



27 September 2022

BUSINESSEUROPE COMMENTS ON THE PUBLIC CONSULTATION ON COMPULSORY LICENCING IN THE EUROPEAN UNION

BUSINESSEUROPE is the leading advocate for growth and competitiveness at European level, standing up for companies across the continent and actively campaigning on the issues that most influence their performance. We speak for all-sized enterprises in 35 European countries whose national business federations are our direct members.

BUSINESSEUROPE has taken note of the public consultation on compulsory licencing of patents launched by the European Commission (EU Commission, DG GROW) to collect the views of all stakeholders on how to build a possible compulsory licencing scheme in the European Union (EU), to try tackle EU-wide and global crises.

BUSINESSEUROPE is happy to contribute to this debate that could have an impact on the patent system over the coming years.

In April 2022, BUSINESSEUROPE provided comments to the EU Commission call for evidence for an impact assessment on compulsory licencing intended to collect input from stakeholders on grounds and procedures for issuing compulsory licencing in crisis situations in the EU.¹ BUSINESSEUROPE stressed that current international and EU frameworks, as well as Member States legislation, are sufficient to regulate compulsory licencing of patents. There is no need for a new EU legislative action in this area.

We refer to these comments as they still reflect the same position with strong concerns in relation to future legislative action in this matter. Hereby, we both reiterate general messages and, reply to some questions of the questionnaire issued on the Better Regulation portal on 7 July 2022.

GENERAL COMMENTS

Patents are meant to stimulate innovation. Compulsory licences weaken the protection granted by patents and they should only be used in knowledge-based economies as a last resort and in very limited circumstances. This covers, for instance, situations whereby the patentee itself cannot supply sufficient quantities to address the crisis, and voluntary license arrangements have failed or are unavailable.

¹ These comments can be accessed here:

https://www.buinesseurop.eu/sites/buseur/files/media/position_papers/legal/2022-04-28_compulsory_licensing_in_the_eu_-_comments.pdf



If compulsory licences are imposed beyond last resort cases, including abuse of the patent and/or absent an adequate remuneration of the patentee, the risk is that innovation would no longer be stimulated especially for emergency situations. Society needs innovation to address the emergency and crises.

BUSINESSEUROPE has always welcomed initiatives intended to harmonise intellectual property legislation in the Member States when there is evidence that these can increase legal certainty, efficiency, as well as bring benefits to businesses. Our members are not convinced that the current “fragmented legislation” on compulsory licensing leads to negative effects in practice. Only if there were concrete cases showing that the existing framework is not working, then there should be a cause for new legislation. In the absence of such evidence, the creation of a new EU instrument on compulsory licensing would bring negative effects on the patent protection and ultimately would be detrimental to innovation in the EU.

PRELIMINARY QUESTION

- IF COMPULSORY LICENCING WAS TRIGGERED, WOULD YOU BE MORE LIKELY TO BECOME:

BUSINESSEUROPE members would assume the role of both licensors and licensees, depending on the case concerned.

QUESTIONNAIRE

- QUESTION 1 - DO YOU CONSIDER IT IMPORTANT THAT PUBLIC AUTHORITIES ARE ENTITLED TO ALLOW PRODUCTION OF CERTAIN PRODUCTS AND/OR USE OF CERTAIN TECHNOLOGIES NECESSARY TO TACKLE A CRISIS THROUGH A COMPULSORY LICENCE?

BUSINESSEUROPE's reply is “Yes”. Our members believe that requirements and limitations imposed to public authorities for the granting of compulsory licences under Article 31 of the TRIPS Agreement and Article 5A (2) of the Paris Convention, are adequate.

Compulsory licences should be a last resort and only be used if all other options fail. Fundamentally, they can only be justified in very limited circumstances to be assessed on a case-by-case basis, in line with Article 31 of the TRIPS Agreement.

- QUESTION 2 - IN WHICH TYPE(S) OF CRISIS SHOULD COMPULSORY LICENCING BE POSSIBLE?

BUSINESSEUROPE's reply is “Other”.

PLEASE EXPLAIN YOUR ANSWER:

Compulsory licensing should be a last resort and only be used if all other options fail. Existing international rules - which are already implemented by national laws especially regarding the terms “national emergency” - provide some indications to the interpretation



of “crisis”. Since the circumstances of exceptional situations with great impact are always complex and differ from each other, our members believe that an assessment must always be made on a case-by-case basis. This is consistent with Article 31 of the TRIPS Agreement. Therefore, further rules are unnecessary.

