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Proposal for a

**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**implementing enhanced cooperation in the area of the creation of unitary patent  
protection**

{COM(2011) 216 final}

{SEC(2011) 482 final}

{SEC(2011) 483 final}

## EXPLANATORY MEMORANDUM

### 1. CONTEXT OF THE PROPOSAL

#### 1.1. History of the proposal

In the European Union (EU), patent protection currently can be obtained either through the national patent offices of the Member States, which grant national patents, or through the European Patent Office (EPO) in the framework of the European Patent Convention (EPC)<sup>1</sup>. However, once a European patent is granted by the EPO, it must be validated in each Member State where protection is sought. For a European patent to be validated in a territory of a Member State, national law may *inter alia* require that the patent proprietor files a translation of the European patent into the official language of that Member State<sup>2</sup>. Therefore, the current patent system in the EU, in particular in terms of translation requirements, involves very high costs and complexity. The overall cost of validation of an average European patent reaches 12 500 EUR if validated only in 13 Member States and over 32 000 EUR if validated in the whole EU. It is estimated that the actual validation costs are around 193 million EUR per year in the EU.

Both the Europe 2020 Strategy<sup>3</sup> and the Single Market Act<sup>4</sup> identified the creation of an economy based on knowledge and innovation as a priority. Both initiatives seek to improve the framework conditions for business to innovate by creating unitary patent protection in the EU Member States together with a unified European patent litigation system.

Despite of broad recognition of the competitive disadvantage European business faces in the absence of unitary patent protection, the Union has not been able to establish unitary patent protection. The Commission first proposed a Council Regulation on the Community patent in August 2000<sup>5</sup>. In 2002, the European Parliament adopted a Legislative Resolution<sup>6</sup>. In 2003, the Council adopted a common political approach<sup>7</sup>, but a final agreement could not be reached. Discussions on the proposal were re-launched in the Council after adoption by the Commission of the Communication "Enhancing the patent system in Europe" in April 2007<sup>8</sup>. The Communication confirmed the commitment to the creation of a single Community patent.

The Lisbon Treaty introduced a more specific legal basis for the creation of European intellectual property rights. According to Article 118(1) of the Treaty on the Functioning of the European Union (TFEU), measures for the creation of European intellectual property rights are to be established by the European Parliament and the Council acting under the ordinary legislative procedure. Article 118(2) TFEU, however, sets out a specific legal basis

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<sup>1</sup> <http://www.epo.org>

<sup>2</sup> In order to reduce the costs caused by validation requirements, in 2000 the EPC Contracting States adopted the so-called "London Agreement" (Agreement on the application of Article 65 EPC, OJ EPO 2001, 550) which is currently in force in eleven EU Member States and results in reduced translation requirements.

<sup>3</sup> COM(2010) 2020.

<sup>4</sup> COM(2010) 608 final/2.

<sup>5</sup> COM(2000) 412.

<sup>6</sup> European Parliament legislative resolution on the proposal for a Council regulation on the Community patent (COM(2000) 412 - C5-0461/2000 - 2000/0177(CNS)) (OJ C 127 E, 29.5.2003, p. 519–526).

<sup>7</sup> Council document 7159/03.

<sup>8</sup> COM(2007) 165.

for the language arrangements for European intellectual property rights, which are to be established under a special legislative procedure by the Council acting unanimously after consulting the European Parliament. Therefore, the translation arrangements for any unitary patent system in the EU must be established by a separate regulation.

In December 2009, the Council adopted conclusions on an "Enhanced patent system for Europe"<sup>9</sup> and a general approach on the proposal for a Regulation on the EU Patent<sup>10</sup>. Translation arrangements, however, were not covered due to the abovementioned change in the legal basis.

On 30 June 2010 the Commission adopted a proposal for a Council Regulation on the translation arrangements for the EU patent<sup>11</sup>. The proposal was accompanied by an Impact Assessment report<sup>12</sup> analysing various options for the possible translation arrangements. Regardless of the significant efforts made by the Presidency of the Council, it was recorded at the Competitiveness Council meeting of 10 November 2010 that no unanimous agreement on the translation arrangements could be reached<sup>13</sup>. It was confirmed at the Competitiveness Council meeting on 10 December 2010<sup>14</sup> that insurmountable difficulties existed, making a decision requiring unanimity impossible now and in the foreseeable future. It follows that the objectives of the proposed Regulations to establish unitary patent protection in the entire European Union can not be attained within a reasonable period by applying the relevant provisions of the Treaties.

