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9226/11 PI 32

Subject: Proposal for a Regulation of the Council and the European Parliament
implementing enhanced cooperation in the area of the creation of unitary patent
protection

Proposal for a Council Regulation implementing enhanced cooperation in the area
of unitary patent protection with regard to the applicable translation arrangements

- Political orientation/exchange of views

I. STATE OF PLAY

1. On 10 March 2011 the Competitiveness Council adopted a Decision authorising enhanced cooperation in the area of the creation of unitary patent protection¹. The Decision authorised Belgium, Bulgaria, the Czech Republic, Denmark, Germany, Estonia, Ireland, Greece, France, Cyprus, Latvia, Lithuania, Luxembourg, Hungary, Malta, the Netherlands, Austria, Poland, Portugal, Romania, Slovenia, Slovakia,

¹ Council Decision of 10 March 2011 authorising enhanced cooperation in the area of the creation of unitary patent protection (2011/167/EU)

Finland, Sweden and the United Kingdom to establish enhanced cooperation between themselves in the area of the creation of unitary patent protection, by applying the relevant provisions of the Treaties. The Decision also confirmed that the conditions for launching enhanced cooperation as laid down in Article 20 of the Treaty on the European Union (TEU) and in Articles 326 and 329 of the Treaty of the Functioning of the European Union (TFEU) are fulfilled.

2. The Council requested the Commission to come forward with proposals for implementing Regulations for the creation of unitary patent protection and set out the key features of such protection. Unitary patent protection should provide uniform protection for European patents throughout the territories of the participating Member States and should be registered in respect of all those Member States by the European Patent Office (EPO). The applicable translation arrangements, which are necessary elements of the unitary patent protection, should be simple and cost-effective and correspond to those provided for in the Commission's proposal for a Council Regulation on the translation arrangements for the European Union patent², combined with the elements of compromise proposed by the Belgian Presidency in November 2010 that had wide support in Council.

3. On 13 April 2011, on the basis of the Council's authorising Decision, the Commission adopted two proposals implementing enhanced cooperation in the area of unitary patent protection. The proposal for a Regulation of the European Parliament and the Council implementing enhanced cooperation in the area of the creation of unitary patent protection³ is based on Article 118(1) TFEU and aims to achieve such protection by giving unitary effect in the post-grant phase, to European patents granted by the EPO. The main feature of European patents with unitary effect is their unitary character, i.e.

² 11805/10 + ADD 1 + ADD 2

³ 9224/11

that they provide uniform protection and have equal effect in all participating Member States entailing that they can only be limited, transferred, revoked or lapse in respect of all these States. The Commission's proposal suggests that participating Member States will need to ensure that the details of unitary patent protection are determined by a Select Committee of the Administrative Council of the European Patent Organisation, with the exception of the level of renewal fees and their distribution between the participating Member States which would be set by the Commission in a delegated act.

The proposal for a Council Regulation implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements⁴ is based on Article 118(2) TFEU and determines the translation regime in line with the requirements of the Council's authorising Decision. Accordingly, the translation arrangements maintain the possibility of filing patent applications in any language of the Union at the EPO and ensure full compensation of the costs related to the translation of applications filed in languages other than an official language of the EPO. European patents continue to be granted only in one of the official languages of the EPO. No further translations are required with the exception of transitional arrangements which are proportionate and require additional translations on a temporary basis, without legal effect and purely for information purposes. These transitional arrangements will terminate when high-quality machine translations become available, subject to an objective evaluation of their quality by an independent expert committee every two years (starting from the sixth year of application). On the basis of this evaluation, the Commission will present a report to the Council and, if appropriate, make proposals for terminating the transitional period. In any case, the transitional period lapses 12 years from the date of application of the Regulation. In the case of a dispute, a mandatory translation obligation applies to the patent proprietor.

4. The Mertens group examined the proposals on four occasions: on 14 April, 3 May, 10 May and 19 May.

⁴ 9226/11

The delegations of the participating Member States unanimously argued in favour of rapid progress in the negotiations and advocated not to reopen issues where consensus was found during the Swedish Presidency and which were widely supported under the Belgian Presidency, in particular on the translation arrangements.

All delegations from the participating Member States expressed their general support for the Commission's proposals. The delegations of the two non-participating Member States were opposed and argued in favour of working towards a compromise between the 27 Member States.

5. The Presidency has presented a set of compromise proposals⁵ to accommodate most requests of the delegations, in particular, on matters where they considered that the Commission departed from the content of the requests for launching enhanced cooperation.

As regards the draft Council Regulation implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements, all delegations of the participating Member States agree that, despite their differing opinions, the Presidency compromise in the Annex represents a fine balance between the different views and that this balance should be maintained. Delegations agree that the Commission should, in addition, present a preliminary assessment of the state of the development of machine translation at the European Patent Office, at the time when the draft regulations are adopted in the Council.

⁵ 10277/11

As regards the draft Regulation implementing enhanced cooperation in the area of the creation of unitary patent protection, all delegations agree with the key features of unitary patent protection as set out in the Presidency compromise in the Annex. Accordingly, unitary effect should be attached to European patents granted by the EPO, with identical scope of protection in all participating Member States, on the basis of a request submitted by the patent holder after grant. European patents with unitary effect should have a unitary character and provide uniform protection and equal effect in all participating Member States. It may only be limited, transferred, revoked or lapse in respect of all participating Member States.

II. KEY ISSUES

1. Despite their general support, delegations identified three key matters where they wish to depart from the Commission's proposal, in order to better reflect the conditions set out in their requests and the Council's authorising decision. The draft proposals were also adjusted to accommodate the additional technical issues raised by delegations.
 - A) All delegations are strongly opposed to empowering the Commission to adopt **delegated acts** on the level of renewal fees for European patents with unitary effect, as well as the distribution of renewal fees between the participating Member States (Articles 15(4), 16(4) and 17 of the Commission's proposal). Delegations argued that this proposal represents a significant departure from the content of their request for launching enhanced cooperation since point 38 of the 2009 Council conclusions on an Enhanced patent system in Europe⁶ which sets out that a "Select Committee of the Administrative Council of the European Patent Organisation should [...] fix both the exact level of the renewal fees and the distribution key for their allocation". One delegation raised some concerns relating to the proposed solution and argued that the tasks entrusted to the Select Committee, including setting the level of the renewal fees and their distribution could also be regulated by implementing acts in accordance with Article 291(2) of the TFEU. The Commission, on the other hand, considers any solution other than the use of delegated acts illegal and insists on the use of the latter instrument for determining the level of renewal fees and their distribution.

