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AMENDMENTS

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Draft report

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(PE753.702v01-00)

Unitary supplementary protection certificate for plant protection products

Proposal for a regulation

(COM(2023)0221 – C9-0152/2023 – 2023/0126(COD))

Amendment 25
Marie Toussaint

Proposal for a regulation
Recital 2

Text proposed by the Commission

(2) The period that elapses between the filing of an application for a patent for a new plant protection product and the authorisation to place that product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research.

Amendment

(2) The period that elapses between the filing of an application for a patent for a new plant protection product and the authorisation to place that product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research. ***Whereas such considerations, governing the grant of supplementary certificate protection, according to Regulation (EEC) No 1768/92, should still apply regardless of its territorial scope.***

Or. en

Amendment 26
Javier Zarzalejos

Proposal for a regulation
Recital 2 a (new)

Text proposed by the Commission

Amendment

(2 a) That situation leads to a lack of protection which penalises plant protection research and the competitiveness of the sector.

Or. en

Amendment 27
Javier Zarzalejos

Proposal for a regulation
Recital 14

(14) The fact that marketing authorisations in respect of a given plant protection product may be granted at different dates in different Member States would in many cases make the grant of a unitary certificate for a given plant protection product impossible, if it was required that authorisations must have been granted in all relevant Member States – i.e. those in which the basic patent has unitary effect – by the time of the filing of the application. An applicant should therefore be allowed to file an application for a unitary certificate where marketing ***authorisations have been applied for in all relevant Member States, provided that such authorisations are granted before the end of the examination process – which for that reason should not be completed earlier than 18 months from the filing of the application.*** Where no authorisation has been granted in a relevant Member State before the completion of the examination, the unitary certificate should not have any effect in respect of that Member State until a valid authorisation is granted in that Member State. However, that suspensory effect should be lifted where an outstanding authorisation is granted after the grant of the unitary certificate but – to ensure legal certainty – before the expiry of the basic patent, following a request to that end by the holder of the unitary certificate, subject to a verification of that request by the Office.

(14) The fact that marketing authorisations in respect of a given plant protection product may be granted at different dates in different Member States would in many cases make the grant of a unitary certificate for a given plant protection product impossible, if it was required that authorisations must have been granted in all relevant Member States – i.e. those in which the basic patent has unitary effect – by the time of the filing of the application. An applicant should therefore be allowed to file an application for a unitary certificate where ***a marketing authorisation has granted at least in one Member State.*** Where no authorisation has been granted in a relevant Member State before the completion of the examination, the unitary certificate should not have any effect in respect of that Member State until a valid authorisation is granted in that Member State. However, that suspensory effect should be lifted where an outstanding authorisation is granted after the grant of the unitary certificate but – to ensure legal certainty – before the expiry of the basic patent, following a request to that end by the holder of the unitary certificate, subject to a verification of that request by the Office.

Or. en

Amendment 28
Javier Zarzalejos

Proposal for a regulation
Recital 17

(17) One of the conditions for the grant of a certificate should be that the product should be protected by the basic patent, in the sense that the product should fall within the scope of one or more claims of that patent, as interpreted by the person skilled in the art **by** the description of the patent **on its** filing date. This should not necessarily require that the active substance of the product be explicitly identified in the claims. Or, in the event of a preparation, this should not necessarily require that each of its active substances be explicitly identified in the claims, provided that each of them is specifically identifiable in the light of all the information disclosed by that patent.

(17) One of the conditions for the grant of a certificate should be that the product should be protected by the basic patent, in the sense that the product should fall within the scope of one or more claims of that patent, as interpreted by the person skilled in the art **in light of** the description of the patent, **on the basis of that person's general knowledge in the relevant field and of the the prior art at the** filing date **or priority date of the basic patent**. This should not necessarily require that the active substance of the product be explicitly identified in the claims. Or, in the event of a preparation, this should not necessarily require that each of its active substances be explicitly identified in the claims, provided that each of them is specifically identifiable in the light of all the information disclosed by that patent.

Or. en

Amendment 29 **Javier Zarzalejos**

Proposal for a regulation **Recital 18**

Text proposed by the Commission

(18) To avoid overprotection, it should be provided that no more than one certificate, whether national or unitary, may protect the same product in a Member State. Therefore it should be required that the product, or any derivative such as salts, esters, ethers, isomers, mixtures of isomers, or complexes, equivalent to the product from a phytosanitary perspective, should not have already been the subject of a prior certificate, **either alone or in combination with one or more additional active ingredients**, whether for the same application or for a different one.

Amendment

(18) To avoid overprotection, it should be provided that no more than one certificate, whether national or unitary, may protect the same product in a Member State. Therefore it should be required that the product, or any derivative such as salts, esters, ethers, isomers, mixtures of isomers, or complexes, equivalent to the product from a phytosanitary perspective, should not have already been the subject of a prior certificate, whether for the same application or for a different one.