- QUESTION 3 - ARE CURRENT NATIONAL LAWS ON COMPULSORY LICENCING FIT TO TACKLE?

	Yes	No	No opinion
National crises	X		
EU-wide crisis	X		
Global crisis	X		

PLEASE EXPLAIN YOUR ANSWER

Our members consider that the existing international framework and national laws are sufficient to regulate compulsory licencing of patents. Our members believe that, currently, there are no controversial divergences between Member States’ legislations on this matter. There is also no evidence and real-life cases showing that imposing compulsory licences at national level does trigger problems.

- QUESTION 4 - THE CONTEXT OF CROSS-BORDER SUPPLY CHAINS (WITH THE MANUFACTURING PROCESS OF COMPLEX PRODUCTS SPANNING ACROSS SEVERAL EU COUNTRIES), SHOULD A COMPULSORY LICENCE BE POSSIBLE TO ENABLE THE MANUFACTURING OF:

	Yes	No	No opinion
Products whose manufacturing process spans several EU countries* (interim products) [*for instance a complex product such as a vaccine, the components of which can originate from different countries]		X	
Products that are needed in certain EU countries facing a crisis, but which can be manufactured only in another EU country (final products)		X	
Other (please specify)		X	

PLEASE EXPLAIN YOUR ANSWER

Our members consider that no further measures are necessary with respect to compulsory licencing. Restrictions on patents are neither suitable nor necessary to ensure efficient crisis management within the EU. This applies particularly to the provision of technically complex products: For their production, the know-how – among other things - is basically required, as well as appropriate trained staff. Compulsory licences cannot ensure this.

- QUESTION 5 - COMPULSORY LICENCING USUALLY CONCERNS ONLY PATENTS. HOWEVER, PATENTS MAY NOT ALWAYS BE ENOUGH TO ALLOW THE MANUFACTURE OF COMPLEX PRODUCTS. SHOULD A COMPULSORY LICENCE APPLY TO:

BUSINESSEUROPE's reply is "Patents" and "Supplementary protection certificates".

PLEASE EXPLAIN YOUR ANSWER.

If anything, the EU framework on compulsory licencing should only cover "Patents" and "Supplementary protection certificates". Compulsory licencing should not be extended to other intellectual property rights, trade secrets, know-how or any other knowledge-based assets.

THE FOLLOWING QUESTIONS APPLY TO COMPULSORY LICENCING COVERED BY ARTICLE 31 OF THE TRIPS AGREEMENT AND THEREFORE DO NOT CONCERN COMPULSORY LICENCING FOR EXPORT PURPOSES

- QUESTION 6 - TO WHAT EXTENT DO YOU AGREE WITH THIS SENTENCE: "COMPULSORY LICENCING IS A LAST-RESORT MECHANISM THAT SHOULD BE AVAILABLE ONLY WHERE VOLUNTARY ARRANGEMENTS HAVE FAILED OR ARE UNAVAILABLE"?

BUSINESSEUROPE's reply is "Strongly agree".

- QUESTION 7 - WHICH ASPECTS SHOULD BE CONSIDERED TO DETERMINE WHETHER VOLUNTARY AGREEMENTS HAVE FAILED?

BUSINESSEUROPE's replies are "The types of voluntary agreement (agreements with suppliers and agreements between competitors) that are unsuccessful/unavailable", "the time period allowed for concluding the voluntary agreements", and "[whether reasonable efforts have] been made by the licence seeker to obtain an agreement with the IP owner", and "Other".

[(*) COMMENTS ARE POSSIBLE ONLY TICKING "OTHER"].

Regarding the time period allowed for concluding the voluntary agreements, there should not be a strict deadline. The terms "time period" should be understood within the meaning of a reasonable time for the conclusion of the agreement.

As a further condition to the availability of compulsory licenses, it is key to consider the adequacy in individual cases, e.g., lack of infrastructure or obstacles in the logistics chain. Logistics chain issues cannot be solved by compulsory licensing.

- QUESTION 8 - WHAT SHOULD BE PRIORITISED IN COMPULSORY LICENCING FOR CRISIS MANAGEMENT?

