



Brussels, 25 July 2023

Interinstitutional files:

2023/0126 (COD)
2023/0127 (COD)
2023/0128 (COD)
2023/0129 (COD)
2023/0130 (COD)
2023/0133 (COD)

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INFORMATION

From:	General Secretariat of the Council
To:	Working Party on Intellectual Property (Patents)
N° Cion doc.:	8869/23; 8851/23; 8894/23; 8887/23; 8900/23; 8901/23
Subject:	Patents Package - Opinion of the Dutch Government on the application of the Principles of Subsidiarity and Proportionality

Delegations will find attached an informal courtesy translation -kindly provided by the Dutch delegation- of the Dutch Government's position on the Supplementary Protection Certificate (SPCs), Standard Essential Patents (SEPs) and compulsory licensing proposals contained in the patent package and as shared with the Parliament of the Netherlands.

The original documents can be found (in Dutch) at:

- Supplementary Protection Certificate: <https://zoek.officielebekendmakingen.nl/kst-1094823>
- Standard Essential Patents : <https://zoek.officielebekendmakingen.nl/kst-1095432>
- Compulsory licensing: <https://zoek.officielebekendmakingen.nl/kst-1095437>

Dutch Gov. Position: Regulations on supplementary protection certificates (SPCs)

COURTESY TRANSLATION

1. General information

a) Title of the proposal

- Proposal for a regulation on the unitary supplementary protection certificate for plant protection
- Proposal for a regulation on the supplementary protection certificate for plant protection products (recast)
- Proposal for a regulation on the unitary supplementary certificate for medicinal products
- Proposal for a regulation on the supplementary protection certificate for medicinal products (recast)

b) Date of receipt of the Commission document

27 April 2023

c) Commission document no.

- COM(2023)221 - Proposal for a regulation on the unitary supplementary protection certificate for plant protection
- COM(2023)223 - Proposal for a regulation on the supplementary protection certificate for plant protection products (recast)
- COM(2023)222 - Proposal for a regulation on the unitary supplementary certificate for medicinal products
- COM(2023)231 - Proposal for a regulation on the supplementary protection certificate for medicinal products (recast)

(d) EUR-Lex

- <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023PC0221>
- <https://eur-lex.europa.eu/legal-content/NL/TXT/?uri=COM%3A2023%3A223%3AFIN&qid=1682602901918>
- <https://eur-lex.europa.eu/legal-content/NL/TXT/?uri=COM%3A2023%3A222%3AFIN&qid=1682602901918>
- <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023PC0231>

(e) No impact assessment Commission and Opinion Regulatory Review Board

SWD(2023) 118 and SEC(2023) 172

(f) Treatment path in Council

Competitiveness Council

(g) Lead ministry

Ministry of Economic Affairs and Climate

(h) Legal basis

Proposal for a regulation on the supplementary protection certificate for plant protection products (recast) and Proposal for a regulation on the supplementary protection certificate for medicinal products (recast): Article 114(1) of the Treaty on the Functioning of the European Union (TFEU)

Proposal for a regulation on the unitary supplementary protection certificate for plant protection and Proposal for a regulation on the supplementary protection certificate for plant protection products (recast) and Proposal for a regulation on the unitary supplementary certificate for medicinal products Article 118, first paragraph, TFEU.

(i) Decision-making procedure Council

Qualified majority

(j) Role of the European Parliament

Codecision

2. Essence of proposal

a) Content of the proposal

The European Commission (Commission) has recently published a legislative package on supplementary protection certificates (SPCs). These are intellectual property rights that extend the term of protection of patents for medicines or plant protection products by up to 5 years. This package aims to simplify the EU's SPC system, as well as improve its transparency and efficiency, by creating a centralised procedure and a unitary SPC for medicines and plant protection products. The proposals are procedural only and do not change the criteria for obtaining an SPC.

