, providing technical criteria, constitutes a guarantee both for the rights of the owners of the industrial property and for the correct functioning of the European system of compulsory licenses.</p> |
| <p>6. The Commission shall adopt an implementing act laying down the rules of procedure for the ad hoc advisory body referred to in paragraph 5. The rules of procedure shall specify that the ad hoc advisory body shall not be set up for a period exceeding the duration of the crisis or emergency. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 24 (3).</p> | <p>ES (Comments): We consider that section 6 of the article should structure the advisory body within a professional, technical and independent framework that guarantees the integrity of its resolutions. The proposed Regulation suffers from the fact that the final decision must be taken by the Commission, which, given that the opinion of the</p> |

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| | advisory body is not binding, may eventually disregard rigorous technical reasons and impose arbitrary reasons to satisfy political or image needs before the public opinion of the moment. |
| Article 7 | |
| Procedure for granting a Union compulsory licence | |
| 1. The competent or, where relevant ad hoc, advisory body referred to in Article 6 shall provide the Commission with an opinion without undue delay. That opinion shall be issued in accordance with the rules of procedure of the advisory body and shall contain an assessment of the need for a Union compulsory licence and the conditions for such licence. The opinion shall take account of the following: | PT (Comments): The expression ‘ without undue delay ’ is not sufficiently clear. A time limit should be established. |
| (a) the nature of the crisis or emergency; | |
| (b) the scope of the crisis or emergency and how it is expected to evolve; | |
| (c) the shortage of crisis-relevant products and the existence of other means than a Union compulsory licence that could adequately and swiftly remedy such shortage. | |
| | |

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| <p>2. The opinion of the advisory body shall not be binding on the Commission. The Commission may set a time limit for the advisory body to submit its opinion. The time limit shall be reasonable and appropriate to the circumstances of the situation, taking particular account of the urgency of the matter.</p> | <p>PT (Comments): 'The time limit shall be reasonable and appropriate' is not sufficiently clear. A time limit should be established.</p> <p>ES (Comments): (According to section 2 of the article “the opinion of the advisory body shall not be binding on the Commission”, in our opinion it is necessary to establish the binding nature of the opinion of the body. It should not be possible to grant compulsory licenses without the advisory body, made up of technically trained people and experts in the field, giving approval. Otherwise, it is not appreciated what value an opinion without technical criteria and not binding on the decision-making body can provide. The participation of the body throughout the process of granting compulsory licenses (articles 1 to 11) and the imposition of fines (articles 16 and 17) should be mandatory and its opinion binding.) If a binding opinion is discarded, then the Commission should propose the Council the initiation of a Compulsory Licensing process through an implementing act like article 14.2 of the Proposal for a Regulation establishing a SMEI On the other hand, art. 7, section 2 provides that the opinion by the advisory body must be issued within a reasonable time, but it does not indicate a maximum period although it would be an emergency situation.</p> <p>DK (Comments): The value of the opinion of the advisory body is vague and unclear. It</p> |

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| | may be considered to introduce some sort of formal process, if the Commission decides to grant a CL against the recommendation of the advisory board. |
| 3. Before the granting of a Union compulsory licence, the Commission shall give the rights-holder and the licensee an opportunity to comment on the following: | <p>ES (Comments): The procedure established in article 7 only allows the owner to be informed and to be heard without the possibility of entering the procedure. The possibility of active participation of the holder in the procedure is a basic characteristic of the Spanish system of compulsory licenses. The procedure established in this article begets legal insecurity for the owner since it does not allow him to present his arguments or receive a motivated response in one sense or another. The holder should not only be able to refute the arguments, but should be able to access all the documents in the file as early as possible.</p> |
| (a) the possibility to reach a voluntary licensing agreement with manufacturers on intellectual property rights for the purpose of manufacturing, using and distributing the crisis-relevant products; | <p>ES (Comments): Prior negotiation should be mandatory between the owner of the IP subject to a compulsory license and the future licensee in order to comply with the exceptionality and last resort tool requirements that the Commission intends to establish. If the negotiation of voluntary agreements is considered to be the most effective option (Recital 1), it is necessary for the Regulation to promote this preliminary phase before initiating the administrative procedure for granting a compulsory license.</p> |
| (b) the need to grant the Union compulsory licence; | |

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| (c) the conditions under which the Commission intends to grant the Union compulsory licence, including the amount of the remuneration. | |
| 4. The Commission shall notify the rights-holder and the licensee as soon as possible of the fact that a Union compulsory licence may be granted. Wherever the identification of the rights-holders is possible and does not cause significant delay, the Commission shall notify them individually. | <p>PT (Comments): 'as soon as possible' is not sufficiently clear. A time limit should be established for the Commission to notify the rights-holder and the licensee.</p> <p>ES (Drafting): Delete sentence crossed out</p> <p>ES (Comments): To preserve the owner's rights, it is necessary to know which titles IP rights can be subject to the procedure. In section 4, the Regulation states that "Wherever the identification of the rights-holders is possible and does not cause significant delay, the Commission shall notify them individually." It must be taken into account that industrial property rights are registration rights, whose data are free accessible in all public databases. This data includes the patent holder, its duration, the countries to which it extends and to which it does not, and of course its detailed technical content in such a way that it can be put into practice. Patent databases are commonly used and are well known by all stakeholders involved in the R&D system</p> |