⁶ 17229/09

The Presidency compromise proposals acknowledge the concerns of the delegations and propose that the level of renewal fees and their distribution should be set by the Select Committee. The Presidency suggests that the draft Regulation should be modified in accordance with the wording set out in Articles 12 and 12a, of the compromise proposal in the Annex.

- B) Almost all delegations underlined the need to **reflect the political link between the creation of unitary patent protection and the unified patent litigation system** in the draft Regulations, as set out in their requests for launching the enhanced cooperation. Consequently, they consider it necessary to establish a legal link between application of the regulations on unitary patent protection and the setting up of the unified jurisdiction. Some delegations underlined that the establishment of such a link should not hinder or block progress in either area. The Commission expressed its understanding towards the request to highlight the political link between the projects through appropriate wording in the draft Regulations.

The Presidency compromise proposals in the Annex provide for a link between the two branches of the reform of the European patent system in Article 22 of the draft Regulation on unitary patent protection and Article 7 of the draft Regulation on the translation arrangements. The Presidency suggests that the draft Regulations should be modified accordingly.

C) A majority of delegations requested the proper reflection of the **criteria for the distribution of renewal fees** to the national patent offices as set out in point 37 of the 2009 Council conclusions on an Enhanced patent system in Europe, according to which the "renewal fees would be payable to the European Patent Office, which would retain 50 percent of the renewal fees and distribute the remaining amount among the Member States in accordance with a distribution key to be used for patent related purposes". Moreover, further details needed to be provided to spell out point 39 of the above conclusions, according to which the "distribution key should be fixed taking into account a basket of fair, equitable and relevant criteria such as for instance the level of patent activity and the size of the market. The distribution key should provide compensation for, among other things, having an official language other than one of the official languages of the European Patent Office, for having disproportionately low levels of patent activity and for more recent EPC-membership". One delegation requested the deletion of all provisions on renewal fees and their distribution from the draft Regulation. Several delegations wished to reopen the discussion on the criteria and requested adding a new element, i.e. "an equal amount per participating Member State determined on the basis of an established percentage of the annual renewal fees". A significant number of delegations as well as the Commission were against this proposal, insisting that such direct transfer had not been foreseen in the compromise achieved under the Swedish Presidency.

The Presidency is of the opinion that the proposals in the Annex represent a balanced compromise between the different positions and respect the agreement enshrined in the 2009 Council conclusions without reopening the principles set therein. The Presidency suggests that the draft Regulation should be modified accordingly.

III. CONCLUSION

In the light of the Presidency's conclusions and suggestions contained in the present Note, the Council (Competitiveness) on 30 May is invited to reach an agreement on a political orientation concerning the two draft Regulations.

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2011/0093 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

implementing enhanced cooperation in the area of the creation of unitary patent protection⁷

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union and the Treaty on the Functioning of the European Union and in particular Article 118(1) thereof,

Having regard to Council Decision 2011/167/EU of 10 March 2011 authorising enhanced cooperation in the area of the creation of unitary patent protection⁸,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) In accordance with Article 3(3) of the Treaty on European Union, the Union shall establish an internal market, shall work for the sustainable development of Europe based on balanced economic growth and shall promote scientific and technological advance. The creation of the legal conditions enabling undertakings to adapt their activities in manufacturing and distributing products across national borders and providing them with more choice and opportunities contributes to attaining these objectives. Uniform patent protection within the internal market, or at least a significant part thereof, should feature amongst the legal instruments which undertakings have at their disposal.

⁷ Changes in relation to the Commission proposal (9224/11) are highlighted.

⁸ OJ L 76, 22.3.2011, p. 53.

- (2) Unitary patent protection should foster scientific and technological advance and the functioning of the internal market by making access to the patent system easier, less costly and legally secure. It should improve the level of patent protection by providing the possibility to obtain uniform patent protection in the territories of the participating Member States and eliminate costs and complexity for undertakings throughout the Union. It should be available to patent applicants from both participating Member States and other States, regardless of nationality, residence or place of establishment.
- (3) Pursuant to Article 118(1) of the Treaty on the Functioning of the European Union (hereinafter "TFEU"), measures foreseen in the context of the establishment and functioning of the internal market include the creation of uniform patent protection throughout the Union and the establishment of centralised Union-wide authorisation, coordination and supervision arrangements.
- (4) On 10 March 2011, the Council adopted Decision 2011/167/EU authorising enhanced cooperation between Belgium, Bulgaria, the Czech Republic, Denmark, Germany, Estonia, Ireland, Greece, France, Cyprus, Latvia, Lithuania, Luxembourg, Hungary, Malta, the Netherlands, Austria, Poland, Portugal, Romania, Slovenia, Slovakia, Finland, Sweden and the United Kingdom (hereinafter "participating Member States") in the area of the creation of unitary patent protection.
- (5) The Convention on the Grant of European Patents (European Patent Convention), as amended (hereinafter "EPC"), established the European Patent Organisation and entrusted it with the task of granting European patents. This task is carried out by the European Patent Office. European patents granted by the European Patent Office under the rules and procedures laid down in the EPC should, on request by the patent proprietor, benefit from unitary effect by virtue of this Regulation in the territories of the participating Member States (hereinafter "European patents with unitary effect").