SPCs are currently issued by national competent authorities (for the Netherlands: OCNL). This is done on the basis of the applicable EU regulations for SPCs, one for pharmaceutical products (for human

and veterinary use) and another for plant protection products. SPCs are designed to compensate for the loss of effective patent protection due to the mandatory and lengthy testing required in the EU for the market authorisation of these products.

The Commission carried out a review of the current system. It follows that the current national procedures in member states for granting SPCs, which are based on separate examination procedures (parallel or successive) in member states, lead to duplication of work. It argues that this results in high costs and more often leads to discrepancies between member states in decisions to grant or refuse SPCs.

Inconsistency between member states in decisions to grant or refuse SPCs is, according to the Commission, the most common reason cited by national courts to submit preliminary questions to the Court of Justice of the European Union on the application of the EU's SPC regime. Current national procedures therefore lead to significant legal uncertainty and administrative burdens, according to the review. In addition, that the unitary patent system will come into force on 1 June 2023, allowing for a single patent offering uniform protection in all participating member states. So far, there is no EU legislation providing for a unitary SPC regime that complements the unitary patent.

New SPC rules are proposed, contained in four regulations. Two regulations introducing a centralised procedure for the grant of national SPCs, by revising and repealing existing EU regulations (one for medicines and the other for plant protection products) and two new regulations creating a new unitary SPC (with the same centralised examination procedure), one for medicines and one for plant protection products.

This leads to a total of four coherent regulations based on the same principles (in particular, the same ABC granting criteria) and containing the same centralised examination procedure. Instead of (up to) 27 separate national procedures to apply for an SPC, the proposed new centralised procedure will require applicants to submit only one central application, where all member states can be specified for which an SPC is requested. Through the new procedure, it will also be possible to apply for a unitary SPC to complement the unitary patent. The central assessment will be conducted by a panel consisting of one member from the European Union Intellectual Property Office (EUIPO) and two examiners from the national competent authorities. The composition of a panel will take into account, inter alia, geographical distribution.

3. Dutch position on the proposal

(a) Essence of Dutch policy in this area

A robust and balanced system of intellectual property rights is an essential part of the attractive innovation climate that the Netherlands aspires to. During the term of patent protection, costly investments can be recouped without competition, while maintaining a healthy competitive environment after the term of protection expires.

Developing drugs and plant protection products is a risky, expensive and lengthy process. Not all research projects result in a product that becomes available to patients or markets. The costs of pathways that fail are partly offset by the revenues from the research pathways that do lead to products that reach the market. Therefore, to stimulate the research, development and marketing of new drugs and plant protection products, a proper and clear regime of protection is needed.

However, encouraging the development of innovative products only makes sense if they also become available to patients or the market (in the case of plant protection products). It is important to strike the right balance between protection of innovations and the availability and affordability of new medicines for patients. Therefore, protection in a balanced system is not unlimited and infinite.

Given the limited validity period of patents and the time that elapses for necessary research into possible side effects and risks to public health and the environment in medicines and plant protection products, the SPC can compensate for the time lost between the patent application and the time when the medicine obtains a marketing authorisation. This prospect may encourage investment for the research, development and marketing of new drugs and plant protection products.

(b) Assessment + commitment to this proposal

The Cabinet welcomes the proposals to revise the SPC Regulations and introduce a unitary SPC and is largely supportive of the measures announced herein. The government supports the introduction of a unitary SPC as a complement to the unitary patent that will come into force on 1 June 2023.

Without a unitary SPC, the holder of a unitary patent is reliant on separate proceedings in the participating 17 member states of the unitary patent, which will lead to greater administrative burdens, higher costs and risk of divergent decisions. The government also sees advantages of introducing a centralised procedure for the grant of national SPCs for the same reasons. However, the government does have some concerns about the quality of the centralised assessment and legal certainty.

