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The EU SPC Reform

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01 Introduction

Current situation, aims and key measures

Current situation

SPCs examined, granted and litigated at a national level. Duplication of work and possibility of different decisions at examination or invalidity procedures in different countries: legal uncertainty, complex litigation in several countries, etc.

Aims

- Simplify the EU's SPC system
- Improve its transparency and efficiency.

Key measures

- Centralised examination procedure
- Unitary certificates
- EUIPO role as centralised SPC office

Changes

Current SPC regimen	*SPC Reform Package*
SPCs for medicinal products (MP): Regulation (EC) 469/2009	Recast SPC Reg for MP (COM(2023)231) Unitary SPC Reg for MP ((COM(2023)222)
SPCs for plant protection products (PPP): Regulation (EC) 1610/96	Recast SPC Reg for PPP (COM(2023)223) Unitary SPC Reg for PPP (COM(2023)221)

EU Commission Proposals

Medicinal/Plant Protection Products	Unitary/ National	COM(2023) proposal	
Plant Protect. Prod.	Unitary	221	COM(2023)221 - Proposal for a regulation of the European Parliament and of the Council on the **unitary** supplementary protection certificate for **plant** protection products = **uSPC Reg for PPP**
Medicinal products	Unitary	222	COM(2023)222 - Proposal for a regulation of the European Parliament and of the Council on the **unitary** supplementary certificate for **medicinal** products = **uSPC Reg for MP**
Plant Protect. Prod.	National	223	COM(2023)223 - Proposal for a regulation of the European Parliament and of the Council on the supplementary protection certificate for **plant** protection products (**recast**) = **Recast SPC Reg for PPP**
Medicinal products	National	231	COM(2023)231 - Proposal for a regulation of the European Parliament and of the Council on the supplementary protection certificate for **medicinal** products (**recast**) = **Recast SPC Reg for MP**

Changes in prosecution, grant, maintenance and litigation

Patents	*SPCs*
National Patents	1990s: National SPCs (examined, granted, maintained and litigated at nation level)
1970's: EP patents (examined *and granted* under centralized procedure; validated, maintained and litigated nationally)	2026?: National or Unitary SPCs ▪ National SPCs: Centralised examination in most of the cases + national grant, maintenance and litigation (national/UPC). ▪ Unitary SPCs: Centralised examination, grant, maintenance and litigation.
2023: UP patents	

02

Centralised SPC application procedure and Unitary SPCs

SPC application procedure for medicinal products: centralized or national?

Basic Patent	Marketing Authorisation procedure	
	Centralised (European Medicines Agency)	**National (purely national, Mutual Recognition Procedure or Decentralized Procedure)**
UP	Centralised SPC appplication [+ Unitary SPC application]	National SPC application
EP	Centralised SPC appplication	National SPC application
National patent	National SPC application	National SPC application

For medicinal products the centrallised SPC application procedure is only available and mandarory when there is:
- a single MA by the EMA (=> approved on a single date) for all the countries concerned **and**
- a [single] EP/UP patent.

With a unitary patent and a centralised approved MA by the EMA, you can optionally file a unitary SPC application.
Unitary patents do not force their proprietors to file a unitary SPC.

Legal bases: Art. 3(2) and Art. 20 (1) and (2) of Recast SPC Reg; and Art 3(1) of uSPC Reg.

SPC application procedure for medicinal products: centralized or national?

SPC Recast Reg
Chapter II: National Applications for a Certificate. Art 3-19
Chapter III: Centralised Procedure for Certificates. Art 20-54

Art. 3

2. By way of derogation from paragraph 1, a certificate shall not be granted under this Chapter, in a Member State, on the basis of a national application where the requirements of Article 20(1) are fulfilled for the filing of a centralised application in which that Member State would be designated.

Art. 20

1. Where the basic patent is a European patent, including a unitary patent, and the authorisation to place the product on the market has been granted through the centralised procedure under Regulation (EC) No 726/2004 or Regulation (EU) 2019/6, the procedure in this Chapter shall apply.
2. When the conditions under paragraph 1 are met, the filing of national applications shall be prohibited, in respect of the same product, in those Member States in which that basic patent is in force.