Or. en

Amendment 30
Javier Zarzalejos

Proposal for a regulation
Recital 21

Text proposed by the Commission

(21) As a further measure to ensure that no more than one certificate may protect the same product in any Member State, the holder of more than one patent for the same product should not be granted more than one certificate for that product. However, where two patents protecting the product are held by two holders, one certificate for that product should be allowed to be granted to each of those holders, where they can demonstrate that they are not *economically linked*. Furthermore, no certificate should be granted to the proprietor of a basic patent in respect of a product which is the subject of an authorisation held by a third party, without that party's consent.

Amendment

(21) As a further measure to ensure that no more than one certificate may protect the same product in any Member State, the holder of more than one patent for the same product should not be granted more than one certificate for that product. However, where two patents protecting the product are held by two holders, one certificate for that product should be allowed to be granted to each of those holders, where they can demonstrate that they are not *part of the same undertaking at the time of filing an application for a certificate*. Furthermore, no certificate should be granted to the proprietor of a basic patent in respect of a product which is the subject of an authorisation held by a third party, without that party's consent.

Or. en

Amendment 31
Javier Zarzalejos

Proposal for a regulation
Recital 24

Text proposed by the Commission

(24) To guarantee a fair and transparent process, ensure legal certainty and reduce the risk of subsequent validity challenges, third parties should have the possibility, after the publication of the unitary certificate application, to submit within 3 months observations to the Office while the centralised examination is being performed. These third parties allowed to

Amendment

(24) To guarantee a fair and transparent process, ensure legal certainty and reduce the risk of subsequent validity challenges, third parties should have the possibility, after the publication of the unitary certificate application, to submit within 3 months observations to the Office while the centralised examination is being performed. These third parties allowed to

submit observations should also include Member States. This, however, should not affect the rights of third parties to initiate subsequent invalidity proceedings before the *Office*. These provisions are necessary to ensure involvement of third parties both before and after the grant of certificates.

submit observations should also include Member States. This, however, should not affect the rights of third parties to initiate subsequent invalidity proceedings before the *Unified Patent Court*. These provisions are necessary to ensure involvement of third parties both before and after the grant of certificates.

Or. en

Amendment 32 **Javier Zarzalejos**

Proposal for a regulation **Recital 25**

Text proposed by the Commission

(25) The examination of an application for a unitary certificate should be conducted, under supervision of the Office, by an examination panel including one member of the Office as well as two examiners employed by the national patent offices. This would ensure that optimal use be made of expertise in supplementary protection certificates matters, located today at national offices only. To ensure an optimal quality of the examination, suitable criteria should be laid down in respect of the participation of specific examiners in the procedure, in particular as regards qualification and conflicts of interest.

Amendment

(25) The examination of an application for a unitary certificate should be conducted, under supervision of the Office, by an examination panel including one member of the Office as well as two examiners employed by the national patent offices. This would ensure that optimal use be made of expertise in supplementary protection certificates ***and related patent matters***, located today at national offices only. To ensure an optimal quality of the examination, ***and related patent matters, located today at national offices only. To ensure an optimal quality of the examination, the Office and the competent national authorities should make sure that designated examiners have the relevant expertise and sufficient experience in the assessment of supplementary protection certificates.*** ***Additional*** suitable criteria should be laid down in respect of the participation of specific examiners in the procedure, in particular as regards qualification and conflicts of interest.

Or. en

Amendment 33
Javier Zarzalejos

Proposal for a regulation
Recital 27

Text proposed by the Commission

Amendment

(27) To safeguard third parties' procedural rights and ensure a complete system of remedies, third parties should be able to challenge an examination opinion, by initiating opposition proceedings within a short duration following the publication of that opinion, and that opposition may result in that opinion being amended.

deleted

Or. en

Amendment 34
Javier Zarzalejos

Proposal for a regulation
Recital 28

Text proposed by the Commission

Amendment

(28) After the completion of the examination of a unitary certificate application, and after the time limits for appeal *and opposition* have expired, or, the case being, after a final decision on the merits has been issued, the Office should implement the examination opinion by granting a unitary certificate or rejecting the application, as applicable.

(28) After the completion of the examination of a unitary certificate application, and after the time limits for appeal have expired, or, the case being, after a final decision on the merits has been issued, the Office should implement *without undue delay* the examination opinion by granting a unitary certificate or rejecting the application, as applicable.

Or. en

Amendment 35
Javier Zarzalejos

Proposal for a regulation
Recital 29

Text proposed by the Commission

(29) Where the applicant or another party is adversely affected by a decision of the Office, the applicant or that party should have the right, subject to a fee, to file within 2 months an appeal against the decision, before a Board of Appeal of the Office. This also applies to the examination opinion, that may be appealed by the applicant. Decisions of that Board of Appeal should, in turn, be amenable to actions before the General Court, which has jurisdiction to annul or to alter the contested decision. In case of a combined application including the designation of additional Member States with a view to the grant of national certificates, a common appeal may be filed.