At all times, a high-quality assessment system, as the Netherlands has, should be maintained. This is to prevent competition from being improperly delayed by incorrect ABC provision. For the time being, the current proposal does not offer sufficient guarantees that the strict assessment criterion as used in the Netherlands, among others, will be maintained. There are also currently insufficient guarantees for a consistent central assessment. In the composition of review panels, geographical balance between participating national authorities is an important factor. However, objective guarantees for quality or consistency between different panels are lacking. This is something the Netherlands will be critical of in further negotiations on the proposals.

Provided that this uniform quality can be guaranteed, the plans offer several advantages. For instance, the plans offer more legal certainty for both innovative companies and generic producers. The plans thus stimulate both innovation and the rapid introduction of generic products to the market after the expiry of ABC. They also lead to a lower administrative burden. In addition, if testing of SPCs becomes stricter for other countries as well, this may have a price-depressing effect.

4. Assessment of subsidiarity and proportionality

1. Subsidiarity

The government's view on subsidiarity is positive. This package aims to simplify the EU SPC system, as well as improve its transparency and efficiency, by creating a centralised procedure and a unitary SPC for medicines and plant protection products. Despite the fact that SPCs are already harmonised by EU legislation, there are still cases where some member states have granted SPCs while identical applications have been refused or granted with a different scope in other countries. Current national procedures also lead to considerable legal uncertainty and administrative burdens. This shows that further harmonisation is needed at EU level and that the objectives cannot be sufficiently achieved by Member States at central, regional or local level. An EU approach is therefore needed. This applies even more strongly to the introduction of unitary SPCs in addition to the unitary patent. This can only be dealt with at EU level, as national regulations cannot provide for unitary protection. Moreover, amending existing EU regulations can only be done at the EU level. For these reasons, action at the EU level is justified.

2. Proportionality

The government's assessment with regard to proportionality is positive. This package aims to simplify the EU SPC system, as well as improve its transparency and efficiency, by creating a centralised procedure and a unitary SPC for medicines and plant protection products. The proposed measures are appropriate to achieve the intended objectives and do not go beyond what is necessary.

Increased EU coordination of the granting of SPCs will improve the level playing field in the field of patent rights. The scope is limited to those aspects that Member States cannot sufficiently achieve on their own and where Union action can deliver better results. For instance, in terms of consistent decisions on SPC applications, reducing administrative burdens and costs, and improving legal certainty and transparency. In this respect, the government is concerned that the different procedures for granting and appealing against whether or not to grant SPCs for medicines or plant protection products should be well coordinated.

Dutch Gov. Proposal: Standard Essential Patents

COURTESY TRANSLATION

1. General Information

(a) Title of proposal

Proposal for a Regulation of the European Parliament and of the Council on standard essential patents and amending Regulation (EU) 2017/1001

(b) Date of receipt of Commission document

27 April 2023

(c) No Commission document

COM (2023) 232

(d) EUR-Lex

EUR-Lex - 52023PC0232 - EN - EUR-Lex (europa.eu)

(e) Nr. impact assessment Commission and Opinion Regulatory Review Board

SWD (2023) 124 and SEC (2023)124

(f) Council consideration

Competitiveness Council

(g) Lead ministry

Ministry of Economic Affairs and Climate

(h) Legal basis

Article 114 of the Treaty on the Functioning of the European Union (TFEU)

(i) Decision-making procedure Council

Qualified majority

(j) Role of the European Parliament

Codecision

2. Essence of proposal

a) Content of the proposal

On 27 April 2023, the European Commission ("the Commission") published a proposal for a regulation on standard essential patents ("SEPs") creating a new framework for dealing with SEPs. The proposal is part of a broader package of patent rights proposals, which also includes the proposals on supplementary protection certificates (for medicinal and plant protection products) and the compulsory licences proposal. Separate BNC sheets have been prepared for these

proposals. The present proposal builds on the Communication on the EU approach to essential patents and the Intellectual Property Action Plan to support the EU's recovery and resilience (IP Action Plan) .