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| | or technological industry. It is naive and shows a great ignorance of the IP system to show that patent data are unknown or confusing or are hidden. We consider that in order to begin any compulsory licensing procedure it is necessary to determine what the necessary product is and what patents are involved in its production. Their prompt and correct identification constitutes a necessary requirement to guarantee the rights of the owners, to allow a prior negotiation that leads to an amicable agreement and avoid the process of granting a compulsory license. |
| 5. When the Commission considers the granting of a Union compulsory licence, it shall without undue delay publish a notice to inform the public about the initiation of the procedure under this article. This notice shall also include, where already available and relevant, information on the subject of the compulsory licence and an invitation to submit comments in accordance with paragraph 3. The notice shall be published in the Official Journal of the European Union. | <p>PT (Comments): ‘it shall without undue delay publish a notice’ is not sufficiently clear. A time limit should be established for publication</p> <p>ES (Comments): It would be necessary for the announcement in the Official Journal of EU referred to in section 5 to mention the fact that the compulsory license is “non-exclusive” and that the entry of new economic operators is permitted.</p> |
| 6. When assessing whether a Union compulsory licence is to be granted, the Commission shall consider the following: | |
| (a) the opinion referred to in paragraph 2; | |
| (b) the rights and interests of the rights-holder and | |

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| the licensee; | |
| | |
| (c) existing national compulsory licences reported to the Commission in accordance with Article 22. | |
| | |
| 7. Where the Commission finds that the requirements for a Union compulsory licence are met, the Commission shall grant it by means of an implementing act. The implementing act shall be adopted in accordance with the advisory procedure referred to in Article 24(2). On duly justified imperative grounds of urgency relating to the impacts of the crisis, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 24(4). In case of procedure under Article 24(4), the implementing act shall remain in force for a period not exceeding 12 months. | PT (Comments): What are the requirements for the grant of a Union compulsory license? The requirements should be properly defined. |
| | |
| 8. When adopting the implementing act, the Commission shall ensure the protection of confidential information. While respecting the confidentiality of the information, the Commission shall ensure that any information relied on for the purpose of its decision is disclosed to an extent that allows to understand the facts and considerations that led up to the adoption of the implementing act. | |
| | |
| Article 8 | |
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| Content of the Union compulsory licence | |
| | |
| 1. The Union compulsory licence shall specify the following: | |
| | |
| (a) the patent, patent application, supplementary protection certificate or utility model for which the licence is granted or, where the identification of those rights would significantly delay the granting of the licence, the non-proprietary name of the products which are to be manufactured under the licence; | <p>EE (Drafting): Article 2(1)(a) of the regulation refers to not <i>unpublished</i> but only <i>published</i> patent applications. In view of this and for the sake of clarity, could the same reference to not simply <i>applications</i> but <i>published applications</i> also be included in article 8(1)(a) and likewise in recital 24 of the regulation?</p> <p>PL (Comments): It seems that specifying the subject-matter of a Union compulsory licence solely by referencing “the non-proprietary name of the products which are to be manufactured under the licence” may be excessively broad. Such a licence could automatically apply to all rights pertaining to the designated product without necessitating the identification of these rights.</p> <p>ES (Drafting): Delete sentence crossed out</p> <p>ES (Comments): As in the previous article, section a) of this article does not promote legal</p> |

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| | certainty by stating that “where the identification of those rights would significantly delay the granting of the licence, the non-proprietary name of the products which are to be manufactured under the licence.” It is necessary to identify the patents, the territories they cover and the remaining validity periods. The inclusion of the NPOs in the advisory body and their participation throughout the process must be guaranteed in order to maintain technical criteria in accordance with the law. |
| (b) the right-holder, provided they can be identified with reasonable efforts having regard to the circumstances, including the urgency of the situation; | <p>PT (Comments): ‘with reasonable efforts’ is not sufficiently clear <i>per se</i>.</p> <p>ES (Comments): Section b) establishes the possibility that the name of the holder may not appear on the compulsory license. The mention of the owner of the affected rights in the license must be a necessary and unavoidable condition for its granting.</p> |
| (c) the licensee, in particular the following information: | |
| (1) name, trade name and registered trade mark; | |
| (2) contact details; | |
| (3) unique identification number in the country where the licensee is established; | |