Amendment

(29) ***To safeguard procedural rights and ensure a complete system of remedies,*** where the applicant or another party is adversely affected by a decision of the Office, the applicant or that party should have the right, subject to a fee, to file within 2 months an appeal against the decision, before a Board of Appeal of the Office. This also applies to the examination opinion, that may be appealed by the applicant. Decisions of that Board of Appeal should, in turn, be amenable to actions before the General Court, which has jurisdiction to annul or to alter the contested decision. In case of a combined application including the designation of additional Member States with a view to the grant of national certificates, a common appeal may be filed.

Or. en

Amendment 36
Marie Toussaint

Proposal for a regulation
Recital 30

Text proposed by the Commission

(30) When appointing members of the Boards of Appeal in matters regarding applications for unitary certificates, their prior experience in supplementary protection certificate or patent matters should be taken into account.

Amendment

(30) When appointing members of the Boards of Appeal in matters regarding applications for unitary certificates, their ***relevant expertise, independence and sufficient*** prior experience in supplementary protection certificate or patent matters should be taken into account.

Or. en

Amendment 37
Javier Zarzalejos

Proposal for a regulation
Recital 30

Text proposed by the Commission

(30) When appointing members of the Boards of Appeal in matters regarding applications for unitary certificates, their prior experience in supplementary protection certificate or patent matters should be taken into account.

Amendment

(30) When appointing members of the Boards of Appeal in matters regarding applications for unitary certificates, their ***relevant expertise and sufficient*** prior experience in supplementary protection certificate or patent matters should be taken into account.

Or. en

Amendment 38
Javier Zarzalejos

Proposal for a regulation
Recital 31

Text proposed by the Commission

(31) Any person may challenge the validity of a unitary certificate by lodging with the ***Office*** an application for a declaration of invalidity.

Amendment

(31) Any person may challenge the validity of a unitary certificate by lodging with the ***Unified Patent Court*** an application for a declaration of invalidity.

Or. en

Amendment 39
Javier Zarzalejos

Proposal for a regulation
Recital 32

Text proposed by the Commission

(32) The Office should have the possibility to charge a fee for the application for a unitary certificate, as well as other procedural fees such as those for ***oppositions***, appeals ***and invalidity***. The fees charged by the Office should be laid down by an implementing act.

Amendment

(32) The Office should have the possibility to charge a fee for the application for a unitary certificate, as well as other procedural fees such as those for appeals. The fees charged by the Office should be laid down by an implementing act.

Amendment 40
Javier Zarzalejos

Proposal for a regulation
Article 3 – paragraph 1 – introductory part

Text proposed by the Commission

1. A unitary certificate shall be granted by the Office on the basis of a basic patent if, ***in each of the Member States in which that basic patent has unitary effect***, at the date of the application, all of the following conditions are fulfilled:

Amendment

1. A unitary certificate shall be granted by the Office on the basis of a basic patent if at the date of the application, all of the following conditions are fulfilled:

Or. en

Amendment 41
Javier Zarzalejos

Proposal for a regulation
Article 3 – paragraph 1 – point a a (new)

Text proposed by the Commission

Amendment

(a a) the product is approved in accordance with Article 4 of Regulation (EC) No 1107/2009;

Or. en

Amendment 42
Javier Zarzalejos

Proposal for a regulation
Article 3 – paragraph 1 – point b

Text proposed by the Commission

(b) a valid authorisation to place the product on the market as a plant protection product has been granted in accordance

Amendment

(b) a valid authorisation to place the product on the market as a plant protection product has been granted in accordance

with Regulation (EC) No 1107/2009;

with Regulation (EC) No 1107/2009, ***in at least one of the Member States in which that basic patent has unitary effect;***

Or. en

Amendment 43
Javier Zarzalejos

Proposal for a regulation
Article 3 – paragraph 2 – subparagraph 2

Text proposed by the Commission

Where two or more applications, whether national or centralised applications for certificates, or applications for unitary certificates, concerning the same product and submitted by two or more holders of different patents are pending for a given Member State, one certificate or unitary certificate for that product may be granted to each of those holders, where they are not ***economically linked***, by a competent national authority or by the Office, as applicable.

Amendment

Where two or more applications, whether national or centralised applications for certificates, or applications for unitary certificates, concerning the same product and submitted by two or more holders of different patents are pending for a given Member State, one certificate or unitary certificate for that product may be granted to each of those holders, where they are not ***part of the same undertaking at the time of filing an application for a certificate***, by a competent national authority or by the Office, as applicable. ***The same principle shall apply mutatis mutandis to applications submitted by the holder concerning the same product for which one or more certificates or unitary certificates have been previously granted to other different holders of different patents.***

Or. en

Amendment 44
Javier Zarzalejos

Proposal for a regulation
Article 3 – paragraph 3

Text proposed by the Commission

3. ***A unitary certificate shall also be***

Amendment

deleted

granted for a given plant protection product if the following conditions are fulfilled:

(a) at the date of the application, in each of the Member States in which the basic patent has unitary effect, an authorisation to place the product on the market as a plant protection product has been applied for in accordance with Regulation (EC) No 1107/2009, but an authorisation has not yet been granted in at least one of these Member States;

(b) before the examination opinion is adopted, valid authorisations have been granted in each of the Member States in which the basic patent has unitary effect.

