JURI REPORT ON UNITARY SUPPLEMENTARY CERTIFICATE FOR MEDICINAL PRODUCTS AND AMENDING REGULATION (EU) 2017/1001, REGULATION (EC) n°1901/2006 AS WELL AS REGULATION (EU) n° 608/2013

FINAL COMPROMISE AMENDMENTS

19 January 2024

COMP 1

Articles 2, 3 and 5

Article 2

Definitions

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

(1) 'medicinal product' means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals;

(2) 'product' means the active ingredient or combination of active ingredients of a medicinal product;

(3) 'European patent' means a patent granted by the European Patent Office ('EPO') under the rules and procedures laid down in the European Patent Convention[1] ('EPC');

(4) 'unitary patent' means a European patent which benefits from unitary effect in those Member States participating in the enhanced cooperation laid down in Regulation (EU) No 1257/2012;

(5) 'basic patent' means a unitary patent which protects a product as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a unitary certificate;

(6) 'application for an extension of the duration' means an application for an extension of the duration of a unitary certificate pursuant to Article 20(3) of this Regulation and Article 36 of Regulation (EC) No 1901/2006;

(7) 'maker' means the person, established in the Union, on whose behalf the making of a product, or a medicinal product containing that product, for the purpose of export to third countries or for the purpose of storing, is carried out;

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[1] Convention on the Grant of European Patents of 5 October 1973, as revised on 17 December 1991 and on 29 November 2000.

(8) 'centralised application' means an application made before the European Union Intellectual Property Office ('the Office') pursuant to Chapter III of Regulation [COM(2023) 231] with a view to the grant of certificates, for the product identified in the application, in the designated Member States;

(9) 'competent national authority' means the national authority that is competent, in a given Member State, for the grant of certificates and for the rejection of applications for certificates.

(9a new) 'economically linked' means, in respect of different holders of two or more basic patents protecting the same product, that one holder, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with another holder. (S&D 12, EPP 92)

Article 3

Conditions for obtaining a unitary certificate

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:

   (a) the product is protected by that basic patent in force;

   (b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with ***[revised Directive 2001/83/EC],*** Regulation (EU) 2019/6, or with the centralised procedure under Regulation (EC) No 726/2004***, as appropriate***; ***(S&D 13, Greens 94)***

   (c) the product has not already been the subject of a certificate, nor of a unitary certificate;

   (d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.

2. The holder of more than one patent for the same product shall not be granted more than one certificate or unitary certificate for that product for any given Member State.

   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 in 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. ***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 (EPP, AM 95).***

Article 5

Effects of the unitary certificate

1. The unitary certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations, in all Member States in which the basic patent has unitary effect.

2. A unitary certificate shall have a unitary character. It shall provide uniform protection and shall have equal effect in all Member States in which the basic patent has unitary effect. The unitary certificate may only be limited, transferred or revoked, or lapse, in respect of all those Member States.

3. By way of derogation from paragraph 1 ***and in accordance with Regulation (EU) .../... [2023/0130(COD)]***, ..." ***(S&D 14, Greens 96)*** the unitary certificate shall not confer protection against certain acts which would otherwise require the consent of the unitary certificate holder, if all of the following conditions are met:

   (a) the acts comprise any of the following:

      (i) making a product, or a medicinal product containing that product, for the purpose of export to third countries; ***or (S&D 15)***

      (ii) any related act that is strictly necessary for ***that*** making in the Union or for the actual export ***itself***; ***or (S&D 16)***

      (iii) making, no earlier than 6 months before the expiry of the unitary certificate, a product, or a medicinal product containing that product, for the purpose of storing it in the Member State of making in order to place that product, or a medicinal product containing that product, on the market of Member States after the expiry of the certificate; ***or (S&D 17, Greens 97)***

      (iv) any related act that is strictly necessary for the making in the Union ***as*** referred to in point (iii), or for the actual storing ***itself***, provided that such related act is carried out no earlier than 6 months before the expiry of the certificate. ***(S&D 18)***

   (b) the maker, through appropriate and documented means, notifies the Office, and the competent industrial property office of the respective Member State, and informs the unitary certificate holder, of the information referred to in paragraph 6 no later than 3 months before the start date of the making in that Member State, or no later than 3 months before the first related act, prior to that making, that would otherwise be prohibited by the protection conferred by a unitary certificate, whichever is the earlier;

   (c) if the information referred to in paragraph 6 of this Article changes, the maker notifies the Office and the competent industrial property office of the respective Member State, and informs the certificate holder, before those changes take effect;

   (d) in the case of products, or medicinal products containing those products, made for the purpose of export to third countries, the maker ensures that a logo, in the form set out in Annex I, is affixed to the outer packaging of the product, or the medicinal product containing that product, referred to in point (a)(i) of this paragraph, and, where feasible, to its immediate packaging;

   (e) the maker complies with paragraph 10 of this Article and, if applicable, with Article 31(4).

4. Paragraph 3 shall not apply to any act or activity carried out for the import of products, or medicinal products containing those products, into the Union merely for the purpose of repackaging, re-exporting or storing.

5. The information provided to the unitary certificate holder for the purposes of paragraph 3, points (b) and (c), shall be used exclusively for the purposes of verifying whether the requirements of this Regulation have been met and, where applicable, initiating legal proceedings for non-compliance.

6. For the purposes of paragraph 3, point (b), the maker shall provide all of the following information:

   (a) the name and address of the maker;

   (b) an indication of whether the making is for the purpose of export, for the purpose of storing, or for the purpose of both export and storing;

   (c) the Member State in which the making and, if applicable, also the storing is to take place, and the Member State in which the first related act, if any, prior to that making is to take place;

   (d) the number of the unitary certificate having effect in the Member State of making, and the number of the certificate or unitary certificate granted in the Member State of the first related act, if any, prior to that making;

   (e) for medicinal products to be exported to third countries, the reference number of the marketing authorisation, or the equivalent of such authorisation, in each third country of export, as soon as it is publicly available.

7. For the purposes of the notifications to the Office and to the competent industrial property office referred to in paragraph 3, points (b) and (c), the maker shall use the standard form for notification set out in Annex II.

