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13.11.2023

AMENDMENTS

17 - 57

Draft report
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(PE753.705v01-00)

Supplementary protection certificate for plant protection products (recast)

Proposal for a regulation
(COM(2023)0223 – C9-0149/2023 – 2023/0128(COD))

Amendment 17
Javier Zarzalejos

Proposal for a regulation
Recital 11

Text proposed by the Commission

(11) One of the conditions for the grant of a certificate should be that the product is 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.

Amendment

(11) One of the conditions for the grant of a certificate should be that the product is 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 on 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 18
Javier Zarzalejos

Proposal for a regulation
Recital 12

Text proposed by the Commission

(12) 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

Amendment

(12) 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.

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 19 **Javier Zarzalejos**

Proposal for a regulation **Recital 15**

Text proposed by the Commission

(15) 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

(15) 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 20 **Javier Zarzalejos**

Proposal for a regulation **Recital 27**

Text proposed by the Commission

Amendment

(27) The Office should have the possibility to charge a fee for the centralised application for a certificate, as well as other procedural fees such as a fee for *opposition or* appeal. The fees charged by the Office should be laid down by an implementing act.

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

Or. en

Amendment 21 **Javier Zarzalejos**

Proposal for a regulation **Recital 32**

Text proposed by the Commission

(32) The examination of a centralised application for a 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 centralised procedure, in particular as regards qualification and conflicts of interest.

Amendment

(32) The examination of a centralised application for a 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 patent related* 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 centralised procedure, in particular as regards qualification and conflicts of interest.

Or. en

Amendment 22 **Javier Zarzalejos**

Proposal for a regulation
Recital 34

Text proposed by the Commission

(34) 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.

Amendment

deleted

Or. en

Amendment 23
Javier Zarzalejos

Proposal for a regulation
Recital 35

Text proposed by the Commission

(35) After the completion of the examination of a centralised 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 opinion should be transmitted to the respective national patent offices of the designated Member States.

Amendment

(35) After the completion of the examination of a centralised 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 opinion should be transmitted to the respective national patent offices of the designated Member States.

Or. en

Amendment 24
Javier Zarzalejos

Proposal for a regulation
Recital 40

Text proposed by the Commission

(40) Where the applicant or another party is adversely affected by a decision of

Amendment

(40) To safeguard procedural rights and ensure a complete system of remedies,

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 a request for a unitary certificate, a common appeal may be filed.

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 a request for a unitary certificate, a common appeal may be filed.

Or. en

Amendment 25 **Javier Zarzalejos**

Proposal for a regulation **Recital 41**

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 26 **Javier Zarzalejos**

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

Text proposed by the Commission

2. The holder of more than one patent

Amendment

2. The holder of more than one patent

for the same product shall not be granted more than one certificate for that product. However, where two or more applications concerning the same product and emanating from two or more holders of different patents are pending, one certificate for that product may be issued to each of those holders , where they are not *economically linked* .

for the same product shall not be granted more than one certificate for that product. However, where two or more applications concerning the same product and emanating from two or more holders of different patents are pending, one certificate for that product may be issued to each of those holders , where they are not *part of the same undertaking at the time of filing an application for a certificate. 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 27
Javier Zarzalejos

Proposal for a regulation
Article 26

Text proposed by the Commission

Amendment

[...]

deleted

Or. en

Amendment 28
Raffaele Stancanelli

Proposal for a regulation
Article 26 – paragraph 2

Text proposed by the Commission

Amendment

2. Opposition may only be filed on the grounds that one or more of the conditions set out in Article 3 are not fulfilled for one or more of the designated Member States.

2. Opposition may only be filed on the grounds that one or more of the conditions set out in Article 3 *or 6* are not fulfilled for one or more of the designated Member States.

Amendment 29
Raffaele Stancanelli

Proposal for a regulation
Article 26 – paragraph 4 – point c a (new)

Text proposed by the Commission

Amendment

(c a) any evidence that is relied upon by the opponent.

Or. en

Amendment 30
Raffaele Stancanelli

Proposal for a regulation
Article 26 – paragraph 6

Text proposed by the Commission

Amendment

6. If the opposition panel notes that the notice of opposition does not comply with paragraphs 2, 3 or 4, it shall reject the opposition as inadmissible, and communicate this to opponent, unless these deficiencies have been remedied before expiry of the opposition filing period referred to in paragraph 1.