Or. en

Amendment 45
Javier Zarzalejos

Proposal for a regulation
Article 3 – paragraph 4

Text proposed by the Commission

Amendment

4. Where the condition set out in paragraph 3, point (a), is fulfilled, the examination opinion shall not be adopted earlier than 18 months after the application was filed.

deleted

Or. en

Amendment 46
Javier Zarzalejos

Proposal for a regulation
Article 3 – paragraph 5 – subparagraph 1

Text proposed by the Commission

Amendment

*By way of derogation from paragraph 3, where **only** the condition set out in*

*Where the condition set out in paragraph 1, point **(b)**, **is not** fulfilled in respect of a*

paragraph 3, point (a), is fulfilled in respect of a Member State in which the basic patent has unitary effect, a unitary certificate shall be granted, but shall not have effect in that Member State.

Member State in which the basic patent has unitary effect, a unitary certificate shall be granted, but shall not have effect in that Member State.

Or. en

Amendment 47
Javier Zarzalejos

Proposal for a regulation
Article 9 – paragraph 1 – point a – point iii a (new)

Text proposed by the Commission

Amendment

(iii a) the number and date of the approval of the product, as referred to in Article 3(1), point (aa);

Or. en

Amendment 48
Marie Toussaint

Proposal for a regulation
Article 9 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. The applicant shall be responsible for the accuracy of the information and documentation submitted in relation to its application.

Or. en

Amendment 49
Javier Zarzalejos

Proposal for a regulation
Article 12 – paragraph 1

Text proposed by the Commission

If the application for a unitary certificate complies with Article 11(1), the Office shall publish the application in the Register.

Amendment

If the application for a unitary certificate complies with Article 11(1), the Office shall publish the application in the Register ***without undue delay***.

Or. en

Amendment 50
Javier Zarzalejos

Proposal for a regulation
Article 13 – paragraph 1

Text proposed by the Commission

1. The Office shall assess the application on the basis of all the conditions in Article **3(1)**, for all Member States in which the basic patent has unitary effect.

Amendment

1. The Office shall assess the application on the basis of all the conditions in Article **3**, for all Member States in which the basic patent has unitary effect.

Or. en

Amendment 51
Javier Zarzalejos

Proposal for a regulation
Article 13 – paragraph 2

Text proposed by the Commission

2. Where the application for a unitary certificate and the product to which it relates comply with Article **3(1) for each of the Member States referred to in paragraph 1**, the Office shall issue a reasoned positive examination opinion in respect of the grant of a unitary certificate. The Office shall notify that opinion to the applicant.

Amendment

2. Where the application for a unitary certificate and the product to which it relates comply with Article **3**, the Office shall issue a reasoned positive examination opinion in respect of the grant of a unitary certificate. The Office shall notify that opinion to the applicant.

Or. en

Amendment 52
Javier Zarzalejos

Proposal for a regulation
Article 13 – paragraph 3

Text proposed by the Commission

3. Where the application for a unitary certificate and the product to which it relates does not comply with Article **3(1) in respect of one or more of those Member States**, the Office shall issue a reasoned negative examination opinion on the grant of a unitary certificate. The Office shall notify that opinion to the applicant.

Amendment

3. Where the application for a unitary certificate and the product to which it relates does not comply with Article **3**, the Office shall issue a reasoned negative examination opinion on the grant of a unitary certificate. The Office shall notify that opinion to the applicant **and publish it on the Register without undue delay**.

Or. en

Amendment 53
Javier Zarzalejos

Proposal for a regulation
Article 15

Text proposed by the Commission

[...]

Amendment

deleted

Or. en

Amendment 54
Javier Zarzalejos

Proposal for a regulation
Article 16 – paragraph 1

Text proposed by the Commission

1. On a request made to the Office, any competent national authority may be appointed by the Office as a participating office in the examination procedure. Once a competent national authority is appointed in accordance with this Article, that

Amendment

1. On a request made to the Office, any competent national authority may be appointed by the Office as a participating office in the examination procedure. Once a competent national authority is appointed in accordance with this Article, that

authority shall designate one or more examiners to be involved in the examination of one or more applications for unitary certificates.

authority shall designate one or more examiners to be involved in the examination of one or more applications for unitary certificates ***on the basis of their relevant expertise and experience in the field.***

Or. en

Amendment 55
Marie Toussaint

Proposal for a regulation
Article 16 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1 a. Once a competent national authority is appointed by the Office as a participating office, it shall appoint its designated examiners based on relevant expertise and whether they have sufficient experience for the centralised examination procedure.

Or. en

Amendment 56
Javier Zarzalejos

Proposal for a regulation
Article 17 – paragraph 1

Text proposed by the Commission

Amendment

1. The ***assessments*** under ***Articles 13, 15 and 22*** shall be conducted by an examination panel including one member of the Office as well as two examiners as referred to in Article 16(1) from two different participating competent national authorities, under supervision of the Office.