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| (4) where available, the Economic Operators Registration and Identification (EORI) number; | |
| (d) the duration for which the Union compulsory licence is granted; | |
| (e) the remuneration to be paid to the rights-holder determined in accordance with Article 9; | |
| (f) the non-proprietary name of the crisis-relevant product which is to be manufactured under the Union compulsory licence and its commodity code (CN code) under which the crisis-relevant product is classified, as defined in Council Regulation (EEC) No 2658/87; | |
| (g) the details referred to in Article 10(1)(c), (d) and (e) allowing the identification of the crisis-relevant product manufactured under the Union compulsory licence and, where applicable, any other specific requirement under Union legislation applicable to the crisis-relevant products and allowing its identification. | <p>PL (Comments): The meaning of the term: “other specific requirements under Union legislation” remains unclear. The absence of precise regulation in this regard raises the question of whether such measures could potentially encompass the obligation to disclose confidential and commercially sensitive know-how or trade secrets. Clarification is needed</p> |
| (h) measures complementing the compulsory licence, which are necessary to achieve the objective of the compulsory | |

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| licence. | <p>PL (Comments): The meaning of the term: “measures complementing the compulsory licence” remains unclear. The absence of precise regulation in this regard raises the question of whether such measures could potentially encompass the obligation to disclose confidential and commercially sensitive know-how or trade secrets. Clarification is needed.</p> <p>ES (Comments): In article h) it would be appropriate to indicate what exactly is meant by “measures complementing the compulsory licence, which are necessary to achieve the objective of the compulsory licence”. It could be understood that the compulsory license would extend to technical know-how or other commercial secrets. In this regard, it is necessary to remember that in the Directive 2016/943, it is stated that a commercial secret include a “diverse range of information that extends beyond technological knowledge to commercial data such as information on customers and suppliers, business plans, and market research and strategies”. If technical knowledge is understood to be affected by compulsory licenses, it could go against the provisions of Article 31 TRIPS, which provides for compulsory licenses only in the case of patents, not for other modalities such as trade secrets, designs or trademarks.</p> |
| 2. By way of derogation from paragraph 1, point (e), the Commission may determine the remuneration after the granting of the licence, by way of an implementing act, where that | |

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| determination requires, further investigation and consultation. This implementing act shall be adopted in accordance with the rules referred to in Article 7(6) (a) and (b), 7(7) and 7(8). | |
| Article 9 | |
| Remuneration | |
| 1. The licensee shall pay an adequate remuneration to the rights-holder. The amount of the remuneration shall be determined by the Commission and specified in the Union compulsory licence. | |
| 2. The remuneration shall not exceed 4 % of total gross revenue generated by the licensee through the relevant activities under the Union compulsory licence. | <p>PL (Comments): It is worth considering the introduction of a mechanism allowing for a more flexible determination of the amount of remuneration in cases where the remuneration set at the specified level proves inadequate. The introduction of an indexation mechanism enabling an increase in remuneration in justified cases may be worthy of consideration.</p> <p>ES (Comments): The consideration of a cap of 4% of the total gross revenue generated by the licensee does not seem reasonable taking into account that this Regulation goes beyond the health and pharmaceutical field from which this figure comes (Regulation 816/2006). Therefore, the assessment of</p> |

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| | <p>remuneration should be based on the type of product to which the compulsory license is being applied to.</p> <p>DK (Comments): The level of 4 pct. seems arbitrary and potentially unproportionate. Please elaborate on the reasons behind.</p> |
| <p>3. When determining the remuneration, the Commission shall consider the following:</p> | |
| <p>(a) the economic value of the relevant activities authorised under the Union compulsory licence.</p> | |
| <p>(b) whether the rights-holder has received public support to develop the invention.</p> | |
| <p>(c) the degree to which development costs have been amortized by the rights-holder.</p> | |
| <p>(d) where relevant, the humanitarian circumstances relating to the granting of the Union compulsory licence.</p> | |
| <p>4. If the published patent application for which a compulsory licence has been granted does not subsequently lead to the granting of a patent, the rights-holder shall refund the remuneration paid under this article to the licensee.</p> | |

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| Article 10 | <p>PL (Comments): There seems to be the need for a precise delineation of the scope of actions to be undertaken by the licensee, as it will facilitate the achievement of the compulsory license’s objective and mitigate the risk of disputes over allegations of improper licensc execution or undue restriction of the rights of the rights-holder. In this regard, particular importance should be accorded to the executive act granting the compulsory licence, wherein it will be imperative to specify the exact number of products that may be manufactured under the licence, principles for designating such products, and the extent of activities permissible under the licence. It is also crucial to establish effective mechanisms for monitoring the execution of the compulsory licence and preventing abuses, including clear principles for judicial oversight of a compulsory licence.</p> |
| Obligations to be fulfilled by the licensee | |
| 1. The licensee shall be authorised to exploit the protected invention covered by the Union compulsory licence only under the following obligations: | |
| (a) the number of crisis-relevant products manufactured under the Union compulsory licence does not exceed what is necessary to meet the needs of the Union; | |