8. Failure to provide the information referred to in paragraph 6, point (e), with regard to a third country shall only affect exports to that third country, and those exports shall not benefit from the exception laid down in paragraph 3.

9. The maker shall ensure that medicinal products made pursuant to paragraph 3, point (a)(i), do not bear an active unique identifier within the meaning of Delegated Regulation (EU) 2016/161[2].

10. The maker shall ensure, through appropriate and documented means, that any person in a contractual relationship with the maker that performs acts falling under paragraph 3, point (a), is fully informed and aware of all of the following:

   (a) that those acts are subject to paragraph 3;

   (b) that the placing on the market, import or re-import of the product, or the medicinal product containing that product, referred to in paragraph 3, point (a)(i), or the placing on the market of the product, or the medicinal product containing that product, referred to in paragraph 3, point (a)(iii), could infringe the unitary certificate referred to in that paragraph where, and for as long as, that certificate applies.

COMP 2

Articles 8, 9, 10, 12

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[2] Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use (OJ L 32, 9.2.2016, p. 1).

Article 8

Application for a unitary certificate

1. The application for a unitary certificate shall be lodged within 6 months of the date on which the authorisation referred to in Article 3(1), point (b), to place the product on the market as a medicinal product was granted.

2. Notwithstanding paragraph 1, where the authorisation to place the product on the market is granted before unitary effect is attributed to the basic patent, the application for a unitary certificate shall be lodged within 6 months of the date on which unitary effect is attributed to the basic patent.

3. The application for an extension of the duration may be lodged at the same time when lodging the application for a unitary certificate or when the application for the unitary certificate is pending and the appropriate requirements of Article 9(1), point (d), or Article 9(2), respectively, are fulfilled.

4. The application for an extension of the duration of a unitary certificate already granted shall be lodged not later than 2 years before the expiry of the unitary certificate.

4 a. An applicant shall submit an application for a unitary certificate electronically to the Office and in the formats made available by the Office. (S&D 20)

Article 9

Content of the application for a unitary certificate

1. The application for a unitary certificate shall contain the following:

   (a) a request for the grant of a unitary certificate, stating the following information:

      (i) the name and address of the applicant;

      (ii) if the applicant has appointed a representative, the name and address of that representative;

      (iii) the number of the basic patent and the title of the invention;

      (iv) the number and date of the first authorisation to place the product on the market, as referred to in Article 3(1), point (b) and, if this authorisation is not the first authorisation for placing the product on the market in the Union, the number and date of that authorisation;

      (iv a) any information on all direct public financial support received for research related to the development of the product for which the SPC is requested. (S&D 23, RE 101, EPP 102, Greens 104)

   (b) a copy of the authorisation to place the product on the market, as referred to in Article 3(1), point (b), in which the product is identified, containing in particular the number and date of the authorisation and the summary of the product characteristics listed in Article 11 of Directive 2001/83/EC of the European Parliament and of the Council[3] or Article 35 of Regulation (EU) 2019/6;

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[3] 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).

(c) where the authorisation referred to in point (b) is not the first authorisation for placing the product on the market as a medicinal product in the Union, information regarding the identity of the product thus authorised and the legal provision under which the authorisation procedure took place, together with a copy of the notice publishing the authorisation in the appropriate official publication or, in the absence of such a notice, any other document proving that the authorisation has been issued, the date on which it was issued and the identity of the product authorised.

(d) where the application for a unitary certificate for a medicinal product includes a request for an extension of the duration:

(i) a copy of the statement indicating compliance with an agreed completed paediatric investigation plan as referred to in Article 36(1) of Regulation (EC) No 1901/2006;

(ii) where necessary, in addition to the copy of the authorisation to place the product on the market as referred to in point (b), proof of possession of authorisations to place the product on the market of all other Member States, as referred to in Article 36(3) of Regulation (EC) No 1901/2006.

(d a) if applicable the consent of the third party in accordance with article 6.2 of this Regulation. (S&D 22, EPP 105)

2. Where an application for a unitary certificate is pending, an application for an extension of the duration in accordance with Article 8(3) shall include the documents referred to in paragraph 1, point (d) of this Article and a reference to the application for a certificate already lodged.

3. The application for an extension of the duration of a unitary certificate already granted shall contain the documents referred to in paragraph 1, point (d), and a copy of the certificate already granted.

4. The applications referred to in this Article shall be filed by using specific application forms.

The Commission is empowered to adopt implementing acts laying down rules on the application form to be used. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55.

Article 10

Lodging of an application for a unitary certificate

The application for a unitary certificate and, where applicable, the application for an extension of the duration of a unitary certificate, shall be lodged ***in electronic form (S&D 24)*** with the Office.

The Office shall put the necessary arrangements in place in order to ensure that exchanges of data and information are made available in electronic formats and shall protect the commercially confidential nature of the information exchanged and be without prejudice to the provisions on regulatory protection. (S&D 25)

Article 12

Publication of the application

If the application for a unitary certificate complies with Article 11(1), or if an application for an extension of the duration of a unitary certificate complies with Article 9(3), the Office shall publish the application in the Register ***without undue delay and no later than five working days after. (S&D 26, EPP 106)***

COMP 3

Articles 13, 14, 15, 16, 17

Article 13

Examination of the application for a unitary certificate

1. The Office shall assess the application on the basis of all the conditions in Article ***3 ~~(1)~~ and 6(2)***, for all Member States in which the basic patent has unitary effect. ***(S&D 27, RE 108, EPP 109)***

2. Where the application for a unitary certificate and the product to which it relates comply with Article ***3 ~~(1)~~ and 6(2)*** 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 ***via the electronic platform and publish the opinion on the dedicated register without undue delay***. ***(S&D 28, EPP 110, 112, RE 111)***

3. Where the application for a unitary certificate and the product to which it relates does not comply with Article ***3 ~~(1)~~ and 6(2)*** 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 ***via the electronic platform and publish the opinion on the dedicated register without undue delay. (S&D 29, EPP 113, RE 114)***

4. The Office shall translate the examination opinion in the official languages of all designated Member States. The Office may use verified machine translation to that effect ***and publish the examination opinion on the Register as soon as possible after it is issued***. ***(RE 115).***