1. The ***assessment*** under ***Article 13*** shall be conducted by an examination panel including one member of the Office as well as two examiners as referred to in Article 16(1) from two different participating competent national authorities, under supervision of the Office.

Or. en

Amendment 57
Marie Toussaint

Proposal for a regulation
Article 17 – paragraph 3 – point -a (new)

Text proposed by the Commission

Amendment

(-a) relevant expertise, independence and sufficient experience in the examination of patents and supplementary protection certificates;

Or. en

Amendment 58
Javier Zarzalejos

Proposal for a regulation
Article 17 – paragraph 3 – point a a (new)

Text proposed by the Commission

Amendment

(a a) relevant expertise and sufficient experience in the examination of patents and supplementary protection certificates, ensuring, in particular, that at least one of them has a minimum of 5 years of experience in patent and supplementary protection certificate examination;

Or. en

Amendment 59
Marie Toussaint

Proposal for a regulation
Article 17 – paragraph 3 – point c

Text proposed by the Commission

Amendment

(c) no *more than one* examiner employed by a competent national authority making use of the exemption set out in Article 10(5) of Regulation [COM(2023) 223].

(c) *that there is* no examiner employed by a competent national authority making use of the exemption set out in Article 10(5) of Regulation [COM(2023) 223].

Amendment 60
Javier Zarzalejos

Proposal for a regulation
Article 17 – paragraph 3 – point c

Text proposed by the Commission

(c) no **more than one** examiner employed by a competent national authority making use of the exemption set out in Article 10(5) of Regulation [COM(2023) 223].

Amendment

(c) no examiner employed by a competent national authority making use of the exemption set out in Article 10(5) of Regulation [COM(2023) 223].

Or. en

Amendment 61
Javier Zarzalejos

Proposal for a regulation
Article 17 – paragraph 4

Text proposed by the Commission

4. The Office shall publish a yearly overview of the number of procedures, including those for examination, **opposition**, appeal **and invalidity**, each competent national authority participated in.

Amendment

4. The Office shall publish a yearly overview of the number of procedures, including those for examination **and** appeal, each competent national authority participated in.

Or. en

Amendment 62
Marie Toussaint

Proposal for a regulation
Article 18 – paragraph 1 – introductory part

Text proposed by the Commission

After the period during which an appeal or an opposition may be filed has expired

Amendment

No later than three months after the period during which an appeal or an

without any appeal nor opposition being filed, or after a final decision on the merits has been issued, the Office shall take one of the following decisions:

opposition may be filed has expired without any appeal nor opposition being filed, or after a final decision on the merits has been issued, the Office shall take one of the following decisions:

Or. en

Amendment 63
Javier Zarzalejos

Proposal for a regulation
Article 18 – paragraph 1 – introductory part

Text proposed by the Commission

After the period during which an appeal *or an opposition* may be filed has expired without any appeal *nor opposition* being filed, or after a final decision on the merits has been issued, the Office shall take one of the following decisions:

Amendment

Immediately after the period during which an appeal may be filed has expired without any appeal being filed, or after a final decision on the merits has been issued, the Office shall take one of the following decisions:

Or. en

Amendment 64
Javier Zarzalejos

Proposal for a regulation
Article 18 – paragraph 1 – subparagraph 1 (new)

Text proposed by the Commission

Amendment

The Office shall inform the applicant of its decision without undue delay.

Or. en

Amendment 65
Javier Zarzalejos

Proposal for a regulation
Article 22 – paragraph 1

Text proposed by the Commission

Amendment

1. Any person may ***file with the Office an application*** for a declaration of invalidity of a unitary certificate.

1. Any person may ***bring an action*** for a declaration of invalidity of a unitary certificate ***before the Unified Patent Court***.

Or. en

Amendment 66
Javier Zarzalejos

Proposal for a regulation
Article 22 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. When the decision taken on the action for declaration of invalidity becomes final, the Unified Patent Court shall without delay send a copy of the judgment to the Office. The Office or any other interested party may request information about such transmission. The Office shall mention the judgment in the Register and shall take the necessary measures to comply with its operative part.

Or. en

Amendment 67
Javier Zarzalejos

Proposal for a regulation
Article 22 – paragraph 3

Text proposed by the Commission

Amendment

3. An application for a declaration of invalidity shall be filed in writing, and shall specify the grounds on which it is made. It shall not be considered as duly filed until the related fee has been paid.

deleted

Or. en

Amendment 68
Javier Zarzalejos

Proposal for a regulation
Article 22 – paragraph 4

Text proposed by the Commission

Amendment

4. The application for a declaration of invalidity shall contain: *deleted*

(a) the references of the unitary certificate against which that application is filed, the name of its holder, and the identification of the product;

(b) the particulars of the person referred to in paragraph 1 ('applicant') and, where applicable, of its representative;

(c) a statement of the grounds on which the application for a declaration of invalidity is based.