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| (b) the relevant activities are carried out solely for the supply of the crisis-relevant products in the Union market; | |
| (c) the products manufactured under the Union compulsory licence are clearly identified, through specific labelling or marking, as being manufactured and marketed pursuant to this Regulation. | |
| (d) the products manufactured under the Union compulsory licence can be distinguished from products manufactured and marketed by the rights-holder or under a voluntary licence granted by the rights-holder by way of special packaging, colouring or shaping, provided that such distinction is feasible and does not have a significant impact on the price of the products; | |
| (e) the packaging of the products manufactured under the Union compulsory licence and any associated marking or leaflet indicate that the products are subject to a Union compulsory licence under this Regulation and specify clearly that the products are exclusively for distribution in the Union and are not to be exported. | |
| (f) before the marketing of the products manufactured under the Union compulsory licence, the licensee shall make | |

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| available on a website the following information: | <p>ES (Comments): In article 6, we pointed out the need for the advisory body to have among its powers the evaluation of the licensee's capabilities and wherewithal to manufacture the product protected by the patent. In section f) of this article it is necessary to establish the obligation for the licensee to have and demonstrate that capacity to manufacture the invention under the terms established in the compulsory license. This capacity must be previously assessed by the advisory body.</p> |
| (1) the quantities of the products manufactured under the Union compulsory licence per Member State of manufacturing; | |
| (2) the quantities of the products supplied under the Union compulsory licence per Member State of supply; | |
| (3) the distinguishing features of the products under the Union compulsory licence. | |
| The address of the website shall be communicated to the Commission. The Commission shall communicate the address of the website to the Member States. | |
| 2. In the event of a failure by the licensee to fulfil the obligations laid down in paragraph 1 of this Article the Commission may: | |

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| (a) terminate the Union compulsory licence in accordance with Article 14(3); or | |
| (b) impose fines or periodic penalties on the licensee in accordance with Articles 15 and 16. | |
| <p>3. The European Anti-Fraud Office (OLAF) in cooperation with the relevant national authorities of the Member States may, at the request of the rights-holder or on its own initiative, request access to books and records kept by the licensee, for the purpose of checking whether the content and the conditions of the Union compulsory licence, and in general the provisions of this Regulation, have been complied with.</p> | |
| <p>4. The Commission is empowered to adopt implementing acts establishing rules for the specific labelling or marking referred to in paragraph 1, point (c), and for the packaging, colouring and shaping referred to in point (d) as well as rules for their use and, where relevant, their positioning on the product. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 24(2).</p> | |
| Article 11 | |
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| Prohibition of export | |
| The export of products manufactured under a Union compulsory licence is prohibited. | <p>IT (Drafting): The export of products manufactured under a Union compulsory licence is prohibited, <i>except for products exclusively destined for export under Regulation 816/2006.</i></p> <p>IT (Comments): We are waiting for comments from customs authority</p> |
| Article 12 | |
| Customs control | |
| 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 ¹⁴ . | <p>IT (Comments): We are waiting for comments from customs authority</p> |
| 2. Customs authorities shall rely on the Union compulsory license and modifications thereof to identify products that may fall under the prohibition laid down in Article 11. For that | <p>DE (Comments): We ask for clarification as to whether the risk-related information from</p> |

¹⁴ REGULATION (EU) No 952/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 October 2013 laying down the Union Customs Code.

| <p style="text-align: center;">Commission proposal 2023/0129 (COD)</p> | <p style="text-align: center;">Drafting Suggestions and Comments PT – AT – EE – PL – NL – DE – CZ – ES – FI – DK – SE – IT</p> |
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| <p>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>the compulsory license (published by means of an implementing act pursuant to Art. 7 (7) of the draft regulation) should be entered into the European customs risk management system (CRMS2) or into the national risk management system of the customs administration.</p> <p>FI (Comments): FI finds that the relationship between national and EU risk management is somewhat unclear.</p> <p>DK (Comments): Denmark finds that the division between the competent authorities and the customs authorities should remain a national matter. It should be the competent authority who is responsible for inserting information on compulsory licensing into the “relevant customs risk management system,” understood as CRMS, as set out in the preamble (30).</p> <p>IT (Comments): We are waiting for comments from customs authority</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</p> | <p>NL (Comments): Consider clarifying the relationship to the exception of the crisis-critical products covered by Regulation (EC) No 816/2006.</p> |