5. The Commission is empowered to adopt implementing acts laying down rules on procedures relating to the filing, and procedures regarding the way in which examination panels examine applications for unitary certificates and prepare examination opinions, as well as the issuance of examination opinions by the Office ***in electronic form***. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55. ***(S&D 30)***

5 a. The Office shall issue an examination opinion within 6 months after publication of the application for a unitary certificate. Without prejudice to Articles 14, 25 and 28 of this Regulation, whenever duly justified for reasons of urgency, the applicant may submit a request for an expedited procedure. Where the request for an expedited examination procedure is deemed justified, the Office shall issue an examination opinion within 4 months from the publication of the application for a unitary certificate. (EPP 116, RE 117)

Article 14

Observations by third parties

1. Any natural or legal person may submit written observations to the Office concerning the eligibility for supplementary protection of the product to which the application relates, in one or more of the Member States in which the basic patent has unitary effect. ***These written observations shall be sent to the Office electronically. (S&D 31)***

2. A natural or legal person that has submitted the written observations in accordance with paragraph 1 shall not be a party to the proceedings.

3. Third party observations shall be submitted within 3 months after publication of the application in the Register.

3a new. Whenever the expedited procedure applies in accordance with to Article 24 (5a), observations shall be submitted within six weeks after publication of the application in the Register (EPP 120).

4. Any observations by a third party shall be submitted ***electronically*** in one of the official languages of the Union and state the grounds on which they are based.

5. Any observations by a third party shall be notified to the applicant. The applicant may comment on the observations within a time limit set by the Office**.** ***(S&D 32)***

Article 15

Opposition

1. Within a period of 2 months following the publication of the examination opinion in respect of an application for a unitary certificate, any person ('opponent') may file with the Office a notice of opposition to that opinion.

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 Member States in which the basic patent has unitary effect.

3. Opposition 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 opposition fee has been paid.

4. The notice of opposition shall contain:

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

   (b) the particulars of the opponent and, where applicable, of its representative;

   (c) a statement of the extent to which the examination opinion is opposed, and of the grounds on which the opposition is based.

   (c a) any evidence the opponent relies on in support of the opposition. (S&D 33, ECR 122, EPP 123)

5. The opposition shall be examined by an opposition panel set up by the Office in accordance with the rules applicable to examination panels as referred to in Article 17. However, the opposition panel shall not include any examiner previously involved in the examination panel that examined the unitary certificate application.

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*~~ ***its decision as well as its reasoning to the*** opponent ***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. ***(S&D 34, ECR 124, EPP 125)***

7. The decision to reject an opposition as inadmissible shall be communicated to the holder of the unitary certificate application, together with a copy of the notice of opposition.

8. 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.

9. Where the opposition is not rejected as inadmissible, the Office shall promptly transmit the notice of opposition to the applicant, and shall publish it in the Register. If several notices of opposition have been filed, the Office shall promptly communicate them to the other opponents.

9 a. In cases where several oppositions have been filed against an examination opinion, the Office shall deal with the oppositions jointly and issue one single decision in regards to all oppositions filed. (S&D 35, EPP 130, ECR 131)

10. The Office shall issue a decision on the opposition ***including a detailed reasoning*** within 6 months, unless the complexity of the case requires a longer period. ***(S&D 36, ECR 128, EPP 129)***

11. 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.

12. 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*~~ ***publish its full decision*** in the Register. ***(ECR 132, EPP 133)***

13. The Commission is empowered to adopt delegated acts in accordance with Article 54 to supplement this Regulation by specifying the details of the procedure for filing and examining an opposition.

(13 a.) Full transparency shall be ensured throughout the whole opposition proceeding, which shall be open, whenever possible, to public participation. (EPP 134, EPP 135)

(13 b) All exchanges between the Office, the holder and the opponent shall take place electronically. (S&D 37)

Article 16

Role of competent national authorities

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 ***based on relevant expertise and sufficient***

experience required for the centralized examination procedure. (S&D 38, EPP 136, Greens 137).

2. The Office and the competent national authority shall conclude an administrative agreement before that competent national authority is appointed as participating office as referred to in paragraph 1.

   The agreement shall specify the rights and obligations of the parties, in particular the formal undertaking by the competent national authority concerned to comply with this Regulation as regards the examination of applications for unitary certificates.

3. The Office may appoint a competent national authority as a participating office as referred to in paragraph 1 for 5 years. That appointment may be extended for further periods of 5 years.

4. The Office shall, before appointing a competent national authority, or extending its appointment, or before any such appointment expires, hear the competent national authority concerned.

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, opposition and invalidity proceedings. Each such competent national authority shall update that list in the event of a change.

Article 17

Examination panels

1. The assessments under Articles 13, 15, 19 and 23 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.

2. Examiners shall be impartial in the exercise of their duties and shall declare to the Office any real or perceived conflict of interest upon their designation.

3. When setting up an examination panel, the Office shall ensure the following:

   (a) ***~~geographical balance amongst the participating offices~~*** ***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; (S&D 39, Greens 141, RE 142, EPP 143)***

   (aa) where possible ensure geographical balance amongst the participating offices;

   (b) the respective workload of the examiners is taken into account;

   (c) ***that there is*** 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) 231]. ***(S&D 39, Greens 144, EPP 145)***

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

5. The Commission is empowered to adopt implementing acts to determine the criteria in the ways the panels are to be set up and the criteria for the selection of examiners.
Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55.

COMP 4

Articles 18, 19, 22, 23, 24

Article 18

Grant of a unitary certificate or rejection of the application for a unitary certificate

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***, without undue delay: (S&D 41, Greens 148)***

(a) where the examination opinion is positive, the Office shall grant a unitary certificate;

(b) where the examination opinion is negative, the Office shall reject the application for a unitary certificate.

The Office shall inform the applicant of its decision without undue delay. (S&D 42, EPP 150)

Article 19

Grant of an extension of the duration of a unitary certificate

1. After ensuring that the application for an extension of the duration of a unitary certificate complies with Article 9(3), the Office shall assess that application on the basis of the conditions laid down in Article 36 of Regulation (EC) No 1901/2006.