Or. en

Amendment 69
Javier Zarzalejos

Proposal for a regulation
Article 22 – paragraph 5

Text proposed by the Commission

Amendment

5. The application for a declaration of invalidity shall be examined by an invalidation panel set up by the Office in accordance with the rules applicable to examination panels. However, the invalidation panel shall not include any examiner previously involved in the examination panel that examined the unitary certificate application, nor, the case being, any examiner involved in possible related opposition proceedings, nor in related appeal proceedings. *deleted*

Or. en

Amendment 70
Javier Zarzalejos

Proposal for a regulation
Article 22 – paragraph 6

Text proposed by the Commission

Amendment

6. *An application for a declaration of invalidity shall be inadmissible where an application relating to the same subject matter and cause of action, and involving the same parties, has been adjudicated on its merits, either by the Office or by a competent court as referred to in Article 24, and the decision of the Office or that court on that application has acquired the authority of a final decision.* *deleted*

Or. en

Amendment 71
Javier Zarzalejos

Proposal for a regulation
Article 22 – paragraph 7

Text proposed by the Commission

Amendment

7. *If the invalidation panel notes that the application for a declaration of invalidity does not comply with paragraphs 2, 3 or 4, it shall reject that application as inadmissible, and communicate this to applicant.* *deleted*

Or. en

Amendment 72
Javier Zarzalejos

Proposal for a regulation
Article 22 – paragraph 8

Text proposed by the Commission

Amendment

8. The decision to reject an application for a declaration of invalidity as inadmissible shall be communicated to the holder of the unitary certificate, together with a copy of that application.

deleted

Or. en

Amendment 73
Javier Zarzalejos

Proposal for a regulation
Article 22 – paragraph 9

Text proposed by the Commission

Amendment

9. Where the application for a declaration of invalidity is not rejected as inadmissible, the Office shall promptly transmit that application to the holder of the unitary certificate, and shall publish it in the Register. If several applications for a declaration of invalidity have been filed, the Office shall promptly communicate them to the other applicants.

deleted

Or. en

Amendment 74
Javier Zarzalejos

Proposal for a regulation
Article 22 – paragraph 10

Text proposed by the Commission

Amendment

10. The Office shall issue a decision on the application for a declaration of invalidity within 6 months, unless the complexity of the case requires a longer period.

deleted

Or. en

Amendment 75
Javier Zarzalejos

Proposal for a regulation
Article 22 – paragraph 11

Text proposed by the Commission

Amendment

11. If the examination of the application for a declaration of invalidity reveals that the one or more of the conditions set out in Article 21 are met, the unitary certificate shall be declared invalid. Otherwise the application for a declaration of invalidity shall be rejected. The outcome shall be mentioned in the Register.

deleted

Or. en

Amendment 76
Javier Zarzalejos

Proposal for a regulation
Article 22 – paragraph 12

Text proposed by the Commission

Amendment

12. The unitary certificate shall be deemed not to have had, as from the outset, the effects specified in this Regulation, *to the extent that it has been declared invalid.*

12. *To the extent that it has been declared invalid,* the unitary certificate shall be deemed not to have had, as from the outset, the effects specified in this Regulation.

Or. en

Amendment 77
Javier Zarzalejos

Proposal for a regulation
Article 22 – paragraph 13

Text proposed by the Commission

Amendment

13. *The Commission is empowered to adopt delegated acts in accordance with Article 49 to supplement this Regulation by specifying the details of the procedure governing the declaration of invalidity.*

deleted

Or. en

Amendment 78
Javier Zarzalejos

Proposal for a regulation
Article 23 – paragraph 2

Text proposed by the Commission

2. The competent court of a Member State shall reject a counterclaim for a declaration of invalidity if a decision taken by the *Office* relating to the same subject matter and cause of action and involving the same parties has already become final.

Amendment

2. The competent court of a Member State shall reject a counterclaim for a declaration of invalidity if a decision taken by the *Unified Patent Court* relating to the same subject matter and cause of action and involving the same parties has already become final.

Or. en

Amendment 79
Javier Zarzalejos

Proposal for a regulation
Article 23 – paragraph 4

Text proposed by the Commission

4. The competent court of a Member State with which a counterclaim for a declaration of invalidity of the unitary certificate has been filed shall not proceed with the examination of the counterclaim, until either the interested party or the court has informed the *Office* of the date on which the counterclaim was filed. *The Office shall record that information in the Register.* If an *application for a* declaration of invalidity of the unitary certificate had already been *filed* before the

Amendment

4. The competent court of a Member State with which a counterclaim for a declaration of invalidity of the unitary certificate has been filed shall not proceed with the examination of the counterclaim, until either the interested party or the court has informed the *Unified Patent Court* of the date on which the counterclaim was filed. If an *action for* declaration of invalidity of the unitary certificate had already been *initiated* before the *Unified Patent Court* before the counterclaim was

Office before the counterclaim was filed, the court shall be informed thereof by the *Office* and stay the proceedings until the decision on the *application is final or the application is withdrawn*.

filed, the court shall be informed thereof by the *Unified Patent Court* and stay the proceedings until the decision on the *action brought before the Unified Patent Court becomes final*.