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| <p>product was manufactured under a Union compulsory license. To assess whether the suspended products correspond to the Union compulsory license, the Commission may consult the relevant rights-holder.</p> | <p>DE (Comments): We ask for clarification as to who should be informed about the suspension of the export procedure. It should be defined whether the owner of the goods concerned, the declarant for export or the owner and the declarant should be informed about the suspension? The Commission has already announced that the data will be transmitted by email. In view of the fact that sensitive data could also be transmitted, it is necessary to include a secure (data protection-compliant) and uninterrupted transmission channel in Article 12 of the draft regulation. From our point of view, this is not possible with a standard e-mail. A secure, possibly end-to-end secure connection must be provided. Furthermore, the competent Commission department that is to be informed must be named. For this purpose, an article or paragraph should be created in which the competent Commission department is named. In addition, it should be defined which "relevant" information should be transmitted to the (competent) Commission department in the event of a violation of Article 11 of the draft regulation being suspected. 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 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.</p> |

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| | <p>The precise identification of the information that needs to be transmitted would also ensure a standardized transmission of information among the Member States.</p> <p>We request that a clear timeframe be specified in the draft regulation for the transmission of information by the customs authority to the COM.</p> <p>FI (Comments): How is the export prohibition communicated to the COM? epäselvää miten viennin keskeyttämisestä ilmoitetaan komissiolle? Traditionally Finnish Customs authorities are not directly in contact with the COM. Will a new interface be created for that purpose?</p> <p>DK (Comments): Denmark finds that it should be clarified in what way customs authorities are to inform the Commission when a goods has been suspended.</p> <p>IT (Drafting): 3. Where customs authorities identify a product that may fall under the prohibition laid down in Article 11, <i>with the exception of products necessary in case of a crisis covered by Regulation (EC) No 816/2006</i>, they suspend its exportation 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 license. To assess whether the suspended products correspond to the Union compulsory license, the Commission may consult the relevant rights-holder.</p> |

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| | IT (Comments): We are waiting for comments from customs authority |
| 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: | IT (Comments): We are waiting for comments from customs authority |
| (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. | |
| 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. | DK (Comments): Denmark notes that with this wording the Commission is seen to be the competent authority, which is unusual and may give rise to new processes. IT (Drafting): 5. Where the Commission concludes that a product manufactured under a |

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| | <p>Union compulsory licence does not comply with the prohibition laid down in Article 11, <i>without prejudice to the exceptions listed in Regulation (EC) No 816/2006</i>, customs authorities shall not authorise its release for export. The Commission shall inform the concerned rights-holder of such non-compliance.</p> <p>IT (Comments): We are waiting for comments from customs authority</p> |
| 6. Where the release for export of a product has not been authorised: | <p>IT (Comments): We are waiting for comments from customs authority</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>NL (Comments): More clarity and safeguards should be provided in order to prevent inappropriate disposal of crisis-relevant products in times of crisis (based on Article 12(6)(b)). Which other actions could be required besides supply to designated MS, what are the timelines, when is it 'appropriate', can the decision of the Commission be challenged? And what if there is a surplus of products after the crisis situation is resolved in the EU, but where non-EU countries can still benefit? Consider clarifying the relationship to the exception of the crisis-critical products covered by Regulation (EC) No 816/2006 in that respect as well.</p> |

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| | <p>DK (Comments): Denmark notes that it should be clarified that the competent authority is responsible for obliging the exporter to take specific actions at their own costs, and what the delimitation is for “specific actions”.</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>DK (Comments): Denmark finds that paragraph 6(b) should not appear in Article 12 on Customs control. It should not be for the customs authorities to decide on either disposal or destruction. The competent authority must make this decision, which with the wording in this article seems to be the Commission. The Customs Agency in Denmark has no authority to dispose or destroy goods. This may also be the case for other customs agencies. For this reason, the paragraph 6(b) should not contain a reference to customs authorities as it is a national matter to determine the division of responsibility and competences for disposal and destruction.</p> |
| Article 13 | |
| Relations between rights-holder and licensee | |
| <p>1. 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</p> | <p>PL (Comments): It may be worth considering clarifying the concept of “acting and</p> |

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| and obligations under this Regulation. | <p>cooperating with each other in good faith” between the right-holder and the licensee.</p> <p>ES (Comments): Good faith is considered necessary in any contractual relationship, not only once the compulsory license has been granted, but throughout the entire process leading to the granting of the license, whether voluntary (through the mandatory negotiation) or compulsory.</p> <p>DK (Comments): The concept of “good faith” is unclear. Reference to a formal legal standard should be made if possible, and it should be explicitly stated that it does not include <i>any</i> obligation to transfer know how or trade secrets.</p> |
| <p>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.</p> | <p>DK (Comments): It seems unclear what is meant by “best effort”, which could be potentially very burdensome. Given the fact that the CL is forced upon the patentholder it seems potentially extensive that the patentholder should “make their best effort” to fulfill a political objective which may be beyond their control.</p> |
| Article 14 | |
| Review and termination of the Union compulsory licence | |
| | |