On the basis of the request of twelve Member States (Denmark, Estonia, Finland, France, Germany, Lithuania, Luxembourg, the Netherlands, Poland, Slovenia, Sweden and the United Kingdom) the Commission submitted a proposal<sup>15</sup> to the Council for authorising enhanced cooperation in the area of unitary patent protection. All Member States specified in their requests that the Commission's legislative proposals within the enhanced cooperation should be based on the recent negotiations in the Council. Following the adoption of the proposal, Belgium, Austria, Ireland, Portugal, Malta, Bulgaria, Romania, the Czech Republic, Slovakia Hungary, Latvia, Greece and Cyprus also requested to join the cooperation. The proposal for the authorising decision was adopted by the Council, after obtaining the consent of the European Parliament, on 10 March 2011. The present regulation implements the enhanced cooperation in the area of the creation of unitary patent protection as authorised by Council Decision 2011/167/EU<sup>16</sup>.

## 1.2. Legal approach

In comparison to the Commission's proposal in 2000, this proposal builds on the existing system of European patents by providing unitary effect to European patents granted for the territories of the participating Member States. The unitary patent protection will be optional

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<sup>9</sup> Council document 17229/09.

<sup>10</sup> Council document 16113/09 Add 1. The terminology changed (from the "Community" to "EU" patent) due to the entry into force of the Lisbon Treaty.

<sup>11</sup> COM(2010) 350.

<sup>12</sup> SEC(2010) 796.

<sup>13</sup> Press Release of the Extraordinary Council meeting "Competitiveness (Internal Market, Industry, Research and Space)", 16041/10, 10.11.2010.

<sup>14</sup> See press release 17668/10.

<sup>15</sup> COM(2010) 790.

<sup>16</sup> Council Decision 2011/167/EU of 10 March 2011 authorising enhanced cooperation in the area of the creation of unitary patent protection (OJ L 76, 22.3.2011, p. 53).

and co-exist with national and European patents. The proprietors of European patents granted by the EPO, may submit a request to the EPO within one month after the publication of the mention of the grant of the European patent, asking for the registration of the unitary effect. Once it is registered, the unitary effect will provide uniform protection and will have equal effect throughout the territories of all participating Member States. European patents with unitary effect may only be granted, transferred, revoked or may lapse in respect of those territories as a whole. The participating Member States shall give the task of the administration of European patents with unitary effect to the EPO.

## 2. CONSULTATIONS WITH THE INTERESTED PARTIES

In January 2006, the Commission launched a broad consultation on the future patent policy in Europe<sup>17</sup>. More than 2500 replies were received from a variety of stakeholders, including businesses in all sectors of the economy, business and SME associations, patent practitioners, public authorities and academics. Respondents were asking for a European patent system that provides incentives for innovation, ensures the diffusion of scientific knowledge, facilitates technology transfer, is available to all players in the market and is legally certain. The replies clearly showed stakeholders' disappointment with the lack of progress in the Community patent project. In particular, nearly all respondents (the users of the patent system) rejected the translation arrangements included in the Council's 2003 common political approach which laid down that the patent holder would have to supply a translation of the claims (having legal effect) into all official Community languages.

Stakeholders expressed an overall support for a "unitary, affordable and competitive" Community patent. This message was repeated at a public hearing held on 12 July 2006, where a large variety of stakeholders stated their support for the creation of a truly unitary high quality patent. They, however, underlined that political compromises should not undermine the usefulness of the project. In particular, the representatives of small and medium-sized enterprises (SMEs) highlighted the importance of moderate patenting costs.