- (6) It is foreseen in Part IX of the EPC that a group of Member States of the European Patent Organisation may provide that European patents granted for those States have a unitary character. This Regulation constitutes a special agreement within the meaning of Article 142 of the EPC, a regional patent treaty within the meaning of Article 45(1) of the Patent Cooperation Treaty of 19 June 1970 and a special agreement within the meaning of Article 19 of the Convention for the Protection of Industrial Property, signed in Paris on 20 March 1883 and last revised on 14 July 1967.
- (7) The creation of unitary patent protection should be achieved by giving unitary effect to European patents in the post-grant phase by virtue of this Regulation and in respect of the participating Member States. The main feature of European patents with unitary effect should be their unitary character, i.e. providing uniform protection and having equal effect in all participating Member States. Consequently, a European patent with unitary effect should only be limited, [...] transferred, revoked or lapse in respect of all the participating Member States. *A European patent with unitary effect may be licensed in respect of the whole or part of the territories of the participating Member States.* To ensure the uniform substantive scope of protection conferred by unitary patent protection, only European patents that have been granted for all the participating Member States with the same set of claims should benefit from unitary effect. [...] Finally, the unitary effect attributed to a European patent should have an accessory nature and should cease to exist or be limited to the extent that the basic European patent has been revoked or limited.
- (8) In accordance with the general principles of patent law and Article 64(1) of the EPC, unitary patent protection should take effect retroactively in the territories of the participating Member States as of the date of the publication of the mention of the grant of the European patent in the European Patent Bulletin. Where unitary effect takes effect, the participating Member States should ensure that the European patent is deemed not to have taken effect on their territory on the date of the publication of the mention of the grant as a national patent to avoid any duplication of patent protection on their territories stemming from the same European patent granted by the European Patent Office.

(9) In matters not covered by this Regulation or Council Regulation .../... [translation arrangements], the provisions of the EPC and national law including rules of private international law shall apply.

(9a) The matter of compulsory licences is not covered by this Regulation. Compulsory licences for European patents with unitary effect should be governed by the national legislations of the participating Member States on their respective territories.

(10) The rights conferred by the European patent with unitary effect should enable the patent proprietor to prevent any third party not having his consent from the direct and indirect use of the invention on the territories of the participating Member States. However, a number of limitations of the patent proprietor's rights should enable third parties to use the invention, for instance for private and for non-commercial purposes, for experimental purposes, for acts allowed specifically under Union law (in the area of veterinary medicinal products, medicinal products for human use, plant variety rights, the legal protection of computer programs by copyright and the legal protection of biotechnological inventions) under international law and for the use by a farmer of protected livestock for farming purposes.

(11) In accordance with the case law of the Court of Justice of the European Union, the principle of the exhaustion of rights should be applied also in relation to European patents with unitary effect. Therefore, rights conferred by a European patent with unitary effect should also not extend to acts concerning the product covered by that patent, which are carried out within the territories of the participating Member States after that product has been put on the market in the Union by the proprietor of the patent.

(12) As an object of property, a European patent with unitary effect should be dealt with in its entirety, and in all the participating Member States, as a national patent of the participating Member State in which, according to the European Patent Register, the proprietor of the patent had his residence or principal place of business on the date of filing of the patent application. If the proprietor of the patent did not have his residence or a place of business in any of the participating Member State, the European patent with unitary effect should be dealt with as a national patent of the Member State where the European Patent Organisation has its headquarters.

- (13) In order to promote and facilitate the economic exploitation of inventions protected by European patents with unitary effect, the patent proprietor should be able to offer its patent to be licensed to anyone complying with the terms and conditions set out by the patent proprietor in return for appropriate compensation. To that end the patent proprietor may file a statement with the European Patent Office that he is prepared to grant a license in return for appropriate compensation. In that case, the proprietor should, after receipt of that statement, benefit from a reduction of the renewal fees.
- (14) The group of Member States making use of Part IX of the EPC may give tasks to the European Patent Office and set up a Select Committee of the Administrative Council of the European Patent Organisation (hereinafter "Select Committee").
- (15) The participating Member States should give the European Patent Office certain administrative tasks relating to European patents with unitary effect, in particular as regards administration of requests for unitary effect, the registration of unitary effect and of any limitation, licence, transfer, revocation or lapse of European patents with unitary effect, the collection and redistribution of renewal fees, the publication of translations for information purposes during a transitional period and the administration of a compensation scheme of translation costs for applicants filing European patent applications in a language other than one of the official languages of the European Patent Office [...].
- (15a) In the framework of the Select Committee, the participating Member States should set the conditions of entrusting the European Patent Office to carry out the tasks entrusted to it by the participating Member States, ensure that requests for unitary effect are filed with the European Patent Office within one month of the date of the publication of the mention of the grant in the European Patent Bulletin and ensure that they are submitted in the language of the proceedings before the European Patent Office together with the translation prescribed for, during a transitional period, by Council Regulation.../... [translation arrangements]. In the framework of the Select Committee, the participating Member States should also set the level of the renewal fees and the share of the distribution of the renewal fees in accordance with the criteria set out in this Regulation.

- (16) Patent proprietors should pay one common annual renewal fee for European patents with unitary effect. Renewal fees should be progressive throughout the term of the patent protection and, together with the fees to be paid to the European Patent Organisation during the pre-grant stage, should cover all costs associated with the grant of the European patent and the administration of the unitary patent protection *in accordance with Article 146 EPC*. The level of the renewal fees should be fixed with the aim of facilitating innovation and fostering the competitiveness of European businesses. It should also reflect the size of the market covered by the patent and be similar to the level of the national renewal fees for an average European patent taking effect in the participating Member States at the time where the level of the renewal fees is first fixed [...].
- (17) In order to determine the appropriate level and distribution of renewal fees and to ensure that all costs of the tasks in relation to the unitary patent protection entrusted on the European Patent Office are fully covered by the resources generated by the European patents with unitary effect and that, together with the fees to be paid to the European Patent Organisation during the pre-grant stage, the revenues from the renewal fees ensure a balanced budget of the European Patent Organisation.
- (18) Renewal fees should be paid to the European Patent Organisation. [...] *The European Patent Office shall retain an amount to cover the expenses generated at the European Patent Office in carrying out tasks in relation to the unitary patent protection. The remaining amount shall be distributed among the participating Member States, which should be used for patent-related purposes. The share of distribution should be set on the basis of fair, equitable and relevant criteria namely the level of patent activity and the size of the market and should guarantee a minimum amount to be redistributed to each participating Member State.* The distribution should provide compensation for having an official language other than one of the official languages of the European Patent Office, having a disproportionately low level of patenting activity *established on the basis of the European Innovation Scoreboard (EIS)* and having acquired membership of the European Patent Organisation relatively recently.
- (19) *[Deleted]*