2. Third parties may also submit observations ***or oppositions*** in respect of an application for an extension of the duration of a unitary certificate***. (S&D 43, EPP 151)***

3. Where the application for an extension of the duration complies with the conditions referred to in paragraph 1, the Office shall grant an extension of the duration of the unitary certificate.

4. Where the application for an extension of the duration does not comply with the conditions referred to in paragraph 1, the Office shall reject that application.

Article 22

Invalidity of the unitary certificate

The unitary certificate shall be invalid in any of the following events:

(a) the certificate was granted contrary to Article 3 ***and 6 (2)***; ***(EPP 152)***

(b) the basic patent has lapsed before its lawful term expires;

(c) the basic patent is revoked or limited to the extent that the product for which the unitary certificate was granted would no longer be protected by the claims of the basic patent or, after the basic patent has expired, grounds for revocation exist which would have justified such revocation or limitation.

Article 23

Application for a declaration of invalidity

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

2. An application for a declaration of invalidity may only be filed on the grounds that one or more of the conditions set out in Article 22 are not fulfilled for one or more of the Member States in which the basic patent has unitary effect.

3. An application for a declaration of invalidity shall be filed ***~~in writing~~ electronically*** 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. ***(S&D 46, Greens 162)***

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

   (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.

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.

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.

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.

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.

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.

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.

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 22 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.

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.

13. The Commission is empowered to adopt delegated acts in accordance with Article 54 to supplement this Regulation by specifying the details of the procedure governing the declaration of invalidity.

Article 24

Counterclaim for the invalidity of a certificate

1. A counterclaim for a declaration of invalidity may only be based on the grounds for invalidity set out in Article 22.

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.

3. If the counterclaim is brought in a legal action to which the holder of the unitary certificate is not already a party, that holder shall be informed thereof and may be joined as a party to the action in accordance with the conditions applicable before the competent court.

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 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.

5. Where the competent court of a Member State has given a judgment which has become final on a counterclaim for a declaration of invalidity of a unitary certificate, a copy of the judgment shall be sent to the Office without delay, either by the court or by any of the parties to the national proceedings. 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.

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.

COMP 5

Articles 28, 29, 31, 32

Article 28

Appeals

1. Any party to proceedings under this Regulation, adversely affected by a decision of the Office, including the adoption of an examination opinion, may appeal the decision to the Boards of Appeal.

2. The filing of the appeal shall have suspensive effect. A decision of the Office that has not been contested shall take effect on the day following the date of expiry of the appeal period referred to in paragraph 3.

3. Notice of appeal shall be filed ***~~in writing~~ electronically*** 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***, including the supporting evidence for those grounds,*** shall be filed ***electronically*** within ***4 3*** months of the date of notification of the decision.

Any written reply to the statement of grounds of appeal shall be submitted no later than 3 months from the statements filing date. The Office shall, where applicable, fix a date for oral proceedings within 3 months following the filing of the reply or within 6 months following the filing of the statement of grounds of appeal, whichever is earlier. The Office will issue a written decision within 3 months from the oral hearing or from the filing of the reply to the statement of grounds of appeal, as applicable. (S&D 47, RE 178, EPP 179, Greens 180, EPP 181. EPP 182)

4. Following an examination of admissibility of the appeal, the Boards of Appeal shall decide on the merits of the appeal.

5. Where an appeal results in a decision which is not in line with the examination opinion, the decision of the Boards ***~~may~~ shall*** annul or alter the opinion. ***(S&D 48, Greens 184)***

6. An action may be brought before the General Court of the European Union against a decision of the Boards of Appeal in relation to appeals, within 2 months of the date of

notification of that decision, on grounds of infringement of an essential procedural requirement, infringement of the Treaty on the Functioning of the European Union, infringement of this Regulation or of any rule of law relating to their application or misuse of power. The action shall be open to any party to proceedings before the Board of Appeal adversely affected by its decision. The General Court shall have jurisdiction to annul or to alter the contested decision.

7. The decisions of the Boards of Appeal shall take effect on the day following the date of expiry of the period referred to in paragraph 6 or, if an action has been brought before the General Court within that period, as from the date following the day of dismissal of such action or of dismissal of any appeal filed with the Court of Justice of the European Union against the decision of the General Court. The Office shall take the necessary measures to comply with the judgement of the General Court or, in the event of an appeal against that judgement, the Court of Justice.

8. The Commission is empowered to adopt delegated acts in accordance with Article 54 to supplement this Regulation by specifying the content and form of the notice of appeal referred to in paragraph 3, the procedure for the filing and examination of an appeal and the content and the form of the Boards of Appeal's decision referred to in paragraph 4.

Article 29

Boards of Appeal

1. In addition to the powers conferred upon it by Article 165 of Regulation (EU) 2017/1001, the Boards of Appeal instituted by that Regulation shall be responsible for deciding on appeals against decisions of the Office taken on the basis of Article 25(1).

2. A Board of Appeal in matters regarding unitary certificates shall consist of three members, at least two of whom are legally qualified. Where the Board of Appeal considers that the nature of the appeal so requires, it may call up to two further members for that case.

3. There shall be no Grand Board as referred to in Article 165(2), (3) and (4), and Article 167(2) of Regulation (EU) 2017/1001 in matters regarding unitary certificates. Decisions taken by a single member as under Article 165(2) of Regulation (EU) 2017/1001 shall not be possible.

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 concerning applications for unitary certificates, due consideration shall be given to their previous experience in matters concerning supplementary protection certificates or patent law. (RE 187, EPP 188)***

4a. The rules set out in Article 166(9) of Regulation (EU) 2017/1001 shall be respected. (S&D 49)

Article 31

Fees

1. The Office shall charge a fee for an application for a unitary certificate, and for an application for the extension of the duration of a unitary certificate.

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

3. The unitary certificate shall be subject to the payment of annual maintenance fees to the Office.

4. The notifications referred to in Article 5(3), points (b) and (c), shall be subject to the payment of a fee to the Office.