The issue of unitary patent protection was also addressed extensively in the consultation on the Small Business Act for Europe, which consisted of a range of initiatives targeted to help European SMEs<sup>18</sup>. Small and medium-sized businesses identified the high level of patent fees and the legal complexity of the patent system as major obstacles<sup>19</sup>. In their submissions to the consultation, businesses in general and SME representatives in particular requested a significant reduction of the costs of patenting for a future unitary patent<sup>20</sup>.

Recent position papers from various stakeholders refer to the unitary patent protection. European business associations, such as BusinessEurope<sup>21</sup>, UEAPME<sup>22</sup> and Eurochambres<sup>23</sup>

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<sup>17</sup> The consultation document, replies from stakeholders and a report on the preliminary findings of the consultation are available at [http://ec.europa.eu/internal\\_market/indprop/patent/consultation\\_en.htm](http://ec.europa.eu/internal_market/indprop/patent/consultation_en.htm).

<sup>18</sup> COM(2008) 394.

<sup>19</sup> <http://ec.europa.eu/enterprise/policies/sme/small-business-act/>

<sup>20</sup> UEAPME Expectations on the Proposal for a European Small Business Act, available at [www.ueapme.com](http://www.ueapme.com). Response to the Consultation on a Small Business Act for Europe, available at <http://www.eurochambres.eu>

<sup>21</sup> Views on key issues of the patent reform debate in Europe, available at <http://www.buinessseurope.eu>

<sup>22</sup> Position on the recent policy developments on the European Community patent, available at <http://www.ueapme.com>

<sup>23</sup> Position paper on the European Patent System, available at <http://www.eurochambres.eu>

confirm that businesses, both large and small, want simplified, cost-effective and accessible patent protection. National business organisations in many Member States and across industry sectors have raised identical issues<sup>24</sup>. Stakeholders underlined that any solution for the unitary patent protection should build on the existing mechanisms for granting patents in Europe and necessitate no revision of the European Patent Convention.

### **3. IMPACT ASSESSMENT**

This proposal is accompanied by an impact assessment which identifies the main problems in the current European patent system: (i) high costs related to translation and publication of European patents, (ii) differences in the maintenance of patents in the Member States (annual renewal fees have to be paid each year in each country where the patent is validated); and (iii) administrative complexity of registering transfers, licences and other rights related to patents. As a consequence, access to comprehensive patent protection in Europe is so costly and complex that it is inaccessible to many inventors and companies.

The impact assessment analyses the impacts of the following options:

Option 1 (Base-line scenario) – the Commission takes no action,

Option 2 – the Commission continues to work with the other institutions towards an EU patent covering 27 Member States,

Option 3 - the Commission presents proposals for regulations implementing enhanced cooperation:

Sub-option 3.1 - the Commission proposes translation arrangements applicable in the area of unitary patent protection that correspond to its proposal of 30 June 2010, or

Sub-option 3.2 – the Commission proposes translation arrangements applicable in the area of unitary patent protection based on its proposal of 30 June 2010 and incorporating elements of a compromise proposal discussed by the Council.

The analysis carried out in the impact assessment has demonstrated that option 3 with sub-option 3.2 is the preferred option.

These problems can only be addressed at EU level, as without an EU legal instrument Member States would not sufficiently be able to establish legal effects attached to patents that are uniform in several Member States.

### **4. LEGAL ELEMENTS OF THE PROPOSAL**

Council Decision 2011/167/EU authorised the Member States listed in its Article 1 to establish enhanced cooperation in the area of the creation of unitary patent protection.

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<sup>24</sup> Position papers from BDI (Bundesverband der Deutschen Industrie), DIHK (Deutscher Industrie- und Handelskammertag), CBI (Confederation of British Industries), CCIP (Chambre de commerce et d'industrie de Paris), CGPME (Confédération générale des petites et moyennes entreprises), Unioncamere, DigitalEurope, Orgalime, ACT (Association for Competitive Technology), Cefic and others.

Article 118 (1) TFEU provides for the legal basis for creating European intellectual property rights providing uniform protection throughout the Union by means of a regulation adopted by the European Parliament and the Council, acting in accordance with the ordinary legislative procedure.

## **5. BUDGETARY IMPLICATIONS**

This proposal has no impact on the Union budget.