6. If the opposition panel notes that the notice of opposition does not comply with paragraphs 2, 3 or 4, it shall reject the opposition as inadmissible, and communicate this to **the** opponent **with reasons as soon as practicable after the filing of the notice of opposition**, unless these deficiencies have been remedied before expiry of the opposition filing period referred to in paragraph 1.

Or. en

Amendment 31
Raffaele Stancanelli

Proposal for a regulation
Article 26 – paragraph 7 – subparagraph 2

Text proposed by the Commission

Amendment

A notice of opposition shall be inadmissible where a previous appeal relating to the same subject matter and cause of action has been adjudicated on its merits by the Office, and the decision of the Office on that appeal has acquired the authority of a final decision.

deleted

Or. en

Amendment 32
Raffaele Stancanelli

Proposal for a regulation
Article 26 – paragraph 9

Text proposed by the Commission

9. The Office shall issue a decision on the opposition within 6 months, unless the complexity of the case requires a longer period.

Amendment

9. The Office shall issue a decision on the opposition within 6 months, unless the complexity of the case requires a longer period. ***The decision shall include detailed reasons.***

Or. en

Amendment 33
Raffaele Stancanelli

Proposal for a regulation
Article 26 – paragraph 10

Text proposed by the Commission

10. If ***the*** opposition ***panel considers that no ground for opposition prejudices the maintenance*** of the examination opinion, ***it shall reject the opposition, and*** the Office shall ***mention this in the Register.***

Amendment

10. If ***more than one*** opposition ***is filed in respect*** of the ***same*** examination opinion, the Office shall ***hear the oppositions jointly and issue a common decision.***

Or. en

Amendment 34

Raffaele Stancanelli

**Proposal for a regulation
Article 26 – paragraph 11**

Text proposed by the Commission

11. If the opposition panel considers that at least one ground for opposition prejudices the maintenance of the examination opinion, it shall adopt an amended opinion, and the Office shall **mention this** in the Register.

Amendment

11. If the opposition panel considers that at least one ground for opposition prejudices the maintenance of the examination opinion, it shall adopt an amended opinion, and the Office shall **publish its full decision** in the Register.

Or. en

**Amendment 35
Raffaele Stancanelli**

**Proposal for a regulation
Article 26 – paragraph 12 – subparagraph 1 (new)**

Text proposed by the Commission

Amendment

Full transparency shall be ensured throughout the whole opposition proceeding, which shall be open, whenever possible, to public participation.

Or. en

**Amendment 36
Javier Zarzalejos**

**Proposal for a regulation
Article 27 – paragraph 1**

Text proposed by the Commission

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

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 centralised applications.

examiners to be involved in the examination of one or more centralised applications, *on the basis of their relevant expertise and experience in the field.*

Or. en

Amendment 37
Javier Zarzalejos

Proposal for a regulation
Article 27 – paragraph 5

Text proposed by the Commission

5. Each competent national authority appointed under this Article shall provide the Office with a list identifying the individual examiners who are available for participation in examination *and opposition* proceedings. Each such competent national authority shall update that list in the event of a change.

Amendment

5. Each competent national authority appointed under this Article shall provide the Office with a list identifying the individual examiners who are available for participation in examination proceedings. Each such competent national authority shall update that list in the event of a change.

Or. en

Amendment 38
Javier Zarzalejos

Proposal for a regulation
Article 28 – paragraph 3 – point 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 39
Javier Zarzalejos

Proposal for a regulation
Article 28 – 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 laid down in Article 10(5).

Amendment

(c) no examiner employed by a competent national authority making use of the exemption laid down in Article 10(5).

Or. en

Amendment 40
Javier Zarzalejos

Proposal for a regulation
Article 28 – 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** and appeal, 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 41
Javier Zarzalejos

Proposal for a regulation
Article 29 – paragraph 3

Text proposed by the Commission

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

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 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.

filed within **3** months of the date of notification of the decision.

Or. en

Amendment 42
Javier Zarzalejos

Proposal for a regulation
Article 29 – 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 issue within 3 months after the date of the oral hearing.

Or. en

Amendment 43
Javier Zarzalejos

Proposal for a regulation
Article 30 – paragraph 4

Text proposed by the Commission

Amendment

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

4. Members of the Boards of Appeal in matters regarding centralised applications for 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 centralised applications for certificates, their prior experience in supplementary protection certificate or patent matters should be***

taken into account.

Or. en

Amendment 44
Javier Zarzalejos

Proposal for a regulation
Article 32 – paragraph 1

Text proposed by the Commission

1. 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 transmit the examination opinion and its translations to the competent national authority of each designated Member State.