5. The Commission is empowered to adopt implementing acts determining the amounts of the fees charged by the Office, the time limits within which they have to be paid, and the ways in which they are to be paid. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55.

Article 32

Combined applications

An application for a unitary certificate may be included in a combined centralised application in which the applicant also requests the grant of national certificates, in the designated Member States, in accordance with the centralised procedure under Regulation [COM(2023) 231]. In that case, Article 39 of that Regulation shall apply.

An applicant shall submit an application for a combined centralised application electronically to the Office and in the formats made available by the Office. (S&D 50)

COMP 6

Articles 34, 35, 36, 38, 39

Article 34

Communications to the Office

1. Communications addressed to the Office ~~***may***~~ ***shall*** be effected by electronic means. The Executive Director shall determine ~~***to what extent and***~~ under which technical conditions those communications ~~***may***~~ ***are to*** be submitted ~~***electronically***~~. **(S&D 52)**

2. The Commission is empowered to adopt delegated acts in accordance with Article 54 to supplement this Regulation by specifying the rules on the means of communication, including the electronic means of communication, to be used by the parties to proceedings before the Office and the forms to be made available by the Office.

Article 35

Register

1. As regards applications for unitary certificates for medicinal products, the Register set up under Article 35 of Regulation [COM(2023) 231][4] shall include, for each unitary certificate, or application for a unitary certificate, or application for an extension of the duration of a unitary certificate, the following information, as applicable:

(a) the name and address of the applicant or certificate holder;

(b) the name and business address of the representative, other than a representative as referred to in Article 38(3);

(c) the application as well as its date of lodging and date of publication;

(d) whether the application relates to a medicinal product or to a plant protection product;

(e) where applicable, an indication that the application includes an application for an extension of the duration;

(f) the number of the basic patent;

(g) an identification of the product for which a unitary certificate is requested;

(h) the number and date of the authorisation to place the product on the market referred to in Article 3(1), point (b), and an identification of the product identified therein;

(i) the number and date of the first authorisation to place the product on the market in the Union;

(ia) information on any direct public financial support received for research related to the development of the product; (S&D 53, ECR 190, Greens 191, EPP 192)

(j) the date and ~~***a summary of***~~ the examination opinion of the Office in respect of each of the Member States in which the basic patent has unitary effect;

(k) where applicable, the number and the duration of the unitary certificate;

(l) where applicable, the date and a summary of the examination opinion relating to an application for an extension of the duration of a unitary certificate;

(m) where applicable, the filing of an opposition, ***its status*** and the outcome of the opposition proceedings, including where applicable a summary of the revised examination opinion; ***(S&D 54, EPP 200, ECR 201***

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[4] Regulation of the European Parliament and of the Council on the supplementary protection certificate for medicinal products [COM(2023) 231].

(n) where applicable, the filing of an appeal, ***its status*** and the outcome of the appeal proceedings, including where applicable a summary of the revised examination opinion; ***(S&D 55, ECR 202, EPP 203)***

(o) where applicable, a mention that a certificate has lapsed or was declared invalid;

(p) where applicable, the filing of an application for a declaration of invalidity and, once available, the outcome of the related proceedings;

(q) where applicable, information relating to a request for conversion, and its outcomes;

(r) information on the payment of annual fees.

2. The Register shall contain changes to the information in paragraph 1, including transfers, each accompanied by the date of recording of such entry.

3. The Register and information referred to in paragraphs 1 and 2 shall be available in all official languages of the Union. The Office may use verified machine translation for the information to be published in the Register.

4. The Executive Director of the Office may determine that information other than those referred to in paragraphs 1 and 2 shall be entered in the Register.

5. The Office shall collect, organise, make public and store the information referred to in paragraphs 1 and 2, including any personal data, for the purposes laid down in paragraph 7. The Office shall keep the Register easily accessible for public inspection.

6. The Office shall provide certified or uncertified extracts from the Register on request and on payment of a fee.

7. The processing of the data concerning the entries set out in paragraphs 1 and 2, including any personal data, shall take place for the purposes of the following:

(a) administering the applications and unitary certificates in accordance with this Regulation and the acts adopted pursuant to it;

(b) maintaining the Register and making it available for inspection by public authorities and economic operators;

(c) producing reports and statistics enabling the Office to optimise its operations and improve the functioning of the system.

8. All the data, including personal data, concerning the entries in paragraphs 1 and 2 shall be considered to be of public interest and may be accessed by any third party. For reasons of legal certainty, the entries in the Register shall be kept for an indefinite period of time.

8a. By way of derogation from Article 35(7), point (b), public authorities shall not use the information provided for in the register for practices of patent linkage, and no regulatory or administrative decisions related to generics or biosimilars shall be based on information provided for in the register and be used for refusal, suspension, delay, withdrawal or revocation of marketing authorisations, pricing and reimbursement decisions or tender bids. (S&D 56, Greens 210, EPP 211, ECR 212)

Article 36

Database

1. In addition to the obligation to keep a Register, the Office shall collect and store in an electronic database all the particulars provided by applicants or any other third party observations pursuant to this Regulation or acts adopted pursuant to it.

2. The electronic database may include personal data, beyond those included in the Register, to the extent that such particulars are required by this Regulation or by acts adopted pursuant to it. The collection, storage and processing of such data shall serve the purposes of:

   (a) administering the applications and/or certificate registrations as described in this Regulation and in acts adopted pursuant to it;

   (b) accessing the information necessary for conducting the relevant proceedings more easily and efficiently;

   (c) communicating with the applicants and other third parties;

   (d) producing reports and statistics enabling the Office to optimise its operations and improve the functioning of the system.

3. The Executive Director shall determine the conditions of access to the electronic database and the manner in which its contents, other than the personal data referred to in paragraph 2 of this Article but including those listed in Article 35, may be made available in machine-readable form, including the charge for such access.

4. Access to the personal data referred to in paragraph 2 shall be restricted and such data shall not be made publicly available unless the party concerned has given his express consent.

5. All data shall be kept indefinitely. However, the party concerned may request the removal of any personal data from the database after 18 months from the expiry of the unitary certificate or, the case being, the closure of the relevant *inter partes* procedure. The party concerned shall have the right to obtain the correction of inaccurate or erroneous data at any time.