Or. en

Amendment 80
Javier Zarzalejos

Proposal for a regulation
Article 23 – paragraph 6

Text proposed by the Commission

Amendment

6. *The competent court hearing a counterclaim for a declaration of invalidity may stay the proceedings on application by the holder of a unitary certificate and after hearing the other parties and may request the defendant to submit an application for a declaration of invalidity to the Office within a time limit which it shall determine. If the application is not made within the time limit, the proceedings shall continue; the counterclaim shall be deemed withdrawn. Where the competent court of a Member State stays the proceedings it may order provisional and protective measures for the duration of the stay.*

deleted

Or. en

Amendment 81
Javier Zarzalejos

Proposal for a regulation
Article 26 – paragraph 3

Text proposed by the Commission

Amendment

3. Notice of appeal shall be filed in writing at the Office within 2 months of the date of notification of the decision. The

3. Notice of appeal shall be filed in writing at the Office within 2 months of the date of notification of the decision. The

notice shall be deemed to have been filed only when the fee for appeal has been paid. In case of an appeal, a written statement setting out the grounds of appeal shall be filed within **4** months of the date of notification of the decision.

notice shall be deemed to have been filed only when the fee for appeal has been paid. In case of an appeal, a written statement setting out the grounds of appeal shall be filed within **3** months of the date of notification of the decision.

Or. en

Amendment 82
Javier Zarzalejos

Proposal for a regulation
Article 26 – paragraph 3 – subparagraph 1 (new)

Text proposed by the Commission

Amendment

Any written statement in reply to the grounds of appeal shall be filed within 3 months from the date of notification of the statement setting out the grounds of appeal. A date for oral hearing shall be set by the Office within 3 months after the filing of the reply to the grounds of appeal or within 6 months of the filing of grounds of appeal, whichever is earlier.

A written decision of the Office shall be issued within 3 months after the date of the oral hearing.

Or. en

Amendment 83
Marie Toussaint

Proposal for a regulation
Article 26 – paragraph 5

Text proposed by the Commission

Amendment

5. Where an appeal results in a decision which is not in line with the examination opinion, the decision of the Boards **may** annul or alter the opinion.

5. Where an appeal results in a decision which is not in line with the examination opinion, the decision of the Boards **shall** annul or alter the opinion.

Amendment 84
Javier Zarzalejos

Proposal for a regulation
Article 27 – paragraph 4

Text proposed by the Commission

4. Members of the Boards of Appeal in matters regarding unitary certificates shall be appointed in accordance with Article 166 (5) of Regulation (EU) 2017/1001.

Amendment

4. Members of the Boards of Appeal in matters regarding unitary certificates shall be appointed in accordance with Article 166 (5) of Regulation (EU) 2017/1001. ***When appointing members of the Boards of Appeal in matters regarding unitary certificates, their prior experience in supplementary protection certificate or patent matters should be taken into account.***

Or. en

Amendment 85
Javier Zarzalejos

Proposal for a regulation
Article 29 – paragraph 2

Text proposed by the Commission

2. The Office shall charge a fee for appeals, ***for oppositions, for applications for a declaration of invalidity*** and for conversions.

Amendment

2. The Office shall charge a fee for appeals and for conversions.

Or. en

Amendment 86
Marie Toussaint

Proposal for a regulation
Article 30 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

The applicant shall be responsible for the accuracy of the information and documentation submitted in respect of its application.

Or. en

Amendment 87
Javier Zarzalejos

Proposal for a regulation
Article 33 – paragraph 1 – point k

Text proposed by the Commission

Amendment

(k) where applicable, the filing of an opposition, and the outcome of the opposition proceedings, including where applicable a summary of the revised examination opinion;

deleted

Or. en

Amendment 88
Javier Zarzalejos

Proposal for a regulation
Article 36 – paragraph 2 – subparagraph 2

Text proposed by the Commission

Amendment

An employee of a legal person may also represent other legal persons which are ***economically linked with*** the legal person being represented by that employee.

An employee of a legal person may also represent other legal persons which are ***part of the same undertaking at the time of filing an application for a certificate as*** the legal person being represented by that employee.

Or. en

Amendment 89
Javier Zarzalejos

Proposal for a regulation
Article 37 – paragraph 1 – point c

Text proposed by the Commission

Amendment

(c) deciding on oppositions against examination opinions;

deleted

Or. en

Amendment 90
Javier Zarzalejos

Proposal for a regulation
Article 37 – paragraph 1 – point d

Text proposed by the Commission

Amendment

(d) deciding on applications for a declaration of invalidity;

deleted

Or. en

Amendment 91
Javier Zarzalejos

Proposal for a regulation
Article 39 – paragraph 2

Text proposed by the Commission

Amendment

2. Oral proceedings before an examination panel, ***opposition panel or invalidity panel*** shall not be public.

2. Oral proceedings before an examination panel shall not be public.

Or. en

Amendment 92
Marie Toussaint

Proposal for a regulation
Article 40 – paragraph 3

Text proposed by the Commission

3. If the Office or the relevant panel considers it necessary for a party, witness or expert to give evidence orally, it shall issue a summons to the person concerned to appear before it. The period of notice provided in such summons shall be at least 1 month, unless they agree to a shorter period.