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| <p>1. The Commission shall review the Union compulsory licence upon reasoned request by the rights-holder or the licensee or on its own initiative and shall, where needed, modify the specifications referred to in Article 8 by means of an implementing act. Where necessary, the Union compulsory licence shall be modified to indicate the complete list of rights and rights-holders covered by the compulsory licence.</p> | |
| <p>2. Where necessary, the Commission shall decide upon reasoned request by the rights-holder or the licensee or on its own initiative on additional measures complementing the Union compulsory licence to ensure it achieves its objective as well as to facilitate and ensure the good collaboration between the rights-holder and the licensee.</p> | <p>ES (Comments): It would be necessary to clarify the scope of the additional measures that the Commission can take in order to complement the Union compulsory licence to ensure that it achieves its objective (Article 14.2). Otherwise, legal uncertainty may arise regarding the limits of the Commission.</p> |
| <p>3. A Union compulsory licence may be terminated by the Commission by means of an implementing act where the circumstances which led to it cease to exist and are unlikely to recur or where the licensee fails to comply with the obligations laid down in this Regulation.</p> | |
| <p>4. When the Commission considers modifying, adopting additional measures as referred to in paragraph 2, or terminating the Union compulsory licence, it may consult the advisory body referred to in Article 6.</p> | <p>ES (Comments): In the event that the compulsory license has to be modified, it needs additional measures or has to be terminated (section 4), the participation of the advisory body must be mandatory and its opinion, based on criteria technical, should be binding.</p> |

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| 5. When terminating the Union compulsory licence, the Commission may require that the licensee, within a reasonable period of time, arrange for any goods in its possession, custody, power or control to be redirected or otherwise disposed of in the manner determined by the Commission in consultation with the rights-holder and at the expense of the licensee. | |
| 6. The implementing acts referred to in paragraph 1, 2 and 3 shall be adopted in accordance with the rules referred to in Article 7(6) (a) and (b), 7(7) and 7(8). | |
| Article 15 | |
| Fines | <p>PL (Comments): It seems necessary to introduce clear criteria for imposing fines and monetary penalties; currently, these criteria are not clear, for example, in the case of the possibility of imposing a fine when parties do not adhere to the principle of good faith, it is difficult to predict what actions may be considered as violating the principle of good faith and consequently lead to the imposition of a fine.</p> <p>ES (Comments): Four articles of the Regulation refer to fines, which will certainly have to be applied. It should be borne in mind that the Regulation does not</p> |

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| | provide for an exhaustive analysis of the licensee's capacities prior to the granting of the licence. Not only the industrial capacities, but in the case of pharmaceuticals, the capacity to obtain the corresponding health marketing authorisation from the health agencies. The regulation is based on the premise, which has been proven wrong in the pandemic, that once the patent licence has been obtained, anyone can manufacture the product. Without requiring a rigorous examination of the licensee's capabilities, bad practices are encouraged and the proliferation of many licensees who are ultimately unable to manufacture the product is possible. |
| 1. The Commission may by decision impose on the licensee or the rights-holder fines not exceeding 6 % of their respective total turnover in the preceding business year where, intentionally or negligently: | <p>ES (Comments): It should be indicated whether the fines will be imposed by the same DG or if it will vary depending on the nature of the crisis.</p> <p>DK (Comments): The level of 6 pct. seems arbitrary and potentially unproportionate. Please elaborate on the reasons behind.</p> |
| (a) the licensee fails to comply with its obligations under Article 9(1) or Article 10(1); | |
| (b) the rights-holder or the licensee fail to comply with the principle of good faith and cooperation referred to in Article 13; or | |
| | |

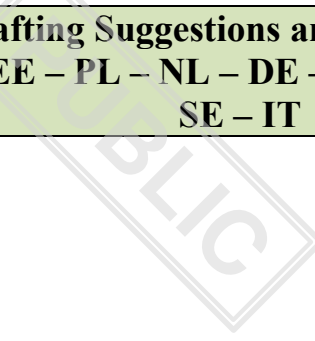
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| (c) the rights-holder or the licensee fail to comply with any obligation resulting from the additional measures complementing the Union compulsory licence as referred to in Articles 8(1)(h) and 14(2), as specified in the relevant implementing act. | |
| 2. In fixing the amount of the fine, regard shall be had to the gravity, to the recurrence of the infringement and to the duration of the infringement. | |
| Article 16 | |
| Periodic penalty payments | PL (Comments): It seems necessary to introduce clear criteria for imposing fines and monetary penalties. |
| 1. The Commission may, by decision, impose on the licensee or the rights-holder periodic penalty payments not exceeding 5 % of their respective average daily turnover in the preceding business year per day and calculated from the date appointed by the decision, in order to compel: | DK (Comments): The level of 5 pct. seems arbitrary and potentially unproportionate. Please elaborate on the reasons behind. |
| (a) the licensee to put an end to an infringement of its obligations under Article 10(1); | |
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| (b) the licensee and the rights-holder to put an end to the infringement of Article 13; or | |
| | |
| (c) the rights-holder or the licensee to comply with any obligation resulting from the additional measures complementing the Union compulsory licence as referred to in Articles 8(1)(h) and 14(2), as specified in the relevant implementing act. | |
| | |
| 2. Where the licensee or the rights-holder have satisfied the obligation which the periodic penalty payment was intended to enforce, the Commission may fix the definitive amount of the periodic penalty payment at a figure lower than that which would arise under the original decision. | |
| | |
| Article 17 | |
| | |
| Limitation period for the imposition of fines and periodic penalty payments | |
| | |
| 1. The powers conferred on the Commission by Articles 15 and 16 shall be subject to a limitation period of five years. | |
| | |
| 2. Time shall begin to run on the day on which the infringement is committed. However, in the case of continuing or repeated infringements, time shall begin to run on the day on | |