(20) An Enhanced partnership between the European Patent Office and central industrial property offices of the Member States should enable the European Patent Office to make regular use, where appropriate, of the result of any search carried out by central industrial property offices on a national patent application the priority of which is claimed in a subsequent European patent application. All central industrial property offices, including those which do not perform searches in the course of a national patent granting procedure, can have an essential role under the enhanced partnership, inter alia by giving advice and support to potential patent applicants, in particular small and medium-sized enterprises, by receiving applications, by forwarding applications to the European Patent Office and by disseminating patent information.

(21) This Regulation should be complemented by Council Regulation .../... implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements, adopted by the Council in accordance with Article 118(2) of the TFEU.

(21a) The jurisdiction for European patents with unitary effect should be established and governed by an instrument setting up a unified patent litigation system.

(22) This Regulation should be without prejudice to the right of Member States to grant national patents and should not replace Member States' laws on patents. Patent applicants should remain free to obtain either a national patent, a European patent with unitary effect, a European patent taking effect in one or more of the Contracting States to the EPC or a European patent with unitary effect validated in addition in one or more other Contracting States to the EPC which are not among the participating Member States.

(23) Since the objective of this Regulation, namely the creation of uniform patent protection, can, by reasons of the scale and effects of this Regulation, be better achieved at Union level, the Union may adopt measures by means of enhanced cooperation where appropriate, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve this objective,

HAVE ADOPTED THIS REGULATION:

CHAPTER I GENERAL PROVISIONS

Article 1 Subject matter

This Regulation implements the enhanced cooperation in the area of the creation of unitary patent protection authorised by Council Decision 2011/167/EU.

This Regulation constitutes a special agreement within the meaning of Article 142 of the Convention on the Grant of European Patents (European Patent Convention), as amended (hereinafter "the EPC").

Article 2 Definitions

For the purposes of this Regulation the following definitions shall apply:

- (a) "Participating Member State" means a Member State which participates, at the time when the request for unitary effect as referred to in Article 12 is made, in enhanced cooperation in the area of the creation of unitary patent protection by virtue of Council Decision 2011/167/EU, or by virtue of a decision adopted in accordance with the second or third subparagraph of Article 331(1) of the TFEU;
- (b) "European patent" means a patent granted by the European Patent Office under the rules and procedures laid down in the EPC;
- (c) "European patent with unitary effect" means a European patent which benefits from unitary effect in the territories of the participating Member States by virtue of this Regulation;
- (d) "European Patent Register" means the register kept by the European Patent Office under Article 127 of the EPC;

- (e) "European Patent Bulletin" means the periodical publication provided for in Article 129 of the EPC.

Article 3
European patent with unitary effect

1. European patents granted with an identical scope of protection in respect of all participating Member States shall benefit from unitary effect in the participating Member States provided that their unitary effect has been registered in the Register for unitary patent protection referred to in Article 12(1)(b).

European patents that were granted with different sets of claims for different participating Member States shall not benefit from unitary effect.

2. A European patent with unitary effect shall have a unitary character. It shall provide uniform protection and shall have equal effect in all participating Member States.

[...] A European patent with unitary effect may only be limited, [...] transferred, revoked or lapse in respect of all the participating Member States.

A European patent with unitary effect may be licensed in respect of the whole or part of the territories of the participating Member States.

3. The unitary effect of a European patent shall be deemed not to have arisen to the extent that the European patent has been revoked or limited.

Article 4
Date of effect

1. A European patent with unitary effect shall take effect in the territories of the participating Member States on the date of the publication, by the European Patent Office, of the mention of the grant of the European patent in the European Patent Bulletin.
2. The participating Member States shall take the necessary measures to ensure that, where the unitary effect of a European patent has been registered, the European patent is deemed not to have taken effect as a national patent in their territory on the date of the publication of the mention of the grant in the European Patent Bulletin.

Article 5
Prior rights

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Article 5a
Law applicable to a European patent with unitary effect

A European patent with unitary effect shall be governed by:

(a) this Regulation and Regulation .../... implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements and Union law;

(b) in matters not covered by (a), the EPC;

(c) in matters not covered by (a) or (b), national law including rules of private international law, determined in accordance with Article 10.

CHAPTER II

EFFECTS OF THE EUROPEAN PATENT WITH UNITARY EFFECT

Article 6
Right to prevent the direct use of the invention

The European patent with unitary effect shall confer on its proprietor the right to prevent any third party not having the proprietor's consent from the following:

- (a) making, offering, placing on the market or using a product which is the subject matter of the patent, or importing or storing the product for those purposes;
- (b) using a process which is the subject matter of the patent or, where the third party knows, or should have known, that the use of the process is prohibited without the consent of the proprietor of the patent, from offering the process for use within the participating Member States;
- (c) offering, placing on the market, using, importing or storing for those purposes a product obtained directly by a process which is the subject matter of the patent.

Article 7
Right to prevent the indirect use of the invention

1. The European patent with unitary effect shall confer on its proprietor the right to prevent any third party from supplying or offering to supply within the participating Member States any person without the proprietor's consent, other than a party entitled to exploit the patented invention, with means, relating to an essential element of that invention, for putting it into effect therein, when the third party knows, or should have known, that those means are suitable and intended for putting that invention into effect.
2. Paragraph 1 shall not apply when the means are staple commercial products, except where the third party induces the person supplied to perform any of the acts prohibited by Article 6.
3. Persons performing the acts referred to in Article 8(a) to (d) shall not be considered to be parties entitled to exploit the invention within the meaning of paragraph 1.