SEPs essentially bring together two seemingly conflicting interests. Whereas standards aim to promote interoperability and compatibility between products and/or services, a patent is a temporary monopoly on an inventive technology or process that allows the holder to prevent others from using that technology and/or to determine to whom it makes the patented technology available. At EU level, there is currently no specific regulation on SEPs, although parties involved in licence negotiations are currently bound by competition law frameworks including the Horizontal Guidelines and the Huawei/ZTE judgment of the Court of Justice of the European Union.

The aim of the proposal is to make the licensing practice around SEPs more transparent, predictable and efficient in order to encourage better use and wider availability of standardised technology on fair and non-discriminatory terms, especially for small and medium-sized enterprises (SMEs). This, according to the Commission, contributes to the EU's sustainable competitiveness and technological sovereignty.

First, the Commission is committed to improving information on SEPs by setting up a central register and database. Information on SEPs is currently already partly accessible through standardisation organisations, but is fragmented and incomplete.

Improved accessibility and accuracy of this information should facilitate licensing negotiations for SEPs. In addition to patent data on registered, granted SEPs, the database will include publicly accessible information on licensing terms and fees, expert opinions on the total maximum fee, case law on FRAND (fair, reasonable and non-discriminatory) terms and other relevant background information. After notification by market participants and upon invitation by the centre of expertise, the holder must register its SEP within 6 months of the invitation. Registration is subject to a fee. SEP holders cannot maintain their patents until they are registered. If the holder does not register within 6 months, the holder is not allowed to collect licence and/or damages for the period until registration.

Second, the Commission wants to clarify whether a particular patent is actually essential to a standard by introducing an essentiality assessment mechanism for SEPs ("essentiality checks"). Because patents are sometimes notified as essential early in the development of a standard (in cases even before the patent is granted), not all patents that are included in a standard are actually essential for the implementation of that standard. In addition, essentiality checks are not always performed at standardisation organisations; moreover, such checks are technically very complex.

The proposal's essentiality checks should ensure the quality of the information in the register and provide clarity on the status of a registered SEP for both holders and parties implementing the standard. The assessments will be carried out annually, on a sample basis or on request, by assessors specialised in the relevant technical area and selected by the centre of expertise. The

assessment procedure involves costs for both the holder whose patent is being assessed and the implementing party requesting an assessment. The outcome of the assessment is not binding; the final verdict on whether a patent is essential to a particular standard is up to the competent court. However, the results of an essentiality assessment can be helpful in licence negotiations, in patent pools or as evidence in litigation.

Thirdly, the Commission intends to remove ambiguities around FRAND conditions. There, the Commission sees a role for alternative dispute resolution within the existing mechanism at the European Union Intellectual Property Office ("EUIPO"). The proposed procedure, according to the Commission, provides a relatively quick, fair and cost-efficient way to reach agreement on FRAND terms prior to possible court proceedings under the guidance of an independent mediator. Both the holder of an SEP and the potential licensee will have to go through the dispute resolution procedure before initiating legal proceedings. It is envisaged that the procedure will take no longer than 9 months. Although the outcome will not be binding, parties will benefit from completing the procedure and complying with the outcome as it will allow licence negotiations to proceed more smoothly and save court proceedings (and associated costs).

Fourth, the proposal provides for increasing transparency on the potential total licence fee for implementation of a standard. Currently, it is not always easy for implementing parties to find out the costs associated with the implementation of a standard and the - often large number of - patents it contains, which moreover belong to different holders. By including in the register the aggregate maximum royalty rate for a given standard, this will give implementers guidance on how to price their products or services and for holders an indication of their potential return on investment. Upon agreement on the maximum fee, holders can notify the centre of expertise, after which it will be published in the register. If there is no agreement, the expertise centre may appoint a mediator or, at the request of a holder or implementing party, have an indicative (non-binding) expert opinion prepared by a panel of specialists. Stakeholders can submit their views to the panel.