Amendment

1. 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 transmit the examination opinion and its translations to the competent national authority of each designated Member State.

Or. en

Amendment 45
Javier Zarzalejos

Proposal for a regulation
Article 33 – paragraph 2

Text proposed by the Commission

2. The Office shall charge a fee for an appeal, *and for an opposition*.

Amendment

2. The Office shall charge a fee for an appeal.

Or. en

Amendment 46
Javier Zarzalejos

Proposal for a regulation
Article 34 – paragraph 1 – point 1

Text proposed by the Commission

Amendment

(l) where applicable, the filing of an opposition, and its outcome, including where applicable a summary of the revised examination opinion; *deleted*

Or. en

Amendment 47
Raffaele Stancanelli

Proposal for a regulation
Article 35 a (new)

Text proposed by the Commission

Amendment

Article 35a

The existence on the Register of a granted or applied for supplementary protection certificate shall not be a valid ground to refuse, suspend, delay, withdraw or revoke decisions relating to marketing authorisations, the price of a medicinal product or its inclusion within the public health insurance system, or the public and private procurement of medicinal products.

Or. en

Amendment 48
Javier Zarzalejos

Proposal for a regulation
Article 37 – 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 49
Javier Zarzalejos

Proposal for a regulation
Article 38 – paragraph 2

Text proposed by the Commission

2. The combined application shall undergo a single centralised examination procedure, as well as a single ***opposition or*** appeal procedure, where it has been filed against an opinion or decision in respect of both the centralised application and the unitary certificate application.

Amendment

2. The combined application shall undergo a single centralised examination procedure, as well as a single appeal procedure, where it has been filed against an opinion or decision in respect of both the centralised application and the unitary certificate application.

Or. en

Amendment 50
Javier Zarzalejos

Proposal for a regulation
Article 39 – paragraph 1 – point c

Text proposed by the Commission

(c) *deciding on oppositions against examination opinions;*

Amendment

deleted

Or. en

Amendment 51
Javier Zarzalejos

Proposal for a regulation
Article 43 – paragraph 2

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 52
Javier Zarzalejos

Proposal for a regulation
Article 48 – 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 26(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 53
Javier Zarzalejos

Proposal for a regulation
Article 50 – paragraph 1

Text proposed by the Commission

1. The losing party in *opposition proceedings, 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 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.

Amendment

1. The losing party in 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 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 54
Javier Zarzalejos

Proposal for a regulation
Article 54 – paragraph 2

Text proposed by the Commission

2. The power to adopt delegated acts referred to in Articles **26(13)**, 29(8), 31, 41(2), 43(4), 44(6), 45(4), 46(5) and 49(3) shall be conferred on the Commission for an indeterminate period of time from the date of entry into force of this Regulation.

Amendment

2. The power to adopt delegated acts referred to in Articles 29(8), 31, 41(2), 43(4), 44(6), 45(4), 46(5) and 49(3) shall be conferred on the Commission for an indeterminate period of time from the date of entry into force of this Regulation.

Or. en

Amendment 55
Javier Zarzalejos

Proposal for a regulation
Article 54 – paragraph 3

Text proposed by the Commission

3. The delegation of power referred to in Articles **26(13)**, 29(8), 31, 41(2), 43(4), 44(6), 45(4), 46(5) and 49(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 specified therein. It shall not affect the validity of any delegated acts already in force.

Amendment

3. The delegation of power referred to in Articles 29(8), 31, 41(2), 43(4), 44(6), 45(4), 46(5) and 49(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 specified therein. It shall not affect the validity of any delegated acts already in force.

Or. en

Amendment 56
Javier Zarzalejos

Proposal for a regulation
Article 54 – paragraph 6

Text proposed by the Commission

6. A delegated act adopted pursuant to Articles **26(13)**, 29(8), 31, 41(2), 43(4),

Amendment

6. A delegated act adopted pursuant to Articles 29(8), 31, 41(2), 43(4), 44(6),

44(6), 45(4), 46(5) and 49(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.

45(4), 46(5) and 49(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 57
Javier Zarzalejos

Proposal for a regulation
Article 58 – paragraph 2

Text proposed by the Commission

Articles 19 to 52, 54 to 56 shall apply from [OP: please insert: the first day of the **12th** month after the entry into force].

Amendment

Articles 19 to 52, 54 to 56 shall apply from [OP: please insert: the first day of the **24th** month after the entry into force].

Or. en