Article 8
Limitation of the effects of the European patent with unitary effect

The rights conferred by the European patent with unitary effect shall not extend to any of the following:

- (a) acts done privately and for non-commercial purposes;
- (b) acts done for experimental purposes relating to the subject matter of the patented invention;
- (c) acts carried out solely for the purpose of conducting the necessary tests and trials in accordance with Article 13(6) of Directive 2001/82/EC⁹ or Article 10(6) of Directive 2001/83/EC¹⁰ in respect of any patent covering the product within the meaning of either of those Directives;

⁹ Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1), as amended.

¹⁰ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67), as amended.

- (d) the extemporaneous preparation for individual cases in a pharmacy of a medicine in accordance with a medical prescription nor acts concerning the medicine so prepared;
- (e) the use on board vessels of countries other than participating Member States of the patented invention, in the body of the vessel, in the machinery, tackle, gear and other accessories, when such vessels temporarily or accidentally enter the waters of participating Member States, provided that the invention is used there exclusively for the needs of the vessel;
- (f) the use of the patented invention in the construction or operation of aircraft or land vehicles or other means of transport of States other than participating Member States, or of accessories to such aircraft or land vehicles, when these temporarily or accidentally enter participating Member States;
- (g) the acts specified in Article 27 of the Convention on International Civil Aviation of 7 December 1944¹¹, where these acts concern the aircraft of a country other than a participating Member State;
- (h) acts as covered by the farmers privilege pursuant to Article 14 of Regulation (EC) No. 2100/94¹² which applies *mutatis mutandis*;
- (i) the use by a farmer of protected livestock for farming purposes, on condition that the breeding animals or other animal reproductive material were sold or otherwise commercialised to the farmer by the patent proprietor or with his/her consent. Such use includes the provision of the animal or other animal reproductive material for the purposes of his/her agricultural activity, but not the sale in the framework of or for the purpose of commercial reproductive activity;
- (j) the acts and the use of the obtained information as allowed under Articles 5 and 6 of Council Directive 91/250/EEC¹³, in particular, by its provisions on decompilation and interoperability; and

¹¹ International Civil Aviation Organization (ICAO), "Chicago Convention", Document 7300/9 (9th edition, 2006)

¹² Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights (OJ L 227, 1.9.1994, p. 1).

¹³ Council Directive 91/250/EEC of 14 May 1991 on the legal protection of computer programs (OJ L 122, 17.5.1991, p. 42).

- (k) the acts allowed pursuant to Article 10 of Directive 98/44/EC of the European Parliament and of the Council¹⁴.

Article 9

Exhaustion of the rights conferred by the European patent with unitary effect

The rights conferred by a European patent with unitary effect shall not extend to acts concerning the product covered by that patent which are carried out within the territories of the participating Member States after that product has been put on the market in the Union by the proprietor of the patent or with his/her consent, unless there are legitimate grounds for the proprietor to oppose further commercialisation of the product.

CHAPTER III
A EUROPEAN PATENT WITH UNITARY EFFECT AS AN OBJECT OF PROPERTY

Article 10

Treating a European patent with unitary effect as a national patent

1. A European patent with unitary effect as an object of property shall be treated in its entirety and in all the participating Member States as a national patent of the participating Member State in which, according to the European Patent Register:
 - (a) the patent proprietor had his/her residence or principal place of business on the date of filing of the application for the patent; or
 - (b) where subparagraph (a) does not apply, the proprietor had a place of business on that date.

¹⁴ Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (OJ L 213, 30.7.1998, p. 13).

2. Where two or more persons are mentioned in the European Patent Register as joint proprietors, paragraph 1(a) shall apply to the joint proprietor indicated first. Where this is not possible, paragraph 1(a) shall apply to the next joint proprietor indicated in the order of entry. Where paragraph 1(a) does not apply to any of the joint proprietors, paragraph 1(b) shall apply accordingly.
3. Where no proprietor has his/her residence or a place of business in a participating Member State for the purposes of paragraphs 1 or 2, the European patent with unitary effect as an object of property shall be dealt with in its entirety and in all the participating Member States as a national patent of the State where the European Patent Organisation has its headquarters in accordance with Article 6(1) of the EPC.
4. The acquisition of a right may not be dependent on any entry in a national patent register.

Article 11
Licenses of right

1. The proprietor of a European patent with unitary effect may file a statement with the European Patent Office that he/she is prepared to allow any person to use the invention as a licensee in return for appropriate compensation.
2. A license obtained under this Regulation shall be treated as a contractual license.

CHAPTER IV
INSTITUTIONAL PROVISIONS

Article 12
Implementation by the participating Member States

1. The participating Member States shall give, within the meaning of Article 143 of the EPC, the European Patent Office the following tasks to be carried out in conformity with the internal rules of the European Patent Office:
 - (a) the administration of requests for unitary effect by proprietors of European patents;

- (b) the inclusion and administration of a Register for unitary patent protection registering unitary effect as well as any limitation, license, transfer, revocation or lapse of a European patent with unitary effect, within the European Patent Register;
- (c) receiving and registering statements on licensing referred to in Article 11, their withdrawal and licensing commitments undertaken in international standardisation bodies;
- (d) the publication of the translations referred to in Article 6 of Council Regulation .../... [translation arrangements] during the transitional period referred to in that Article;
- (e) the collection and administration of renewal fees for European patents with unitary effect, in respect of the years following the year in which the Register referred to in point b) mentions their grant; the collection and administration of additional fees paid in cases of late payment of renewal fees within six months of the due date, as well as the distribution of a part of the collected renewal fees to the participating Member States; and
- (f) the administration of a compensation scheme of translation costs for applicants filing European patent applications in one of the official languages of the Union that is not an official language of the European Patent Office.

[...]

2. *[Deleted]*
3. The participating Member States shall ensure effective legal protection before the competent court against the decisions of the European Patent Office in carrying out the tasks referred to in paragraph 1.