	High Priority	Medium Priority	Low Priority	Not Relevant
Speed of ensuring access to the required products/ technologies	X			



Protection of rights holders (reasonable period of time to allow negotiations between the licence seeker and the rights holder, clear limitation of the duration of the compulsory licence, adequate remuneration for rights holder, etc.)	X			
Interests raised by civil society organisations			X	
Interests raised by manufacturers* [*in this context, “manufacturers” means companies that are appointed to manufacture products under a compulsory licence and who, for this purpose, would need to adapt their manufacturing facilities and process [if yes, please specify]		X		
Other, including other third-party interests (please explain)				X
None of the above				

- QUESTION 9 - AS FAR AS THE GRANTING PROCEDURE IS CONCERNED, WHICH OF THE FOLLOWING COULD SPEED UP THE GRANTING OF COMPULSORY LICENCING FOR CRISIS MANAGEMENT?

BUSINESSEUROPE's reply is “Other”.

[(*) COMMENTS ARE POSSIBLE ONLY TICKING “OTHER”].

Our members are of the view that no further EU initiatives are needed with respect to compulsory licencing. Our members are concerned that a granting procedure could be used in a “blackmail” manner.

- QUESTION 10 - WHICH OF THE FOLLOWING POLICY OPTIONS COULD SPEED UP THE COMPULSORY LICENCING PROCESS FOR CRISIS MANAGEMENT?

BUSINESSEUROPE's reply is “facilitating communication and information exchange between EU countries (e.g., communication on the request/granting of compulsory licences, sharing of information between EU countries about and, conditions for the compulsory licence)”.

The COVID-19 pandemic has not showed that the current framework on compulsory licencing raises any issues requiring an EU legislative initiative. A mechanism to facilitate the exchange of information among Members States might help. However, the COVID-19 pandemic has demonstrated that Members States are able to communicate and exchange information even in the absence of a specific framework.

- QUESTION 11 - IN THE CONTEXT OF UNIFORM RULES ON COMPULSORY LICENCES FOR CRISIS MANAGEMENT, WHICH ASPECTS SHOULD BE ALIGNED (SELECT ALL THAT APPLY)?

BUSINESSEUROPE is “Other”.



[() COMMENTS ARE POSSIBLE ONLY TICKING "OTHER"].*

BUSINESSEUROPE members consider that there is no need for an EU harmonised framework on compulsory licencing of patents.

If uniform rules are to be introduced, these rules should ensure that compulsory licencing is a last resort measure.

- QUESTION 12 - IF THE GROUNDS FOR GRANTING A COMPULSORY LICENCE ARE TO BE ALIGNED, PLEASE SPECIFY WHAT SHOULD BE ALIGNED (SELECT ALL THAT APPLY)

BUSINESSEUROPE is "Other".

[() COMMENTS ARE POSSIBLE ONLY TICKING "OTHER"].*

BUSINESSEUROPE members submit that there is no need for an EU harmonised framework on compulsory licencing of patents.

If uniform rules are to be introduced, these rules should ensure that compulsory licences are a last resort measure.

- QUESTION 13 - IF THE SCOPE OF WHAT A COMPULSORY LICENCE COVERS IS TO BE ALIGNED, PLEASE SPECIFY TO WHAT EXTENT:

BUSINESSEUROPE's reply is "Other".

[() COMMENTS ARE POSSIBLE ONLY TICKING "OTHER"].*

BUSINESSEUROPE members consider that there is no need for an EU harmonised framework on compulsory licencing of patents.

If uniform rules are to be introduced, then "The alignment of the scope should be limited (e.g., patents and published patent applications only)".

- QUESTION 14 - SHOULD THE ALIGNED SCOPE ALSO COVER REGULATORY DATA PROTECTION?

BUSINESSEUROPE's reply is "No".

- QUESTION 15 – IF THE CONDITIONS FOR GRANTING A COMPULSORY LICENCE ARE TO BE ALIGNED, PLEASE SPECIFY WHICH CONDITIONS SHOULD BE ALIGNED (SELECT ALL THAT APPLY):

BUSINESSEUROPE's reply "Other".



[(*) COMMENTS ARE POSSIBLE ONLY TICKING "OTHER"].

BUSINESSEUROPE members consider that there is no need for an EU harmonised framework on compulsory licencing of patents.