To carry out the aforementioned procedures and tasks, a centre of expertise will be established at EUIPO. The expert centre will also provide information and training specifically aimed at SMEs on (licensing of) SEPs. In addition to this support for SMEs, the proposal also provides for simplified procedures and reduced fees for SMEs.

3. Dutch position on the proposal

(a) Essence of Dutch policy in this field

Innovations are indispensable for the future earning capacity of the Netherlands. For innovative companies and knowledge institutions, the protection and exploitation of intellectual property is of great importance. The competitiveness of the Netherlands benefits from a predictable and balanced system of intellectual property rights.

The importance of standardisation in general and SEPs in particular is increasing. Standards used to play a prominent role especially in the ICT sector, but increasingly other sectors, such as the

automotive industry or Internet of Things, also depend on standardised technology. To ensure that high-quality innovative technologies continue to be included in standards in the future and thus (continue to) become widely available for new applications, it is crucial to monitor the balance between the interests of the patent holder and (potentially) implementing parties. For the patent holder, this means that he has opportunities to get a return on his investments in R&D, while for other market parties, the threshold should not be too high to buy licences.

For an attractive innovation climate in the EU, effective enforcement options are important. The government has therefore always strongly supported the realisation (by 1 June 2023) of the Unified Patent Court (UPC). The UPC simplifies the judicial enforcement of patents in the EU. Instead of having to go through separate national procedures with associated administrative burdens, the UPC offers the possibility of obtaining a judgment in patent disputes (e.g. for SEPs on FRAND terms) from a single body with direct effect throughout almost the entire EU.

b) Assessment + commitment on this proposal

The government endorses the importance of a well-functioning system of SEPs. The proposal constitutes a far-reaching package to adjust the framework for SEPs and licensing on FRAND terms. The government is not unwilling to improve the SEP system where useful and necessary, but at the same time underlines that, as far as it is known, there are no major market distortions in the current system. For this reason, the cabinet considers the proposal unbalanced. Moreover, in the Cabinet's view, the proposal is too narrowly aligned with already well-functioning practice initiatives, such as patent pools.

The ruling of the Court of Justice of the EU in the Huawei/ZTE case and the subsequent case law at national level provide an important guideline that has proved workable in practice. It is expected that the UPC will also play an important role in the further harmonisation of patent jurisprudence in the EU, further contributing to the creation of a level playing field. That prospect reinforces doubts as to whether the scope and intrusiveness of the proposed measures are proportionate to the scale of the problem identified. In addition, there are doubts as to whether the EUIPO can provide sufficient expertise to ensure a smooth handling of the proposed procedures.

At the same time, the current system can be improved in a number of respects and the proposal itself suggests concrete improvements. For instance, the government supports the idea of improving and centralising the provision of information. In general, this would improve the reliability and accessibility of the system and could be helpful for parties on both sides in the negotiation process. The government does make two observations in this regard. First, patent holders face additional administrative burdens due to the envisaged mandatory registration of SEPs. The mandatory nature of the registration is understandable from the point of view of making the register as complete and accurate as possible. Nevertheless, according to the government, the consequence associated with no or late registration - not being able to enforce and not being able to collect licence and/or damages until registration - is far out of proportion to the importance of an accurate register, especially in the initial phase when the registration obligation may not yet be widely known.

For this reason, the government questions the legitimacy and desirability of such a curtailment of property rights and will therefore push for voluntary registration of SEP information during negotiations. It may be explored whether there are other ways to encourage SEP holders to register. Second, within some of the European and international standardisation organisations, there are already arrangements for registration of SEPs. However, these arrangements are fragmented and inconsistent. The proposal can contribute to harmonisation of existing schemes, however, this will have to be done in close cooperation with the relevant standardisation organisations.

The government also welcomes in principle the idea behind the possibility of an assessment mechanism to determine whether a patent is actually essential for a particular standard. This could contribute to improved transparency and thus better balance the playing field between SEP holder and licensee. However, the government wonders whether the chosen procedure will achieve that goal, partly given the potentially large number of essentiality checks it entails. During the negotiations, the government will therefore push for an essentiality check procedure that does not go beyond what is necessary to safeguard the quality of the register and that is also in line with existing practice in patent pools.