Article 12a
Select Committee

1. In their capacity as Contracting States to the EPC, the participating Member States shall ensure the governance and supervision of the activities related to the tasks referred to in Article 12 by the European Patent Office. To that end they shall set up a Select Committee of the Administrative Council of the European Patent Organisation within the meaning of Article 145 of the EPC.

2. The participating Member States in the framework of the Select Committee shall:
 - (a) set the conditions of entrusting the European Patent Office to carry out the tasks referred to in Article 12(1);
 - (b) ensure that requests by the patent proprietor for unitary effect for a European patent are filed in the language of the proceedings as defined in Article 14(3) of the EPC no later than one month after the mention of the grant is published in the European Patent Bulletin;
 - (c) ensure that the unitary effect is indicated in the Register for unitary patent protection, where a request for unitary effect has been filed and, during the transitional period provided for in Article 6 of Council Regulation .../... [translation arrangements], has been submitted together with the translations referred to in that Article; and that the European Patent Office is informed of limitations and revocations of European patents with unitary effect;
 - (d) set the level of the renewal fees in accordance with Article 15; and
 - (e) set the share of distribution of the renewal fees in accordance with Article 16.

CHAPTER V FINANCIAL PROVISIONS

Article 13 Principle

The expenses incurred by the European Patent Office in carrying out the additional tasks given, within the meaning of Article 143 of the EPC, by Member States to the European Patent Office shall be covered by the fees generated by the European patents with unitary effect.

Article 14 Renewal fees

1. Renewal fees and additional fees for the late payment of renewal fees for European patents with unitary effect shall be paid to the European Patent Organisation by the patent proprietor. Those fees shall be due in respect of the years following the year in which the European Patent Register mentions the grant of the European patent which benefits from unitary effect by virtue of this Regulation.
2. A European patent with unitary effect shall lapse if a renewal fee and, where applicable, any additional fee have not been paid in due time.
3. In the case of Article 11(1), renewal fees for the patent which fall due after receipt of the statement shall be reduced.

Article 15 Level of renewal fees

1. Renewal fees for European patents with unitary effect shall be
 - (a) progressive throughout the term of the unitary patent protection, and
 - (b) sufficient not only to cover all costs associated with the grant of the European patent and the administration of the unitary patent protection but also,
 - (c) sufficient together with the fees to be paid to the European Patent Organisation during the pre-grant stage, to ensure a balanced budget of the European Patent Organisation.

2. The level of the renewal fees shall be fixed with the aim of
 - (a) facilitating innovation and fostering the competitiveness of European businesses,
 - (b) reflecting the size of the market covered by the patent and
 - (c) being similar to the level of the national renewal fees for an average European patent taking effect in the participating Member States at the time where the level of the renewal fees is first fixed [...].
3. In order to reach these objectives set out in this Chapter, [...] the level of renewal fees shall be set a level that
 - (a) is equivalent to the level of renewal fee to be paid for the average geographical coverage of current European patents,
 - (b) reflects the renewal rate of current European patents, and
 - (c) the number of requests for unitary protection.
4. *[Deleted]*

*Article 16
Distribution*

1. The European Patent Office shall retain 50 percent of the renewal fees referred to in Article 14 paid for European patents with unitary effect. The remaining amount shall be distributed to the participating Member States in accordance with the share of distribution of the renewal fees set in accordance with Article 12a(2)(e).
2. In order to reach these objectives set out in this Chapter, [...] the share of distribution of renewal fees referred to in paragraph 1 among the participating Member States shall be set on the basis of the following fair, equitable and relevant criteria:
 - (a) the number of patent applications,

- (b) the size of the market expressed in the number of population,
- (c) provision of compensation to Member States for having an official language other than one of the official languages of the European Patent Office, *and/or* having a disproportionately low level of patenting activity and *or* having acquired membership of the European Patent Organisation relatively recently.

3. *[Deleted]*

4. *[Deleted]*

Article 17
Exercise of the delegation

[Deleted]

CHAPTER VI
FINAL PROVISIONS

Article 18
Cooperation between the Commission and the European Patent Office

The Commission shall establish a close cooperation through a working agreement with the European Patent Office in the fields covered by this Regulation. This cooperation shall include regular exchanges of views on the functioning of the working agreement and in particular on the issue of renewal fees and the impact on the budget of the European Patent Organisation.

Article 19
Application of competition law and the law relating to unfair competition

This Regulation is without prejudice to the application of competition law and the law relating to unfair competition.

Article 20
Report on the operation of this Regulation

1. Not later than six years from the date on which the first European patent with unitary effect takes effect in the territories of the participating Member States, the Commission shall present to the Council a report on the operation of this Regulation and, where necessary, make appropriate proposals for amending it. Subsequent reports on the operation of this Regulation shall be presented by the Commission every six years.
2. The Commission shall submit reports regularly on the functioning of the renewal fees referred to in Article 14 with particular emphasis on the continued compliance with the principles set out in Article 15.

Article 21
Notification by the participating Member States

The participating Member States shall notify the Commission of the measures adopted in accordance with Articles 4(2) and 12 by the date set in Article 22(2).

Article 22
Entry into force and application

1. This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.
2. It shall apply from [a specific date will be set and it will coincide with the date of application of Council Regulation .../... on the implementation of enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements] or the date of the entry into force of the instrument creating a unified patent litigation system and the setting up of such a system, whichever is the later.
3. The participating Member States shall ensure that the rules referred to in Articles 4(2) and 12 are in place prior to or on the date set in paragraph 2.
4. Unitary patent protection may be requested for any European patent granted on or after the date set out in paragraph 2.