## **6. DETAILED DESCRIPTION**

### **Article 1 – Subject matter**

This Article defines the subject-matter of this Regulation which implements the enhanced cooperation in the area of the creation of unitary patent protection authorised by Council Decision 2011/167/EU. It is made clear that this Regulation constitutes a special agreement within the meaning of Article 142 of the EPC.

### **Article 2 - Definitions**

This Article provides for definitions of the main terms used in this Regulation.

### **Article 3 - European patent with unitary effect**

This Article provides that European patents may benefit from unitary effect in the participating Member States provided that their unitary effect has been registered in the Register for unitary patent protection. In addition, the main features of the European patent with unitary effect are laid down: unitary character, providing uniform protection and having equal effect in all participating Member States. It follows that, as a general rule, a European patent with unitary effect may only be limited, licensed, transferred, revoked or lapse in respect of all the participating Member States. Finally, 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**

A European patent with unitary effect shall take effect in the participating Member States on the date of the publication by the EPO of the mention of the grant of the European patent. In case unitary effect has been registered, it is specified that the participating Member States shall take the necessary measures to ensure that a 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**

In the event of limitation or revocation on the ground of lack of novelty pursuant to Article 54(3) EPC, the limitation or revocation of a European patent with unitary effect shall take effect only in respect of the participating Member State(s) designated in the earlier European patent application as published.

## **Article 6 - Right to prevent the direct use of the invention**

This Article lays down the right of the proprietor of a European patent with unitary effect to prevent third parties not having his consent from 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 these purposes. In addition, the patent proprietor can prevent third parties from using a process which is the subject matter of the patent or, when a third party knows or should have known that the use of the process is prohibited without the consent of the proprietor, from offering the process for use within the participating Member States. Finally, the proprietor can prevent third parties from 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**

This Article lays down the right of the proprietor of a European patent with unitary effect to prevent third parties not having his consent from supplying or offering to supply within the participating Member States any person, 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. This shall not apply, however, where the means are staple commercial products, except when the third party induces the person supplied to commit acts prohibited by Article 6.

## **Article 8 - Limitation of the effects of the European patent with unitary effect**

This Article provides a number of limitations of the effects conferred by the European patent with unitary effect. In particular, such effects shall not extend to acts done privately and for non-commercial purposes, to acts done for experimental purposes relating to the subject-matter of the patented invention or to the extemporaneous preparation for individual cases in a pharmacy of a medicine in accordance with a medical prescription. Other acts allowed under Union law, in particular relating to veterinary medicinal products, to medicinal products for human use, to plant variety rights and to the legal protection of computer programs by copyright and of biotechnological inventions, are also not prohibited. Finally, the effects conferred by the European patent with unitary effect shall not extend to the use of the patented invention on board vessels, aircrafts or land vehicles of countries other than participating Member States, when such vessels, aircrafts or vehicles temporarily or accidentally enter the waters of participating Member States and to the use by a farmer of protected livestock for farming purposes, on condition that the breeding animals or other animal reproductive material was sold or otherwise commercialised to the farmer by the patent proprietor or with his consent.

## **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 consent, unless there are legitimate grounds for the proprietor to oppose further commercialisation of the product.

## **Article 10 - Treating a European patent with unitary effect as a national patent**

A 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 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 application for the patent. Where this does not apply, the European patent with unitary effect as an object of property shall be dealt with as a national patent of the participating Member State in which the proprietor had a place of business on that date. Special rules are provided for in case of joint proprietors. Where no proprietor has his residence or a place of business in a participating Member State, the European patent with unitary effect as an object of property shall be dealt with as a national patent of the State where the European Patent Organisation has its seat.

The creation of unitary patent protection has to be accompanied by appropriate jurisdictional arrangements responding to the needs of the users of the patent system. In order for the unitary patent protection to work properly in practice, appropriate jurisdictional arrangements should allow for patents to be enforced or revoked throughout the territory of the participating Member States and at the same time should ensure high quality judgements and legal security for companies. Specific jurisdictional arrangements will be proposed as soon as possible, taking also into account the recent opinion of the Court of Justice of the European Union (A-1/09) on the compatibility of the draft agreement on the European and EU Patents Court with the Treaties.