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| which the infringement ceases. | |
| | |
| <p>3. Any action taken by the Commission or by a competent authority of the Member States for the purpose of the investigation or proceedings in respect of an infringement shall interrupt the limitation period for the imposition of fines or periodic penalty payments.</p> | |
| | |
| <p>4. Each interruption shall start time running afresh. However, the limitation period for the imposition of fines or periodic penalty payments shall expire at the latest on the day on which a period equal to twice the limitation period has elapsed without the Commission having imposed a fine or a periodic penalty payment. That period shall be extended by the time during which the limitation period has been suspended pursuant to paragraph 5.</p> | |
| | |
| <p>5. The limitation period for the imposition of fines or periodic penalty payments shall be suspended for as long as the decision of the Commission is the subject of proceedings pending before the Court of Justice of the European Union.</p> | |
| | |
| Article 18 | |
| | |
| Limitation period for the enforcement of fines and periodic penalty payments | |

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| <p>1. The power of the Commission to enforce decisions taken pursuant to Articles 15 and 16 shall be subject to a limitation period of five years.</p> | |
| <p>2. Time shall begin to run on the day on which the decision becomes final.</p> | |
| <p>3. The limitation period for the enforcement of penalties shall be interrupted:</p> | |
| <p>(a) by notification of a decision varying the original amount of the fine or periodic penalty payment or refusing an application for variation;</p> | |
| <p>(b) by any action of the Commission, or of a Member State acting at the request of the Commission, designed to enforce payment of the fine or periodic penalty payment.</p> | |
| <p>4. Each interruption shall start time running afresh.</p> | |
| <p>5. The limitation period for the enforcement of penalties shall be suspended for so long as:</p> | |
| <p>(a) time to pay is allowed;</p> | |

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| <p>(b) enforcement of payment is suspended pursuant to a decision of the Court of Justice of the European Union or to a decision of a national court.</p> | |
| <p>Article 19</p> | |
| <p>Right to be heard and access to the file</p> | |
| <p>1. Before adopting a decision pursuant to Article 15 or 16, the Commission shall give the licensee or the rights-holder the opportunity of being heard on the alleged infringement which is to be made subject to a fine or periodic penalty payments.</p> | <p>ES (Comments): This article should guarantee the procedural rights of the owner. Not only must he be heard, but he should be able to be a full party to the procedure and his arguments should be answered through a reasoned resolution, giving him the possibility of appealing the resolutions he considers appropriate.</p> |
| <p>2. The licensee or the rights-holder may submit its observations on the alleged infringement within a reasonable period set by the Commission, which may not be less than 14 days.</p> | |
| <p>3. The Commission shall base its decisions only on objections on which the parties concerned have been able to comment.</p> | |
| <p>4. The rights of defence of the parties concerned shall be</p> | |