Article 38

Representation

1. Natural or legal persons having neither their domicile nor their principal place of business or a real and effective industrial or commercial establishment in the European Economic Area

shall be represented before the Office in accordance with this Article in all proceedings provided for by this Regulation, other than the filing of an application for a unitary certificate.

2. Natural or legal persons having their domicile or principal place of business or a real and effective industrial or commercial establishment in the Union may be represented before the Office by an employee.

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.

The second subparagraph also applies where those other legal persons have neither their domicile nor their principal place of business nor a real and effective industrial or commercial establishment within the Union.

Employees who represent natural or legal persons shall, at the request of the Office or, where appropriate, of the party to the proceedings, file with the Office a signed authorisation for insertion in the files.

3. A common representative shall be appointed where there is more than one applicant or more than one third party acting jointly.

4. Only a practitioner established in the Union, entitled to act as a professional representative in patent matters before a national patent office or the European Patent Office, or a lawyer authorised to practise before the courts or tribunals of a Member State, may represent natural or legal persons before the Office

Article 39

Supplementary Protection Certificates Division

A Supplementary Protection Certificate Division ('SPC Division') shall be set up within the Office and, in addition to the responsibilities under Regulations [COM(2023) 231] and

[COM(2023) 223], shall be responsible for implementing the tasks set out in this Regulation and in Regulation [COM(2023) 221], including in particular:

(a) receiving and supervising the examination of applications for unitary certificates, applications for an extension of the duration of unitary certificates, appeals and observations by third parties;

(b) adopting examination opinions on behalf of the Office in relation to applications for unitary certificates, as well as in relation to applications for an extension of the duration of unitary certificates;

(c) deciding on oppositions against examination opinions;

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

(e) processing conversion requests;

(f) maintaining the register and the database.

COMP 7

Articles 40, 41, 42, 46, 48, 50, 54, 56

Article 40

Decisions and communications of the Office

1. Decisions of the Office under this Regulation shall include examination opinions and shall state the reasons on which they are based. They shall be based only on reasons or evidence on which the parties concerned have had an opportunity to present their comments. Where oral proceedings are held before the Office, the decision may be given orally. Subsequently, the decision or opinion shall be notified ~~***in writing***~~ ***electronically*** to the parties. ***(S&D 58)***

2. Any decision, opinion, communication or notice from the Office under this Regulation shall indicate the SPC Division and the relevant panel as well as the name or the names of the examiners responsible. It shall be signed by these examiners, or, instead of a signature, carry a printed or stamped seal of the Office. The Executive Director may determine that other means of identifying the SPC Division and the name of the examiners responsible, or an identification other than a seal, may be used where decisions or other communications are transmitted by any technical means of communication.

3. Decisions of the Office under this Regulation which are open to appeal shall be accompanied by a written communication indicating that any notice of appeal is to be filed ~~***in writing***~~ ***electronically*** at the Office within 2 months of the date of notification

of the decision in question. That communication shall also draw the attention of the parties to the provisions laid down in Article 28. The parties may not plead any failure on the part of the Office to communicate the availability of appeal proceedings. ***(S&D 59)***

Article 41

Oral proceedings

1. If the Office considers that oral proceedings would be expedient they shall be held either at the instance of the Office or at the request of any party to the proceedings.

2. ~~***Oral proceedings before an examination panel, opposition panel or invalidity panel shall not be public.***~~ ***(RE 216)***

3. Oral proceedings before ***an examination panel, an opposition panel or*** the Boards of Appeal, including delivery of the decision and, as the case may be, of a revised opinion, shall be public, unless the ***examination panel, the opposition panel or the*** Boards of Appeal decide otherwise in cases where admission of the public ***to all or a part of the oral proceedings*** could have serious and unjustified disadvantages, in particular for a party to the proceedings. ***(EPP 217, RE219)***

4. The Commission is empowered to adopt delegated acts in accordance with Article 54 to supplement this Regulation by setting out the detailed arrangements for oral proceedings.

Article 42

Taking of evidence

1. In any proceedings before the Office, the means of giving or obtaining evidence shall include the following:

   (a) hearing the parties;

   (b) requests for information;

   (c) the production of documents and items of evidence;

   (d) hearing witnesses;

   (e) opinions by experts;

   (f) statements in writing sworn or affirmed or having a similar effect under the law of the State in which the statement is drawn up.

2. The relevant panel may commission one of its members to examine the evidence adduced.

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 summonsed, 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. ***(S&D 60, Greens 221)***

4. The parties shall be informed of the hearing of a witness or expert before the Office. They shall have the right to be present and to put questions to the witness or expert.

5. The Executive Director shall determine the amounts of expenses to be paid, including advances, as regards the costs of taking of evidence as referred to in this Article.

6. The Commission is empowered to adopt delegated acts in accordance with Article 54 to supplement this Regulation by setting out the detailed arrangements for the taking of evidence.

Article 46

Restitutio in integrum

1. The applicant for or holder of a unitary certificate, or any other party to proceedings before the Office under this Regulation, who, in spite of all due care required by the circumstances having been taken, was unable to comply with a time limit vis-à-vis the Office shall, upon application, have his rights re-established if the obstacle to compliance has the direct consequence, by virtue of the provisions of this Regulation, of causing the loss of any right or means of redress.

2. The application for re-establishment shall be filed ***~~in writing~~ electronically*** within 2 months of the removal of the obstacle to compliance with the time limit. The omitted act shall be completed within this period. The application shall only be admissible within the year immediately following the expiry of the unobserved time limit. ***(S&D 61)***

3. The application for re-establishment shall state the grounds on which it is based and shall set out the facts on which it relies. It shall not be deemed to be filed until the fee for re-establishment of rights has been paid.

4. The SPC Division, or where applicable the Boards of Appeal, shall decide upon the application.

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).

Article 48

Costs

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 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.

2. Where each party succeeds on some and fails on other heads, or if reasons of equity so dictate, the SPC Division or Board of Appeal shall decide a different apportionment of costs.