Alternative dispute resolution ("ADR") can in principle be a low-threshold and quick alternative to a court decision, but requires voluntary participation and acceptance of the outcome by both parties. The proposal to agree on FRAND terms through a mediation procedure can be useful in specific cases. However, the procedure as proposed by the Commission is not voluntary in the sense that recourse to court can only be taken after the procedure has ended. The additional time (up to 9 months) involved is a severe impediment in situations where speedy enforcement is essential and may have a detrimental effect on the innovation environment. Moreover, it partially negates the speed and efficiency with which the UPC is expected to rule. It is not clear to the government what advantage the proposed ADR procedure has over other ADR procedures such as at the World Intellectual Property Organisation (WIPO) and the UPC's Arbitration and Mediation Centre. The government will therefore work in negotiations to ensure that a mediation procedure does not unnecessarily hamper the enforcement options of patent holders.

In principle, the cabinet welcomes the Commission's intention to support SMEs in this context, but points out that the proposal also entails costs and administrative burdens for SMEs. In the negotiations, the government will endeavour to first get a clear picture of the regulatory burden effects and costs. The government also emphasises that the nuisance experienced by SMEs in the licensing practice around SEPs is currently relatively limited and that other provisions to support SMEs in the implementation of standards could be less drastic and possibly more effective. An exemption from licence fees up to a certain number of production units could be considered. The government will explore support for this alternative during negotiations.

Regarding the proposal for a non-binding expert opinion on the maximum fee, the government believes that this may be useful in specific cases, but that it is up to market players to make use of

it. Licences purchased through patent pools are essentially based on a maximum fee and therefore do not need to be subject to expert opinion. Care should also be taken to ensure that this procedure does not actually delay the negotiation process and lead to higher licence fees. The government will work towards this during the negotiations.

4. Assessment of subsidiarity and proportionality

(a) Subsidiarity

The government's assessment of subsidiarity is positive. The aim of the proposal is to make the licensing practice around SEPs more transparent, predictable and efficient in order to encourage better use and wider availability of standardised technology on fair and non-discriminatory terms, especially for SMEs. These objectives, given the cross-border nature of SEP licensing, cannot be achieved with the same effectiveness at local, regional and Member State levels. Moreover, action at these levels could lead to different outcomes (e.g. of essentiality checks), increasing the risk that parties will choose the jurisdiction where they expect to obtain the most favourable outcome (forum shopping). The proposed measures improve the level playing field in the field of SEPs and remove barriers in the internal market for standardised technology. Insofar as the proposal amends Regulation (EU) 2017/1001, this can only take place at EU level. For these reasons, action at EU level is justified.

(b) Proportionality

The government's view on the proportionality of the proposal is negative. The aim of the proposal is to make the licensing practice around SEPs more transparent, predictable and efficient in order to encourage better use of standardised technology and its wider availability on fair and non-discriminatory terms, especially for SMEs. Despite the fact that the government sees the added value of the proposed measures that look at improving transparency around SEP information, the procedures that are being set up to determine essentiality, FRAND conditions and the maximum fee are not suitable to achieve the intended goal. Indeed, these procedures entail significant time and additional costs for users of the SEP system (including SMEs) that are disproportionate to the objectives. In addition, these procedures may entail a disproportionate curtailment of property rights in parts and may therefore be too intrusive to achieve the intended objective. Moreover, some procedures are mandatory while the outcome is non-binding. In this light, the government doubts whether these parts of the proposal are useful and necessary to achieve the intended improvements to the SEP system. This doubt is reinforced by the fact that the government does not consider the identified problem of inefficient licensing practice to be significant. Moreover, the proposed action goes beyond what is necessary because the objectives can be achieved in other, less intrusive ways, such as under the UPC or patent pools, and through other measures, such as an exemption from licence fees up to a certain number of production units to accommodate SMEs.