This Regulation shall be binding in its entirety and directly applicable in the participating Member States in accordance with the Treaties.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

2011/0094 (CNS)

Proposal for a

COUNCIL REGULATION

implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements¹⁵

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 118(2) thereof,

Having regard to Council Decision 2011/167/EU of 10 March 2011 authorising enhanced cooperation in the area of the creation of unitary patent protection¹⁶,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

Having regard to the opinion of the European Parliament¹⁷,

Acting in accordance with a special legislative procedure,

Whereas:

- (1) Pursuant to Council Decision 2011/167/EU authorising enhanced cooperation in the area of the creation of unitary patent protection, Belgium, Bulgaria, the Czech Republic, Denmark, Germany, Estonia, Greece, France, Ireland, Cyprus, Latvia, Lithuania, Luxembourg, Hungary, Malta, the Netherlands, Austria, Poland, Portugal, Romania, Slovenia, Slovakia, Finland, Sweden and the United Kingdom (hereinafter "participating Member States") were authorised to establish enhanced cooperation between themselves in the area of the creation of unitary patent protection.

¹⁵ Changes in relation to the Commission proposal (9226/11) are highlighted.

¹⁶ OJ, L 76, 22.3.2011, p. 53.

¹⁷ OJ C , , p. .

- (2) Under Regulation of the European Parliament and of the Council xx/xx implementing enhanced cooperation in the area of the creation of unitary patent protection¹⁸, certain European patents granted by the European Patent Office under the rules and procedures of the Convention on the Grant of European Patents of 5 October 1973, as amended (hereinafter "EPC") may be given unitary effect in the territories of the participating Member States upon the request of the patent proprietor.
- (3) Translation arrangements for European patents with unitary effect in the territories of the participating Member States (hereinafter "European patent with unitary effect") should be established by a separate Regulation in accordance with Article 118(2) of the Treaty on the Functioning of the European Union (hereinafter "TFEU").
- (4) In accordance with Council Decision 2011/167/EU authorising enhanced cooperation in the area of the creation of unitary patent protection, the translation arrangements for European patents with unitary effect should be simple and cost-effective and correspond to those provided for in the proposal for a Council Regulation on the translation arrangements for the European Union patent¹⁹, presented by the Commission on 30 June 2010, combined with the elements of compromise proposed by the Presidency in November 2010 that had wide support in the Council²⁰.
- (5) Translation arrangements applicable to European patents with unitary effect that are cost-effective, simplified and ensure legal certainty should stimulate innovation and should, in particular, benefit small and medium-sized enterprises. Such translation arrangements should make access to the European patent with unitary effect and to the patent system as a whole easier, less costly and less risky.
- (6) Since the European Patent Office is responsible for the grant of European patents, the translation arrangements for the European patent with unitary effect should be built on the current procedure in the European Patent Office. Those arrangements should aim at achieving the necessary balance between the interests of economic operators and the public interest in terms of the cost of proceedings and the availability of technical information.

¹⁸ OJ C , , p. .

¹⁹ COM(2010) 350.

²⁰ 15385/10, 15385/10 + ADD 1.

- (7) Without prejudice to certain transitional arrangements, where the specification of a European patent with unitary effect has been published in accordance with Article 14(6) of the EPC, no further translations should be required. Article 14(6) of the EPC provides that the specification of a European patent is published in the language of the proceedings before the European Patent Office and includes a translation of the claims into the other two official languages of the European Patent Office.
- (8) In the case of a dispute concerning a European patent with unitary effect, it is a legitimate requirement that the patent proprietor should provide a full translation of the patent into an official language of the participating Member State in which either the alleged infringement took place or in which the alleged infringer is domiciled. The patent proprietor should also be required to provide, at the request of a court competent in the territory of the participating Member States for disputes concerning the European patent with unitary effect, a full translation of the patent into the language of proceedings of that court. Such translations should not be carried out by automated means and should be provided at the expense of the patent proprietor. In the case of a dispute concerning a claim for damages the court hearing the dispute should take into consideration that, before having been provided with a translation in his own language, the alleged infringer may have acted in good faith and may have not known or had reasonable grounds to know that he was infringing the patent. The competent court should assess the circumstances of the individual case and *inter alia* should take into account whether the alleged infringer is a small and medium-sized enterprise operating only at local level, the language of the proceedings before the European Patent Office and, during the transitional period, the translation submitted together with the request for unitary effect.

- (9) In order to facilitate access to European patents with unitary effect, in particular for small and medium-size enterprises, applicants who do not have a language in common with one of the official languages of the European Patent Office should be able to file their patent applications at the European Patent Office in any other official language of the Union. As a complementary measure, for applicants obtaining European patents with unitary effect and having their residence or principal place of business within a Member State of the Union which has as an official language a language other than one of the official languages of the European Patent Office, a system of additional reimbursements of the costs related to the translation from that language into the language of the proceedings of the European Patent Office, beyond what is currently already in place at the European Patent Office, should be administered by the European Patent Office in accordance with Article 12 of Regulation xx/xx [substantive provisions].
- (10) In order to promote the availability of patent information and the dissemination of technological knowledge, machine translations of patent applications and specifications into all official languages of the Union should be available as soon as possible. Machine translations are being developed by the European Patent Office and are a very important tool seeking to improve access to patent information and to disseminate widely the technological knowledge. The timely availability of high quality machine translations of European patent applications and specifications into all official languages of the Union would benefit all the users of the European patent system. Machine translations are a key feature of European Union policy. Such machine translations should serve for information purposes only and should not have any legal effect.

- (11) During a transitional period, before a system of high quality machine translations into all official languages of the Union becomes available, a request for unitary effect as referred to in Article 12 of Regulation xx/xx [substantive provisions] shall be accompanied by a full translation of the specification of the patent into English where the language of the proceedings before the European Patent Office is French or German, or into any official language of the [...] Member States that is an official language of the Union where the language of the proceedings before the European Patent Office is English. Those arrangements would ensure that during a transitional period all European patents with unitary effect are made available in English which is the language customary in the field of international technological research and publications. Furthermore, they would ensure that with respect to European patents with unitary effect translations would be published in other official languages of the participating Member States. Such translations should not be carried out by automated means and their high quality should contribute to the training of translation engines by the European Patent Office. They would also enhance the dissemination of patent information. The transitional period should terminate as soon as high quality machine translations into all official language of the Union are available, subject to an objective evaluation of the quality. The quality of machine translations should be regularly and objectively evaluated by an independent expert committee established by the participating Member States in the framework of the European Patent Organisation and composed of the representatives of the European Patent Office and the users of the European patent system. Given the technological development, the maximum period for the development of high quality machine translations cannot be considered to exceed 12 years. Consequently, the transitional period should lapse 12 years from the date of application of this Regulation, unless it has been decided to terminate that period earlier.
- (12) Since the substantive provisions applicable to a European patent with unitary effect are governed by Regulation xx/xx implementing enhanced cooperation in the area of the creation of unitary patent protection and are completed by the translation arrangements provided for in this Regulation, this Regulation should apply on the same date as Regulation xx/xx [substantive provisions] [*the date to be determined*].