Amendment

3. If the Office or the relevant panel considers it necessary for a party, witness or expert to give evidence orally, it shall issue a summons to the person concerned to appear before it. ***Where an expert is summoned, it shall be verified that that expert is free of any conflict of interest.*** The period of notice provided in such summons shall be at least 1 month, unless they agree to a shorter period.

Or. en

Amendment 93
Javier Zarzalejos

Proposal for a regulation
Article 44 – paragraph 5

Text proposed by the Commission

5. This Article shall not be applicable to the time limits referred to in paragraph 2 of this Article, ***or in Article 15(1) and (3).***

Amendment

5. This Article shall not be applicable to the time limits referred to in paragraph 2 of this Article.

Or. en

Amendment 94
Javier Zarzalejos

Proposal for a regulation
Article 46 – paragraph 1

Text proposed by the Commission

1. The losing party in ***opposition proceedings and*** proceedings for a declaration of invalidity, including in related appeal proceedings, shall bear the fees paid by the other party. The losing party shall also bear all costs incurred by the other party that are essential to the proceedings, including travel and subsistence and the remuneration of a

Amendment

1. The losing party in proceedings for a declaration of invalidity, including in related appeal proceedings, shall bear the fees paid by the other party. The losing party shall also bear all costs incurred by the other party that are essential to the proceedings, including travel and subsistence and the remuneration of a representative, within the maximum rates

representative, within the maximum rates set for each category of costs in the implementing act to be adopted in accordance with paragraph 7. The fees to be borne by the losing party shall be limited to the fees paid by the other party in those proceedings.

set for each category of costs in the implementing act to be adopted in accordance with paragraph 7. The fees to be borne by the losing party shall be limited to the fees paid by the other party in those proceedings.

Or. en

Amendment 95
Javier Zarzalejos

Proposal for a regulation
Article 49 – paragraph 2

Text proposed by the Commission

2. The power to adopt delegated acts referred to in Articles **15(13)**, **22(13)**, 26(8), 28, 32(2), 39(4), 40(6), 41(4), 42(5) and 45(3) shall be conferred on the Commission for an indeterminate period of time from XXX [OP please insert the date = date of entry into force].

Amendment

2. The power to adopt delegated acts referred to in Articles 26(8), 28, 32(2), 39(4), 40(6), 41(4), 42(5) and 45(3) shall be conferred on the Commission for an indeterminate period of time from XXX [OP please insert the date = date of entry into force].

Or. en

Amendment 96
Javier Zarzalejos

Proposal for a regulation
Article 49 – paragraph 3

Text proposed by the Commission

3. The delegation of power referred to in Articles **15(13)**, **22(13)**, 26(8), 28, 32(2), 39(4), 40(6), 41(4), 42(5) and 45(3) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect on the day following the publication of the decision in the Official Journal of the European Union or at a later

Amendment

3. The delegation of power referred to in Articles 26(8), 28, 32(2), 39(4), 40(6), 41(4), 42(5) and 45(3) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect on the day following the publication of the decision in the Official Journal of the European Union or at a later date

date specified therein. It shall not affect the validity of any delegated acts already in force.

specified therein. It shall not affect the validity of any delegated acts already in force.

Or. en

Amendment 97
Javier Zarzalejos

Proposal for a regulation
Article 49 – paragraph 6

Text proposed by the Commission

6. A delegated act adopted pursuant to Articles **15(13)**, **22(13)**, 26(8), 28, 32(2), 39(4), 40(6), 41(4), 42(5) and 45(3) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two 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 two months at the initiative of the European Parliament or of the Council.

Amendment

6. A delegated act adopted pursuant to Articles 26(8), 28, 32(2), 39(4), 40(6), 41(4), 42(5) and 45(3) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two 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 two months at the initiative of the European Parliament or of the Council.

Or. en

Amendment 98
Marie Toussaint

Proposal for a regulation
Article 51 – paragraph 1

Text proposed by the Commission

By xxxxxx [OP, please insert: five years after the date of application], and every five years thereafter, the Commission shall evaluate the implementation of this Regulation.

Amendment

By xxxxxx [OP, please insert: five years after the date of application], and every five years thereafter, the Commission shall evaluate the implementation of this Regulation **and present a report on the main findings to the European**

Parliament and to the Council. In its report, the Commission shall evaluate and assess whether the creation of a central authorisation procedure for plant protection products under the European Food Safety Authority is appropriate and also whether it is efficient and necessary.

Or. en