Dutch Gov. Position: Regulation on compulsory licensing for crisis management

COURTESY TRANSLATION

1. General information

(a) Title of the proposal

Proposal for a regulation on compulsory licensing for crisis management and amending Regulation (EC) 816/2006

(b) Date of receipt Commission document

27 April 2023

(c) Commission document number

COM(2023)224

(d) EUR-Lex

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2023:224:FIN>

(e) Nr. impact assessment Commission and Opinion Regulatory Review Board

Impact assessment: SWD(2023) 121

Regulatory Review Board opinion: SEC(2023) 173

(f) Council discussion path

Competitiveness Council

(g) Lead ministry

Ministry of Economic Affairs and Climate.

(h) Legal basis

The proposal is based on Articles 114 and 207 of the Treaty on the Functioning of the European Union ('TFEU').

(i) Decision-making procedure Council

Qualified majority

(j) Role of the European Parliament

Codecision

2. Essence of proposal

a) Content of the proposal

On 27 April last, the European Commission (hereinafter: the Commission) published a proposal for a regulation on compulsory licences for crisis management. A compulsory licence is an exception to a patent right. A compulsory licence limits the rights of a patent holder, authorising a third party, for an appropriate fee, to use an invention for production for the domestic market or for export to countries lacking sufficient production capacity.

There is currently no EU-wide harmonisation of compulsory licences for the internal market. This applies both to national patents and to the unitary patent that will come into force from 1 June 2023, which will allow a single patent offering uniform protection in the 17 participating member states. Instead, there is a patchwork of different national rules and procedures on compulsory licences. National rules have insufficient territorial scope, for example because products manufactured under a compulsory licence in one Member State cannot be supplied to another Member State. National procedures also differ, which can lead to ambiguities.

Against this background, this proposal aims to provide the single market with an efficient compulsory licensing system for crises with a cross-border dimension. It aims to enable the Commission to grant compulsory licences under EU crisis instruments, ensuring the supply and free circulation in the internal market of products or processes that are indispensable for responding to a crisis or emergency, or for addressing the consequences of an emergency.

The proposal introduces a procedure and sets conditions for granting a Union compulsory licence to deal with crises in the EU. To ensure that the Union compulsory licence works effectively during crises, the scope of the compulsory licence includes patents, published

patent applications, supplementary protection certificates and utility models Under the proposal, the Commission is entitled to grant a Union compulsory licence when a crisis or emergency mode has been activated or declared at EU level, more particularly in the context of SMEI , serious cross-border health threats , HERA , Chips Act and measures to safeguard security of gas supply. This aims to complement these EU crisis mechanisms by using compulsory licences as part of such mechanisms.

Furthermore, the proposal lays down the following: (i) general conditions to be taken into account by the Commission when granting a Union compulsory licence, (ii) rules for the consultation of an advisory body intended to provide a non-binding opinion to the Commission when considering a Union compulsory licence, (iii) the procedure for granting a Union compulsory licence, (iv) requirements for the content of the Union compulsory licence, (v) criteria for appropriate remuneration for the right holder (vi) specific conditions for the Union compulsory licence to be complied with by the licensee (vii) an export ban on products manufactured under a Union compulsory licence, but thereby expanding the existing possibility for exports of medical products to third countries with public health problems by introducing the possibility of using a Union compulsory licence granted by the Commission instead of separate national compulsory licences in a cross-border manufacturing process (viii) control measures taken by customs services, (ix) the principle of good faith in the relationship between right holder and licensee (x) the right for the Commission to amend the compulsory licence, supplement it with additional measures or terminate it under certain conditions (xi) subject to conditions, the right for the Commission to impose (periodic) fines if one of the parties to the compulsory licence fails to comply with its obligations and (xii) a requirement for Member States to notify the Commission if a national compulsory licence has been granted to deal with a crisis situation.