SPC application procedure for medicinal products: centralized or national?

uSPC Reg for MP

Art. 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 Regulation (EU) 2019/6, or with the centralised procedure under Regulation (EC) No 726/2004;

(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.

PS: I consider that the drafting is erroneous as under Regulation (EC) No 726/2004 all procedures are centralized, while under Regulation (EU) 2019/6 for veterinary products, both centralized and national procedures are considered. However, Recitals 6 and 13 make it clear that 'a valid authorisation to place the product on the market as a medicinal product granted in accordance with Regulation (EU) 2019/6' suitable for a unitary SPC must be granted under a centralised procedure only.

Combined SPC application

Basic Patent	Marketing Authorisation procedure	
	Centralised (European Medicines Agency)	**National (pure national, MRP or DCP)**
UP (UP countries) (for non-UP countries)	Unitary SPC application Centralised SPC appplication	National SPC application
EP	Centralised SPC appplication	National SPC application
National patent	National SPC application	National SPC application

Combined SPC application =
Unitary SPC application (for UP countries) + Centralized SPC application (for the other states) based on the UP.

It ends up with a unitary SPC (for the states in which the unitary patent has effect) and national SPCs (in the other designated member states not having unitary effect).

Legal bases: Recitals 26 and 61, Art 39 of Recast SPC Reg for MP and
Recitals 14 and 15 and Art 32 of uSPC Reg for MP.

Art 39: Combined applications

Recast SPC Reg for MP

1. A centralised application may also include a request for the grant of a unitary certificate, as defined in Regulation [COM(2023) 222]* ('combined application').

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.

3. The Member States for which the basic patent has unitary effect shall not be designated in the combined application for the parallel grant of national certificates. Any designation, in the combined application, of a Member State for which the basic patent has unitary effect shall be disregarded for the purpose of the examination of the combined application.

*Regulation of the European Parliament and of the Council concerning the unitary supplementary protection certificate for medicinal products [COM(2023) 222]. = uSPC Reg for MP

Centralised SPCs applications for plant protection products: no centralized approval required

Plant protection products (PPPs) are not approved under a centralised procedure.

However, SPCs protecting them can be applied by the centralised procedure if:

a) The basic patent is EP/UP
b) Authorisations to place the product on the market have been granted in at least one Member State