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| <p>fully respected in the proceedings. They shall be entitled to have access to the Commission's file under the terms of a negotiated disclosure, subject to the legitimate interest of the licensee or the rights-holder or other person concerned in the protection of their commercially sensitive information and trade secrets. The Commission shall have the power to adopt decisions setting out such terms of disclosure in case of disagreement between the parties. The right of access to the file of the Commission shall not extend to confidential information and internal documents of the Commission, other competent authorities or other public authorities of the Member States. In particular, the right of access shall not extend to correspondence between the Commission and those authorities. Nothing in this paragraph shall prevent the Commission from disclosing and using information necessary to prove an infringement.</p> |  |
| <p>5. If the Commission considers it necessary, it may also hear other natural or legal persons. Applications to be heard on the part of such persons shall, where they show a sufficient interest, be granted.</p> | |
| <p>Article 20</p> | |
| <p>Publication of decisions</p> | |
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| <p>1. The Commission shall publish the decisions it adopts pursuant to Article 15 and Articles 16. Such publication shall state the names of the parties and the main content of the decision, including any fines or penalties imposed.</p> | |
| <p>2. The publication shall have regard to the rights and legitimate interests of the licensee, the rights-holder or any third parties in the protection of their confidential information.</p> | |
| <p>Article 21</p> | |
| <p>Review by the Court of Justice of the European Union</p> | |
| <p>In accordance with Article 261 TFEU, the Court of Justice of the European Union has unlimited jurisdiction to review decisions by which the Commission has imposed fines or periodic penalty payments. It may cancel, reduce or increase the fine or periodic penalty payment imposed.</p> | <p>ES (Comments): Recital 31 states that “The legal validity of the implementing act granting the Union compulsory license, or any subsequent implementing act, should be subject to judicial review”. Recital 35, relating to fines, states that “All decisions taken by the Commission under this Regulation are subject to review by the Court of Justice of the European Union in accordance with the TFEU”. Despite these indications, throughout the Regulation, the Court of Justice only appears in this article relating to fines imposed by the Commission. It seems appropriate to modify the article in order to clarify that the reasoned decisions that have determined the granting of the license may be subject to appeal so as not to deprive the holder of this tool during the procedure.</p> |

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| Article 22 | |
| Reporting on national compulsory licences | |
| When a national compulsory licence has been granted for the purpose of addressing a national crisis or emergency, the Member State shall notify the Commission of the granting of the licence and of the specific conditions attached to it. The information provided shall include the following: | <p>ES (Comments): If a Member State has granted or is planning to grant a Compulsory License on the same patents. Would this be proportional to the patent holder? If there's both a national and an EU Compulsory License this procedure loses its exceptional nature.</p> |
| (a) the purpose of the national compulsory licence and its legal basis in national law; | |
| (b) the name and address of the licensee; | |
| (c) the products concerned and, to the extent possible, the concerned intellectual property rights and rights-holders; | |
| (d) the remuneration to be paid to the rights-holder; | |
| (e) the quantity of products to be supplied under the licence; | |
| (f) the duration of the licence. | |

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| Article 23 | |
| Amendments to Regulation (EC) No 816/2006 | |
| Regulation (EC) No 816/2006 is amended as follows: | |
| (a) The following Article 18a is inserted: | |
| “Article 18a | |
| Union compulsory licence | |
| 1. The Commission may grant a compulsory licence where the activities of manufacture and sale for export spread across different Member States and would therefore require compulsory licences for the same product in more than one Member State. | ES (Comments): Will Member States be able to continue granting this type of compulsory licenses when manufacturing and sales activities for export are not carried out in different Member States? Is there any plan to avoid duplication of regimes in this case? |
| 2. Any person may submit an application for a compulsory licence under paragraph 1. The application shall fulfil the requirements laid down in Article 6 (3) and shall specify the Member States to be covered by the compulsory licence. | |
| 3. The compulsory licence granted in accordance with | |

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| paragraph 1 shall be subject to the conditions set out in Article 10 and shall specify that it is applicable to the whole territory of the Union. | |
| 4. In the event of an application referred to in paragraph 2 under this Article, the competent authority referred to in Articles 1 to 11, 16 and 17 shall be the Commission. | |
| 5. The Commission is empowered to adopt implementing acts in order to: | |
| (a) grant a compulsory licence; | |
| (b) reject the application for a compulsory licence; | |
| (c) amend or terminate the compulsory licence. | |
| Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 18b (2). On duly justified imperative grounds of urgency relating to the impacts of the public health problems, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 18b (3).” | |
| (b) The following Article 18b is inserted: | |
| | |

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| “Article 18b Committee Procedure | |
| 1. The Commission shall be assisted by a committee (‘the Compulsory Licensing Committee’). That committee shall be a committee within the meaning of Regulation (EU) No 182/2011. | |
| 2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply. | |
| 3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 4 thereof, shall apply.” | |
| Article 24 | |
| Committee Procedure | |
| 1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011. | |
| 2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply. | |

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| 3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply. | |
| 4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 4 thereof, shall apply. | |
| Article 25 | |
| Evaluation | |
| The Commission shall, by the last day of the third year following the granting of the Union compulsory licence in accordance with Article 7, present an evaluation report to the Council, the European Parliament and the European Economic and Social Committee on the application of this Regulation. | |
| Article 26 | |
| Entry into force | |
| This Regulation shall enter into force on the day following that of its publication in the <i>Official Journal of the European Union</i> . | |
| | |

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| <p>This Regulation shall be binding in its entirety and directly applicable in all Member States.</p> | |
| | |
| <p>Done at Brussels,</p> | |
| | |
| <p>For the European Parliament For the Council</p> | |
| | |
| <p>The President The President</p> | |
| | |
| | <p>End</p> |