The proposed measure leaves national compulsory licensing systems unchanged. The Union compulsory licensing system introduced in this proposal does not aim to deal with purely national crises, but only aims to deal with crises that have a cross-border dimension within the EU, which do not fall within the scope of national compulsory licensing systems.

Currently, member states can only act at the national level, meaning they can only grant a compulsory licence for their own territory. This may be sufficient for purely national crises,

where both the crisis and the production capacity are in the same member state. However, this will not be sufficient when a crisis has a cross-border dimension.

3. Dutch position on the proposal

(a) Essence of Dutch policy in this area

Innovations are indispensable for the future earning capacity of the Netherlands. For innovative companies and knowledge institutions, the protection and exploitation of intellectual property (IP) is of great importance. The competitiveness of the Netherlands benefits from a predictable and balanced system of IP rights.

Even in crisis situations, the IP system contributes to the development of innovative solutions, e.g. vaccines and medicines. In addition, the IP system gives parties a basis to cooperate and safely share rights and necessary knowledge, for example to scale up production. Collaborations can take place worldwide because intellectual property rights offer companies a fast and secure way to share their intellectual property, technology and knowledge.

Because of the above reasons, when it comes to the use of compulsory licences, the government believes that this tool can only be used as a last resort and as a safety net. A compulsory licence only comes into the picture for reasons of public interest and if the patent holder is not prepared to grant the licence voluntarily under reasonable conditions, other instruments do not help, deployment of the compulsory licence is proportionate towards the patent holder and can actually lead to availability of the patented technology.

For the Netherlands, the granting of compulsory licences is regulated by Article 57 of the Dutch Patent Act 1995 (ROW 1995). For compulsory licences of pharmaceutical products for export to countries with public health problems, Regulation (EC) No 816/2006 applies directly in the Netherlands. When a compulsory licence is granted, a reasonable fee for use of the patent should be determined that takes into account the economic value of the licence.

(b) Assessment + commitment to this proposal

The government 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.

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 offer a solution.

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. The cabinet is still considering the usefulness and necessity of including all mentioned crisis instruments. The cabinet 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.

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. The government will also question the Commission on ensuring sufficient knowledge, including in the field of intellectual property, in the competent 'advisory body' and the relationship between the proposal and the requirements of parts of the WTO Agreement on Trade-

Related Aspects of Intellectual Property Rights (TRIPS Agreement), 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. During the negotiations, the government will work to ensure and clarify the above points.

4. Assessment of subsidiarity and proportionality

(a) Subsidiarity

Given the EU's exclusive competence in the area of the common commercial policy, the subsidiarity principle does not apply to those parts of the proposal that relate to the common commercial policy.

The government's assessment regarding the subsidiarity of the other parts of the proposal is positive. The regulation aims to provide the internal market with an efficient compulsory licensing system for crises with a cross-border dimension. Action at EU level is justified to ensure the smooth functioning of the internal market in cross-border crisis situations. Currently, member states can only act at national level, meaning they can only grant a compulsory licence for their own territory. This may be sufficient for purely national crises, where both the crisis and the production capacity are in the same member state. However, this will not be sufficient when a crisis has a cross-border dimension. There are also differences between national systems to grant compulsory licences. The proposed measures address this by creating a Union compulsory licence with a streamlined procedure. For these reasons, action at EU level is justified.

(b) Proportionality

The government's assessment with regard to proportionality is positive. The regulation aims to provide the internal market with an efficient compulsory licensing system for crises with a cross-border dimension. The proposed measures, such as the granting of compulsory licences by the Commission under the EU crisis instruments, are appropriate to achieve this

goal, as they can guarantee the supply and free circulation in the internal market of products or processes that are indispensable for responding to a crisis or emergency situation. Moreover, the proposal does not go beyond what is necessary to achieve the identified objectives. It is limited to those aspects where member states cannot achieve a satisfactory result on their own and where the EU can act more effectively, efficiently and with more added value.