If uniform rules are to be introduced, the following conditions should be aligned: "Remuneration", "Duration of the licence", "Framework and duration of the negotiations", "Determination of who can initiate proceedings for a compulsory licence (e.g., public authority, licence seeker)", "Content of an application for a compulsory licence (e.g., indicate the patent, the owner of the patent, the concerned products, etc.)".

- QUESTION 16 – IF THE PROCEDURE FOR GRANTING A COMPULSORY LICENCE IS TO BE ALIGNED, PLEASE SPECIFY WHICH ASPECTS OF THE PROCEDURE SHOULD BE ALIGNED (SELECT ALL THAT APPLY):

BUSINESSEUROPE's reply is "Other".

[(*) COMMENTS ARE POSSIBLE ONLY TICKING "OTHER"].

BUSINESSEUROPE members consider that there is no need for an EU harmonised framework on compulsory licencing of patents.

If uniform rules are to be introduced, the following aspects of the procedure should be aligned: "Type of procedure (e.g., administrative or judicial procedure, interim procedure, etc.) [judicial procedure]", and "Whether or not the manufacturing should be subject to a final decision on all aspects of the negotiation".

- QUESTION 17 - IF THE RECOURSE PROCEDURE FOR GRANTING A COMPULSORY LICENCE IS TO BE ALIGNED, PLEASE SPECIFY WHICH ASPECTS OF THE PROCEDURE SHOULD BE ALIGNED (SELECT ALL THAT APPLY):

BUSINESSEUROPE's reply is "Other".

[(*) COMMENTS ARE POSSIBLE ONLY TICKING "OTHER"].

BUSINESSEUROPE members consider that there is no need for an EU harmonised framework on compulsory licencing of patents.

If uniform rules are to be introduced, the following aspects of the procedure should be aligned: "The time limit within which the application of an appeal is admissible", "The suspensive effect of an appeal (crucial for the start of production under a compulsory licence)", and "An accelerated appeal procedure (a specified time limit within which a decision on the appeal must be taken)".

- QUESTION 18 - AT WHICH LEVEL SHOULD A DECISION ON TRIGGERING A COMPULSORY LICENCE BE TAKEN?

BUSINESSEUROPE's reply is "At national level only, even in the case of EU-wide crisis". Our members consider that there is no need for an EU harmonised framework on compulsory licencing of patents.

- QUESTION 19 - REGARDING THE GRANTING OF COMPULSORY LICENCES, WHAT ROLE SHOULD THE EUROPEAN INSTITUTIONS HAVE IN THE EVENT OF AN EU-WIDE CRISIS?

BUSINESSEUROPE's replies are "A consultative role on request (e.g., EU countries, public authorities, rights holders, licence seekers, etc. can ask for advice)" and "A coordinating role (e.g., by setting up channels/forums and methods for information sharing among EU countries and steering mutual assistance between EU countries)".

THE FOLLOWING QUESTIONS REFER TO COMPULSORY LICENCING FOR EXPORT PURPOSES (ARTICLE 31BIS OF THE TRIPS AGREEMENT)

- QUESTION 20 - TO WHAT EXTENT DO YOU AGREE WITH THE FOLLOWING STATEMENT: "REGULATION 816/2006 ALLOWS FOR SPEEDY AND EFFICIENT PROCEDURES FOR GRANTING COMPULSORY LICENCES TO EXPORT PHARMACEUTICAL PRODUCTS TO NON-EU COUNTRIES"?

BUSINESSEUROPE's reply is "No opinion".

- QUESTION 21 - WHILE STAYING WITHIN THE BOUNDARIES OF THE TRIPS AGREEMENT, SHOULD IN YOUR VIEW SOME ELEMENTS OF REGULATION 816/2006 BE STREAMLINED TO ENSURE THAT THE REGULATION IS FIT FOR PURPOSE?

	Yes	No	No opinion
Conditions to submit an application			X
Calculation of the remuneration			X
Simplified and accelerated procedure			X
Other (please specify)			X

- QUESTION 22 - WHILE STAYING WITHIN THE BOUNDARIES OF THE TRIPS AGREEMENT, DO YOU CONSIDER THAT THE PROCEDURE SET BY REGULATION 816/2006 SHOULD BE MADE MORE FLEXIBLE TO ADAPT TO THE NEEDS OF THE IMPORTING COUNTRY?