- (13) This Regulation is without prejudice to the rules governing the languages of the Institutions of the Union established in accordance with Article 342 TFEU and to Council Regulation 1/1958 determining the languages to be used by the European Economic Community²¹. This Regulation is based on the linguistic regime of the European Patent Office and should not be considered as creating a specific linguistic regime for the Union, or as creating a precedent for a limited language regime in any future legal instrument of the Union.
- (14) In accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union, the objective of the action to be taken, namely the creation of a uniform and simplified translation regime for European patents with unitary effect, can be only achieved at European level. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve this objective.

HAS ADOPTED THIS REGULATION:

Article 1
Subject matter

This Regulation implements the enhanced cooperation in the area of the creation of unitary patent protection authorised by Council Decision No 2011/167/EU with regard to the applicable translation arrangements.

Article 2
Definitions

For the purposes of this Regulation, the following definitions shall apply:

- (a) "European patent with unitary effect" means a European patent which benefits from unitary effect in the territories of the participating Member States by virtue of Regulation xx/xx [substantive provisions].
- (b) "Specification of the European patent" means a specification of the European patent as defined in Rule 73 of the Implementing Regulations of the Convention on the Grant of European Patents of 5 October 1973, as amended (hereinafter "EPC");

²¹ Council Regulation 1/1958 determining the languages to be used by the European Economic Community (OJ 17, 6.10.1958, p. 385 – 386).

- (c) "Language of the proceedings" means the language in the proceedings before the European Patent Office as defined in Article 14(3) of the EPC.

Article 3

Translation arrangements for the European patent with unitary effect

1. Without prejudice to Articles 4 and 6 of this Regulation, where the specification of a European patent with unitary effect has been published in accordance with Article 14(6) of the EPC, no further translations are required.
2. A request for unitary effect as referred to in Article 12 of Regulation xx/xx [substantive provisions] shall be submitted in the language of the proceedings.

Article 4

Translation in the case of a dispute

1. In the case of a dispute relating to a European patent with unitary effect, the patent proprietor shall provide at the request and the choice of an alleged infringer, a full translation of the patent into an official language of the participating Member State in which either the alleged infringement took place or in which the alleged infringer is domiciled.
2. In the case of a dispute relating to a European patent with unitary effect, the patent proprietor shall provide in the course of legal proceedings, at the request of a court competent in the territories of the participating Member States for disputes concerning European patents with unitary effect, a full translation of the patent into the language of the proceedings of that court.
3. The cost of the translations referred to in paragraphs 1 and 2 shall be borne by the patent proprietor.
4. In the case of a dispute concerning a claim for damages, the court hearing the dispute shall take into consideration that the alleged infringer may have acted without knowing or having reasonable grounds to know that he was infringing the patent before having been provided with the translation referred to in paragraph 1.

Article 5
Administration of a compensation scheme

Given the fact that European patent applications may be filed in any language under Article 14(2) of the EPC, in accordance with Article 12 of Regulation xx/xx [substantive provisions], the participating Member States, shall give, within the meaning of Article 143 of the EPC, the European Patent Office the task of administering a compensation scheme of reimbursing all translation costs up to a ceiling, from the fees referred to in Article 13 of that Regulation, for applicants filing patent applications at the European Patent Office in one of the official languages of the Union that is not an official language of the European Patent Office.

Article 6
Transitional measures

1. During a transitional period starting on the date of application of this Regulation in accordance with Article 7(2) of this Regulation, a request for unitary effect as referred to in Article 12 of Regulation xx/xx [substantive provisions] shall be submitted together with the following:
 - (a) where the language of the proceedings is French or German, a full translation of the specification of the European patent into English; or
 - (b) where the language of the proceedings is English, a full translation of the specification of the European patent into any official language of the [...] Member States that is an official language of the Union.

2. In accordance with Article 12 of Regulation xx/xx [substantive provisions], the participating Member States, shall give, within the meaning of Article 143 of the EPC, the European Patent Office the task of publishing the translations referred to in paragraph 1 as soon as possible after the date on which a request for unitary effect as referred to in Article 12 of Regulation xx/xx [substantive provisions] is filed. The text of such translations shall have no legal value and be for information purposes only.

3. Every two years from the sixth year calculated from the date of application of this Regulation, an objective evaluation of the availability of high quality machine translations of patent applications and specifications into all official languages of the Union as developed by the European Patent Office shall be carried out by an independent expert committee. This expert committee shall be established by the participating Member States in the framework of the European Patent Organisation and shall be composed of representatives of the European Patent Office and of the non-governmental organisations representing users of the European patent system invited by the Administrative Council of the European Patent Organisation as observers in accordance with Article 30(3) of the EPC.
4. On the basis of the evaluation referred to in paragraph 3, every two years the Commission shall present a report to the Council and, if appropriate, make proposals for terminating the transitional period.
5. If the transitional period is not terminated on the basis of a proposal of the Commission, it shall lapse 12 years from the date of application of this Regulation.

Article 7
Entry into force

1. This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.
2. It shall apply from [*a specific date will be set and it will coincide with the date of application of Regulation xx/xx on the implementation of enhanced cooperation in the area of the creation of unitary patent protection*] or the date of the entry into force of the instrument creating a unified patent litigation system and the setting up of such a system, whichever is the later.

This Regulation shall be binding in its entirety and directly applicable in the participating Member States in accordance with the Treaties.

Done at Brussels,

For the Council
The President