## **Article 11 - Licenses of right**

This Article enables the proprietor of a European patent with unitary effect to file a statement with the EPO that he is prepared to allow any person to use the invention as a licensee in return for appropriate compensation (contractual license).

## **Article 12 - Implementation by the participating Member States**

This Article lays down the tasks, within the meaning of Article 143 EPC, which the participating Member States entrust to the EPO. The EPO shall carry out these tasks in conformity with its internal rules. The EPO shall administer requests for unitary effect, include and administer in the European Patent Register entries relating to European patents with unitary effect, receive and register statements on licensing, ensure the publication of the translations required during the transitional period, collect and administer the renewal fees (as well as additional fees), the distribution of a part of the collected renewal fees to the participating Member States and administer 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 EPO.

The participating Member States shall ensure that requests by the patent proprietor for unitary effect are submitted 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. The participating Member States shall also ensure that the unitary effect is indicated in the Register for unitary patent protection, where the relevant conditions are fulfilled. The EPO shall be informed of limitations and revocations of European patents with unitary effect.

This Article also lays down that the participating Member States shall set up a Select Committee within the framework of the Administrative Council of the European Patent Organisation in order to ensure the governance and supervision of the tasks entrusted to the EPO. Finally, the participating Member States shall ensure effective legal protection before a national court against the administrative decisions of the EPO in carrying out the tasks entrusted to it.

### **Article 13 – Principle**

This Article provides the principle that the expenses incurred by the EPO in carrying out the additional tasks shall be covered by the fees generated by European patents with unitary effect.

### **Article 14 – Renewal fees**

Renewal fees in respect of European patents with unitary effect shall be paid to the European Patent Organisation. If a renewal fee is not been paid in due time, the European patent with unitary effect shall lapse.

### **Article 15 – Level of renewal fees**

This Article sets out a number of rules and conditions to be taken into account when determining the level of renewal fees. In particular, it provides that renewal fees for European patents with unitary effect shall be progressive throughout the term of the patent and shall be sufficient not only to cover all costs associated with the grant and administration of the unitary patent protection but also, together with the fees to be paid to the European Patent Organisation during the pre-grant stage, to ensure a balanced budget of the Organisation.

Finally, the Article lays down that the Commission is empowered to adopt delegated acts concerning the fixing of the level of the renewal fees for European patents with unitary effect.

### **Article 16 – Distribution**

The share for distributing 50 percent of the amount of the renewal fees paid for European patents with unitary effect minus the costs associated with the administration of the unitary patent protection among the participating Member States shall be set by the Commission on the basis of fair, equitable and relevant criteria listed in this Article. The participating Member States shall use the amount of the renewal fees allocated to them for patent-related purposes.

The Commission is empowered to adopt delegated acts concerning the distribution of the renewal fees between the participating Member States.

### **Article 17 – Exercise of the delegation**

This Article provides particulars relating to the power conferred on the Commission to adopt delegated acts. The delegation is made for an indeterminate period of time and may be revoked at any time by the European Parliament (EP) or by the Council. Any delegated act must be notified to the EP and to the Council that may express their objection within a period of 2 months.

### **Article 18 - Cooperation between the Commission and the European Patent Office**

This Article provides that the Commission shall establish close cooperation with the EPO in the fields covered by this Regulation.

### **Article 19 - Application of competition law and the law relating to unfair competition**

This Article provides that the 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**

Every six years the Commission shall present to the Council a report on the operation of this Regulation and where necessary make appropriate proposals for amending it.

### **Article 21 – Notification by the participating Member States**

The Article requires the participating Member States to inform the Commission of the measures they adopt under Articles 4(2) and 12.

### **Article 22 - Entry into force and application**

This Article provides that this Regulation shall enter into force on the twentieth day after its publication in the *Official Journal of the European Union*. However, since the language arrangements applicable to European patents with unitary effect would be governed Council Regulation .../... while the substantive provisions applicable to such patents are governed by this Regulation, these two Regulations should be applied jointly as of one specific date. 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 of application. Finally, it is laid down that unitary patent protection may be requested for any European patent granted on or after the date on which this Regulation applies.