3. Where proceedings are terminated the costs shall be at the discretion of the SPC Division or Board of Appeal.

4. Where the parties conclude before the SPC Division or Board of Appeal a settlement of costs differing from that provided for in paragraphs 1 to 3, the body concerned shall take note of that agreement.

5. The SPC Division or Board of Appeal shall fix the amount of the costs to be paid pursuant to paragraphs 1 to 3 of this Article when the costs to be paid are limited to the fees paid to the Office and the representation costs. In all other cases, the registry of the Board of Appeal or SPC Division shall fix, on request, the amount of the costs to be reimbursed. The request shall be admissible only for the period of 2 months following the date on which the decision for which an application was made for the costs to be fixed becomes final and shall be accompanied by a bill and supporting evidence. For the costs of representation an assurance by the representative that the costs that have been incurred shall be sufficient. For other costs, it shall be sufficient if their plausibility is established. Where the amount of the costs is fixed pursuant to the first sentence of this paragraph, representation costs shall be awarded at the level laid down in the implementing act adopted pursuant to paragraph 7 of this Article and irrespective of whether they have been actually incurred.

6. Decisions on the fixing of costs adopted in accordance with paragraph 5 shall state the reasons on which they are based, and may be reviewed by a decision of the SPC Division or Board of Appeal on a request filed within 1 month of the date of notification of the awarding of costs. It shall not be deemed to be filed until the fee for reviewing the amount of the costs has been paid. The SPC Division or the Board of Appeal, as the case may be, shall take a decision on the request for a review of the decision on the fixing of costs without oral proceedings.

7. The Commission shall adopt implementing acts specifying the maximum rates for costs essential to the proceedings and actually incurred by the successful party. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55.

8. When specifying the maximum rates with respect to travel and subsistence costs, the Commission shall take into account the distance between the place of residence or business of the party, representative or witness or expert and the place where the oral proceedings are held, the procedural stage at which the costs have been incurred, and, as far as costs of representation are concerned, the need to ensure that the obligation to bear the costs may not be misused for tactical reasons by the other party. In addition, subsistence expenses shall be calculated in accordance with the Staff Regulations of Officials of the Union and the Conditions of Employment of Other Servants of the Union, laid down in Council Regulation (EEC, Euratom, ECSC) No 259/6839. The losing party shall bear the costs for one party in the proceedings only and, where applicable, one representative only.

Article 50

Amendment to Regulation (EU) 2017/1001 Regulation (EU) 2017/1001 is amended as follows:
(1) Article 151(1) is amended as follows:
(a) point (c) is replaced by the following:
‘(c) promoting convergence of practices and tools in the fields of trade marks and designs as well as supplementary protection certificates, in cooperation with the central industrial property offices in the Member States, including the Benelux Office for Intellectual Property’;
(b) the following points (f) and (g) are added:

'(f) the tasks referred to in Chapter III of Regulation [COM(2023) 231] and in Chapter III of Regulation [COM(2023) 223] as well as in Regulations [COM(2023) 222] and [COM(2023) 221];
(g) on the basis of requests for participation in the centralised examination procedure, and after giving the Commission an opportunity to comment on them, appointing, by concluding an agreement, those competent national authorities whose examiners will be able to participate in the centralised examination of centralised applications for certificates under Regulations [COM(2023) 231] and [COM(2023) 223], including opposition proceedings, and of applications for unitary certificates under Regulation [COM(2023) 222] and Regulation [COM(2023) 221], including opposition and invalidity proceedings';

(2) in Article 152(1), the first subparagraph is replaced by the following: 'The Office and the central industrial property offices of the Member States and the Benelux Office for Intellectual Property shall cooperate with each other to promote convergence of practices and tools in the field of trade marks, designs, and supplementary protection certificates.'.

Article 54

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 power to adopt delegated acts referred to in Articles 15(13), 23(13), 28(8), 30, 34(2), 41(4), 42(6), 43(4), 44(5) and 47(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].

3. The delegation of power referred to in Articles 15(13), 23(13), 28(8), 30, 34(2), 41(4), 42(6), 43(4), 44(5) and 47(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.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 15(13), 23(13), 28(8), 30, 34(2), 41(4), 42(6), 43(4), 44(5) or 47(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.

Article 56

Evaluation

*By **...** [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, the Council and the European Economic and Social Committee**. **Special emphasis shall be given to the effects of opposition under Article 15 and whether the possibility of opposition leads to significant delays in granting unitary certificates and to the effects of this Regulation to recover R&D investments in the light of Directive (EU) No XXX/XX [COM(2023)192]. (S&D 62, Greens 228, RE 229, EPP 230)***

COMP 8

All recitals

(1) Pharmaceutical research plays a decisive role in the continuing improvement in public health ***and in ensuring the Union's competitiveness***. Medicinal products, in particular those that are the result of long, costly research will not continue to be developed in the Union unless they are covered by favourable rules that provide for sufficient protection to encourage such research. ***However, it is hard to establish a direct link between those favourable rules and EU competitiveness because while such rules make EU markets more attractive, medicines' geographical origin and authorised medicines from third countries are equally eligible to receive all EU incentives, just as EU based innovative companies can equally benefit from incentives in third countries. (S&D 1, EPP 63, EPP 64)***

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

(2 a) That situation leads to a lack of protection which penalises pharmaceutical research and there is a risk that research centres situated in the Member States relocate to countries that offer greater protection. (EPP 66)

(11) In particular, the duration of the protection granted by a unitary certificate should be identical to the duration provided for as regards national certificates under Regulation [COM(2023) 231]; namely, the holder of both a unitary patent and a unitary certificate should be able to enjoy an overall maximum of 15 years of exclusivity from the time the medicinal product in question first obtains an authorisation to be placed on the market in the Union. Since the unitary certificate would take effect at the expiry of the basic patent, and in order to take into account discrepancies in national practices regarding the date of expiry of a patent which may result in 1-day differences, this Regulation should clarify when exactly the protection conferred by a unitary certificate should take effect.