BUSINESSEUROPE's reply is "No opinion".

- QUESTION 23 - WHILE STAYING WITHIN THE BOUNDARIES OF THE TRIPS AGREEMENT, DOES IN YOUR VIEW REGULATION 816/2006 PROVIDE SUFFICIENT GUARANTEE AGAINST TRADE DIVERSION (I.E. MEASURES, SUCH AS LABELLING AND MARKING PRODUCTS SUBJECT TO A COMPULSORY LICENCING, TO GUARANTEE THEIR EXPORT AND DISTRIBUTION TO THE CONCERNED COUNTRY ONLY)?

BUSINESSEUROPE's reply is "No opinion".

- QUESTION 25 - IN VIEW OF RECENT CRISES (SUCH AS THE COVID-19 PANDEMIC AND THE WAR IN UKRAINE), WHAT CONCLUSIONS/LESSONS DO YOU DRAW FROM THE POSSIBILITY TO USE COMPULSORY LICENCING AS A CRISIS MANAGEMENT TOOL?

The role of compulsory licences in addressing recent crises is very limited. In addition, there is a misunderstanding within the general public which may consider patents as a problem whereas they are actually often the solution in case of crisis situations.

- QUESTION 26 - IN YOUR VIEW, WHICH IMPACT (POSITIVE OR NEGATIVE) DOES THE GRANTING OF THE COMPULSORY LICENCE HAVE ON THE VARIOUS PLAYERS INVOLVED (RIGHTS HOLDERS, MANUFACTURERS, COMPETENT AUTHORITIES, SOCIETY IN GENERAL, ETC.)?

The number of compulsory licences granted so far has been very limited. If more compulsory licences were to be granted in the future, this would have negative impact on innovators/right holders. Patents are an important incentive to innovation as they provide a potential possibility for innovators, who have invested and invented a patented solution, to recoup investment thanks to the patents' exclusive rights. Any attempt to reduce this exclusivity might ultimately discourage innovators to invest and take the associated risks in the EU. The EU would diminish its ability to tackle future crisis.

- QUESTION 28 - THANK YOU FOR PROVIDING YOUR GENERAL VIEWS. THE FOLLOWING QUESTIONS (29 TO 33) CONCERN THE TECHNICAL AND PROCEDURAL ASPECTS OF A PROCEDURE FOR GRANTING A COMPULSORY LICENCE. WOULD YOU LIKE TO PROCEED? IF NOT, PLEASE CONTINUE WITH QUESTION 31.

BUSINESSEUROPE's reply is "No".

QUESTIONS FOR ALL

- QUESTION 34 - WHAT COULD BE THE ECONOMIC, LEGAL AND/OR SOCIAL IMPACT(S) OF INTRODUCING A UNIFORM COMPULSORY LICENCING SCHEME ACROSS THE EU ON:

	Highly positive	Positive	Neutral	Negative	Highly negative	No opinion
The EU single market?				X		
EU businesses?				X		
EU IP owners?				X		
The EU patent system?				X		

The EU's ability to tackle crisis?				X		
Access to critical goods for the public (e.g., impact on the supply and availability of critical goods in all EU countries)?			X			
Other (please specify)?						X

PLEASE EXPLAIN YOUR ANSWER

BUSINESSEUROPE believes that there is no need for an EU harmonised framework on compulsory licencing of patents.

If it was easy to obtain a compulsory licence, there would be no incentives for EU innovators and EU implementers to prepare for future crises. They would become even more dependent on providers of proprietary technology from third countries. The global competition between innovators would be disruptive. In general, compulsory licencing limits EU companies' competitiveness. It has a negative effect on the EU single market and the EU ability to tackle future crisis.

- QUESTION 35 - IN THE CONTEXT OF A UNIFORM COMPULSORY LICENCING SCHEME ACROSS THE EU, WHAT COULD BE THE ECONOMIC, LEGAL AND/OR SOCIAL IMPACT(S) OF ALLOWING COMPULSORY LICENCES TO BE GRANTED AT NATIONAL LEVEL ONLY (EVEN IN THE EVENT OF AN EU-WIDE CRISIS) ON:

	Highly positive	Positive	Neutral	Negative	Highly negative	No opinion
The EU single market?				X		
EU businesses?				X		
EU IP owners?					X	
The EU patent system?				X		
The EU's ability to tackle crisis?				X		
Access to critical goods for the public (e.g., impact on the supply and availability of critical goods in all EU countries)?			X			
Other (please specify)?						X

PLEASE EXPLAIN YOUR ANSWER

See explanation to our reply to Question 34.