Proposal for a

**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**implementing enhanced cooperation in the area of the creation of unitary patent protection**

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 protection<sup>25</sup>,

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.
- (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

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<sup>25</sup> OJ L 76, 22.3.2011, p. 53.

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, licensed, transferred, revoked or lapse in respect of all 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. However, to ensure legal certainty in the event of a limitation or revocation on the ground of lack of novelty pursuant to Article 54(3) EPC, the limitation or revocation of a European patent with unitary effect should take effect only in respect of the participating Member State(s) designated in the earlier European patent application as published. 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.
- (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. The participating Member States should 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 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].

- (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. 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 by the Commission.
- (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. 50 percent thereof minus expenses incurred by the European Patent Office in carrying out tasks in relation to the unitary patent protection 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. 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 and having acquired membership of the European Patent Organisation relatively recently.
- (19) In order to ensure the appropriate level and distribution of renewal fees in compliance with the principles set out in this Regulation, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of the level of the renewal fees for European patents with unitary effect and the distribution of such fees between the European Patent Organisation and the participating Member States. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing-up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.

- (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.
- (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.

Without prejudice to Article 5, a European patent with unitary effect may only be limited, licensed, transferred, revoked or lapse in respect of all 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*

In the event of a limitation or a revocation on the ground of lack of novelty pursuant to Article 54(3) of the EPC, the limitation or revocation of a European patent with unitary effect shall take effect only in respect of the participating Member State(s) designated in the earlier European patent application as published.

**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/EC<sup>26</sup> or Article 10(6) of Directive 2001/83/EC<sup>27</sup> in respect of any patent covering the product within the meaning of either of those Directives;
- (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 1944<sup>28</sup>, 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. 2100/94<sup>29</sup> 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

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<sup>26</sup> 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.

<sup>27</sup> 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.

<sup>28</sup> International Civil Aviation Organization (ICAO), "Chicago Convention", Document 7300/9 (9th edition, 2006)

<sup>29</sup> Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights (OJ L 227, 1.9.1994, p. 1).

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/EEC<sup>30</sup>, in particular, by its provisions on decompilation and interoperability; and
- (k) the acts allowed pursuant to Article 10 of Directive 98/44/EC of the European Parliament and of the Council<sup>31</sup>.

*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.
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.

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<sup>30</sup> Council Directive 91/250/EEC of 14 May 1991 on the legal protection of computer programs (OJ L 122, 17.5.1991, p. 42).

<sup>31</sup> 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).

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.

For the purposes of point a), the participating Member States shall 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.

For the purposes of point b), the participating Member States shall 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.

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

## **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 by the Commission.
3. In order to reach these objectives set out in this Chapter, the Commission shall set the level of renewal fees at 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. The Commission shall be empowered to adopt delegated acts in accordance with paragraphs 1-3 and Article 17 concerning the fixing of the level of the renewal fees for European patents with unitary effect.

*Article 16*  
*Distribution*

1. The part of the collected renewal fees to be distributed to the participating Member States referred to in Article 12(1)(e) shall be 50 percent of the renewal fees referred to in Article 14 paid for European patents with unitary effect minus the costs associated with the administration of the unitary patent protection referred to in Article 12.

2. In order to reach these objectives set out in this Chapter, the Commission shall set the share of distribution of renewal fees referred to in paragraph 1 among the participating Member States 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, having a disproportionately low level of patenting activity and having acquired membership of the European Patent Organisation relatively recently.
3. The participating Member States shall use the amount allocated to them in accordance with paragraph 1 to patent-related purposes.
4. The Commission shall be empowered to adopt delegated acts in accordance with paragraphs 1-3 and Article 17 concerning the setting of the distribution of renewal fees between the participating Member States.

*Article 17*  
*Exercise of the delegation*

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The delegation of power referred to in Articles 15 and 16 shall be conferred for an indeterminate period of time from the *[date of entry into force of this Regulation]*.
3. The delegation of powers referred to in Articles 15 and 16 may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
5. A delegated act adopted pursuant to Articles 15 and 16 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of 2 months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 2 months at the initiative of the European Parliament or the Council.

## **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*].
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*