(14 a) To avoid unnecessary administrative and financial burden both for the pharmaceutical industry, the national authorities and the Office, certain streamlining measures should be introduced. Electronic applications for unitary and combined applications for supplementary protection certificates should be made possible. An applications submitted to the Office, should follow the digital by default principle and hence be sent to the Office in electronic form. Applications should be assessed based on the file submitted by the applicant in accordance with the different legal basis provided by this Regulation. (S&D 2)

(16) 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 ***and drawings*** of the patent***, on the basis of that person's general knowledge in the relevant field and of the prior art at the*** filing date ***or priority date of the basic patent***. This should not necessarily require that the active ingredient of the product be explicitly identified in the claims or, in the event of a combination product, this should not necessarily require that each of its active ingredients be explicitly identified in the claims, provided that each ~~***of them***~~ ***active ingredient*** is specifically identifiable in the light of all the information disclosed by that patent, ***on the basis of the prior art at the filing date or priority date of the basic patent. (EPP 69)***

(17) 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 ~~***therapeutically equivalent***~~ derivative such as salts, esters, ethers, isomers, mixtures of isomers, complexes or biosimilars, 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 therapeutic indication or for a different one. ***(EPP 71)***

(19) To ensure balanced protection, however, a unitary certificate should entitle its holder to prevent a third party from manufacturing not only the product identified in the unitary certificate but also therapeutically equivalent derivatives of that product, such as salts, esters, ethers, isomers, mixtures of isomers or complexes, as well as biosimilars, even where such derivatives are not explicitly mentioned in the product description on the unitary certificate. There is therefore a need to consider that the protection conferred by the unitary certificate extends to such equivalent derivatives, within the limits of the protection conferred by the basic patent.

(20) 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.

20a new) For the purposes of ensuring a broad supply of products protected by supplementary protection certificates, holders of unitary supplementary protection certificates are encouraged to exercise their rights under such certificates in a way that allows the supply of products in markets where they do not have the intention to launch any product. In that respect, holders might reach voluntary agreements to licence the unitary supplementary protection certificate rights in those markets. The objective is to allow the

supply of products by licensees where the holders of unitary supplementary protection certificates decide not to put any product on the market.

(21) Where the marketing authorisation submitted in support of the application for a certificate for a biological medicinal product identifies that product by means of its International Nonproprietary Name (INN), the protection conferred by the certificate should extend to ***~~all therapeutically equivalent products~~ biosimilar*** having the same International Nonproprietary Name as the product referred to in the marketing authorisation, irrespective of possible minor differences between a subsequent biosimilar and the product authorised, which are usually unavoidable given the nature of biological products. ***(S&D 3, EPP 74, EPP75)***

(21 a) The timely entry of generics and biosimilars onto the Union market is important, notably to increase competition, to reduce prices and to ensure both the sustainability of national healthcare systems and better access to affordable medicines by patients in the EU. The importance of such timely entry has been underlined by the Council in its conclusions of 17 June 2016 on strengthening the balance in the pharmaceutical systems in the Union and its Member States. (S&D 4, Greens 76). On the other hand, it should be borne in mind that intellectual property rights remain one of the cornerstones of innovation, competitiveness and growth in the internal market.

(22) Regulation [COM(2023) 231] provides for an exception according to which, under narrowly defined circumstances and subject to various safeguards, the protection conferred by a national supplementary protection certificate for medicinal products does not extend to a product that would be manufactured in the Union by a person other than the holder of that certificate, where it is manufactured for the purpose of being exported to a third country ***markets, where protection does not exist or has expired*** or of being ***made and*** stored in the Union in view of ***~~its entry into the Union~~ entering the*** market ***of any Member State*** upon expiry of the ***corresponding*** certificate ***(EU 'Day-one' entry) and any acts related thereto***. To avoid discrimination between applicants for certificates under Regulation [COM(2023) 231] and for unitary certificates under this Regulation, similar rights and limitations should be conferred by certificates under Regulation [COM(2023) 231] and by unitary certificates, and therefore that exception should also be available in respect of unitary certificates. The reasons for the introduction for the waiver and the conditions for its application should be applicable for unitary certificates. ***(S&D 5, EPP 77)***

(22 a) In these specific and limited circumstances, and in order to create a level playing field between Union-based makers and third country makers, it is appropriate to restrict the protection conferred by a supplementary protection certificate in accordance to Regulation (EU) 2019/933 so as to allow making for the exclusive purpose of export to third countries and any related acts in the Union strictly necessary for making or for the actual export itself, where such acts would otherwise require the consent of a certificate holder ('related acts'). For instance, such acts could include the possession, supply, offering to supply, import, using or synthesis of an active ingredient for the purpose of making a medicinal product containing that product, or temporary storage of the product or advertising for the exclusive purpose of export to third country destinations. The exception should also apply to related acts performed by third parties who are in a contractual relationship with the maker. (S&D 6)

(25) 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.

(26) 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, ***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. ***(S&D 7, EPP 80, Greens 81)***

(26 a) To guarantee an effective protection of innovation, in certain urgent situations, including where the expiry of the basic patent is imminent, an expedited examination procedure may be needed, notwithstanding the possibility for third parties to submit observations and other remedies provided under this Regulation. Therefore, a mechanism for applicants to request an expedited examination procedure should be foreseen. (EPP 82)

(28) 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.

(29) 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 ***without undue delay*** the examination opinion by granting a unitary certificate or rejecting the application, as applicable. ***(EPP 84)***

(30) ***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. ***(EPP 85)***

(31) 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. ***(S&D 8, Greens 86, EPP 87)***

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

(33) The Office should have the possibility to charge a fee for the application for a unitary certificate and for an application for the extension of duration of a unitary certificate ***for*** paediatric medicinal products ***in accordance with Article 86 of [revised Directive 2001/83/EC]***, 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. ***(S&D 9, EPP 89)***

(35) To ensure transparency, a register should be set up that can serve as a single access point providing information on applications for unitary certificates as well as granted unitary certificates and their status. The register should be available in all official languages of the Union. ***However, the information provided for within the register shall not be used in regards to practices of patent linkage and no regulatory or administrative decisions related to generics or biosimilars shall be based on information provided for in the register such marketing authorisations, pricing and reimbursement decisions or tender bids to the existence of the SPC. (S&D 10, EPP 91)***