- QUESTION 36 - IN CONTRAST, IN THE CONTEXT OF A UNIFORM COMPULSORY LICENCING SCHEME ACROSS THE EU, WHAT COULD BE THE ECONOMIC, LEGAL AND/OR SOCIAL IMPACT(S) OF ALLOWING A COMPULSORY LICENCE TO BE GRANTED AT EU LEVEL, IN THE EVENT OF AN EU-WIDE CRISIS, ON:

	Highly positive	Positive	Neutral	Negative	Highly negative	No opinion
The EU single market?				X		
EU businesses?				X		
EU IP owners?					X	
The EU patent system?				X		
The EU's ability to tackle crisis?			X			
Access to critical goods for the public (e.g., impact on the supply and availability of critical goods in all EU countries)?			X			
Other (please specify)?						X

PLEASE EXPLAIN YOUR ANSWER

[See explanation to our reply to Question 34.](#)

- QUESTION 37 - WHAT COULD BE THE ECONOMIC, LEGAL AND/OR SOCIAL IMPACT(S) OF INTRODUCING, FOR CRISIS-MANAGEMENT PURPOSES, A MECHANISM FOR COORDINATING COMPULSORY LICENCING AMONG EU COUNTRIES, ON:

	Highly positive	Positive	Neutral	Negative	Highly negative	No opinion
The EU single market?		X				
EU businesses?				X		
EU IP owners?					X	
The EU patent system?				X		
The EU's ability to tackle crisis?				X		
Access to critical goods for the public (e.g., impact on the supply and availability of critical goods in all EU countries)?			X			
Public authorities' decision-making processes?						X
Other (please specify)?						X

PLEASE EXPLAIN YOUR ANSWER

A mechanism for coordinating compulsory licencing among EU Member States would still have negative effects on the patent system and discourage innovation in the EU. Third countries may then be considered as better places for the promotion of, and to attract, innovation.

- QUESTION 38 - WHAT COULD BE THE ECONOMIC, LEGAL AND/OR SOCIAL IMPACT(S) OF CREATING AN EU SINGLE CONTACT POINT AND COORDINATION MECHANISM BETWEEN MEMBER STATES TO ADDRESS A COMPULSORY LICENCING REQUEST FOR EXPORT OF PHARMACEUTICAL PRODUCTS TO NON-EU COUNTRIES?

	Highly positive	Positive	Neutral	Negative	Highly negative	No opinion
The EU single market?						X
EU businesses?						X
EU IP owners?						X
The EU patent system?						X
The EU's ability to tackle crisis?						X
Access to critical goods for the public (e.g., impact on the supply and availability of critical goods for non-EU countries)?						X
Other (please specify)?						X

- QUESTION 39 - WHAT COULD BE THE ECONOMIC, LEGAL AND/OR SOCIAL IMPACT(S) OF AN EU-LEVEL CENTRALISED PROCEDURE TO GRANT COMPULSORY LICENCING ON EXPORT OF PHARMACEUTICAL PRODUCTS TO NON-EU COUNTRIES?

	Highly positive	Positive	Neutral	Negative	Highly negative	No opinion
The EU single market?						X
EU businesses?						X
EU IP owners?						X
The EU patent system?						X
The EU's ability to tackle crisis?						X
Access to critical goods for the public (e.g., impact on the supply and availability of critical goods for non-EU countries)?						X
Other (please specify)?						X



- QUESTION 40 - PLEASE FEEL FREE TO SHARE ANY OTHER OBSERVATIONS, PUBLICATIONS OR ANALYSIS ON THE SUBJECT.

[Further to these Replies, see also BUSINESSEUROPE Comments to the call for evidence for an impact assessment on compulsory licencing in the European Union (EU), of 28 April 2022, available at https://www.business-europe.eu/sites/buseur/files/media/position_papers/legal/2022-04-28_compulsory_licencing_in_the_eu_-_comments.pdf].