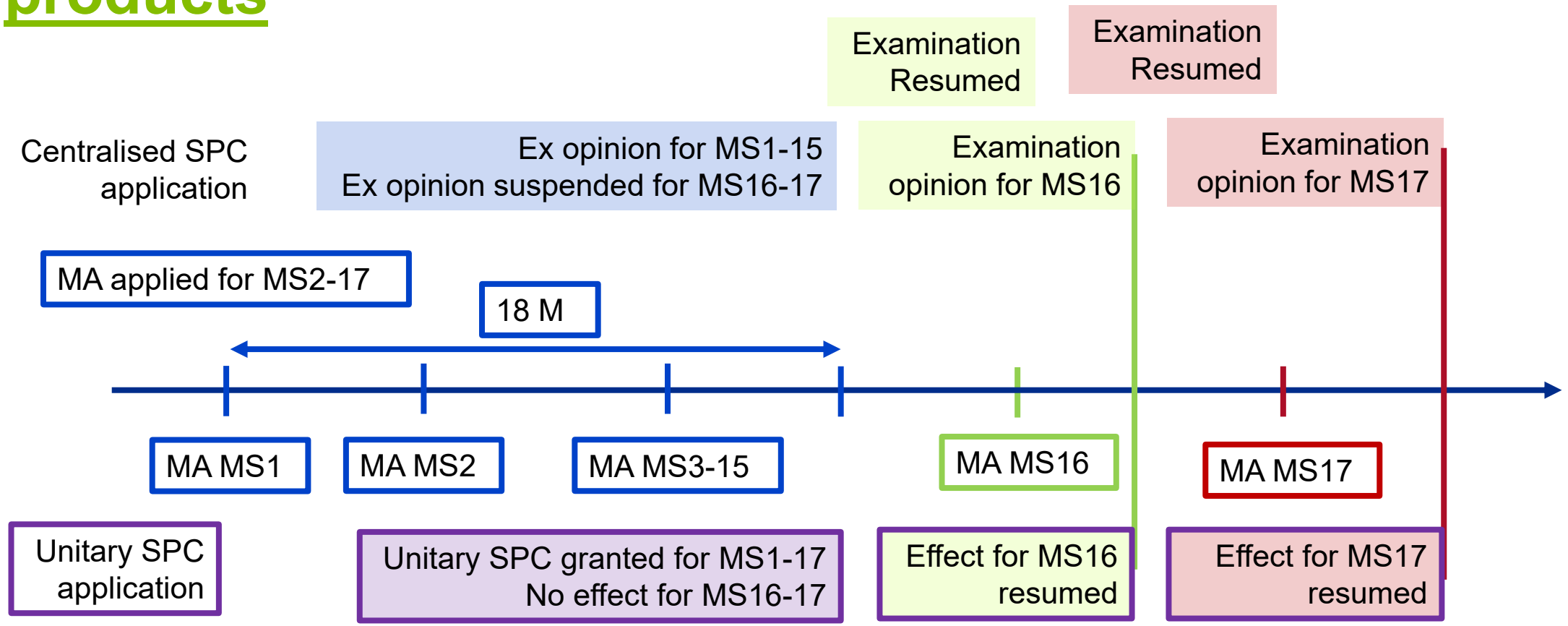
Legal bases: Arts. 19 and 24 of Recast SPC Reg for Plant Protection Products.
Art 33 and the following of Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market

Centralised SPCs applications for plant protection products: no centralized approval required

Plant protection products (PPPs) are not approved under a centralised procedure. Accordingly, unlike for medicinal products, there is no requirement of a centralized approval of the PPP for using the centrallised SPC application procedure.

PPPs might be approved by a Mutual Recognition Procedure with some states approving the product first (Reference Member States, one of them is chosen in each of the climatic zones of interest defined) and other states basing their later approval on the first. They are approved nationally after the active substances containing them are approved at EU level.

Centralised/unitary SPC applications for plant protection products



EP/UP granted
Marketing Authorisation (MA) granted in at least 1 member state (MS1)
MA applied for in other MSs (MS2-17) but not granted.
For uSPCs, a MA application in all MS where the unitary patent has unitary effect is required

Centralised SPCs applications for plant protection products: no centralized approval required

Article 24: Extended conditions for obtaining a certificate (Recast SPC Reg for PPP)

1. By way of derogation from Article 3(1), point (b), the Office shall adopt a positive opinion for a given plant protection product, on the basis of a centralised application, for each designated Member State where both of the following conditions are fulfilled:
   (a) at the date of that application, an authorisation to place the product on the market as a plant protection product has been applied for in accordance with Regulation (EC) No 1107/2009;
   (b) a valid authorisation was granted before the examination opinion is adopted.
2. The examination opinion shall not be adopted earlier than 18 months after the centralised application was filed, unless a valid authorisation to place the product on the market as a plant protection product has been granted in accordance with Regulation (EC) No 1107/2009 in each of the designated Member States, at the filing date of the centralised application.
3. In respect of a designated Member State in which no authorisation was granted earlier than 18 months after the centralised application was filed, the Office shall suspend the examination proceedings, and shall resume those proceedings if and when such an authorisation is granted by the competent national authority, and is submitted to the Office by the applicant before the expiry of the basic patent.

Unitary SPCs for plant protection products

Procedure is complex. Unitary SPCs can be applied for before the marketing authorisation is granted for some countries (but a marketing authorization has to be applied for all countries where the patent has unitary effect)...

Legal bases: Art. 3 of uSPC Reg for Plant Protection Products.

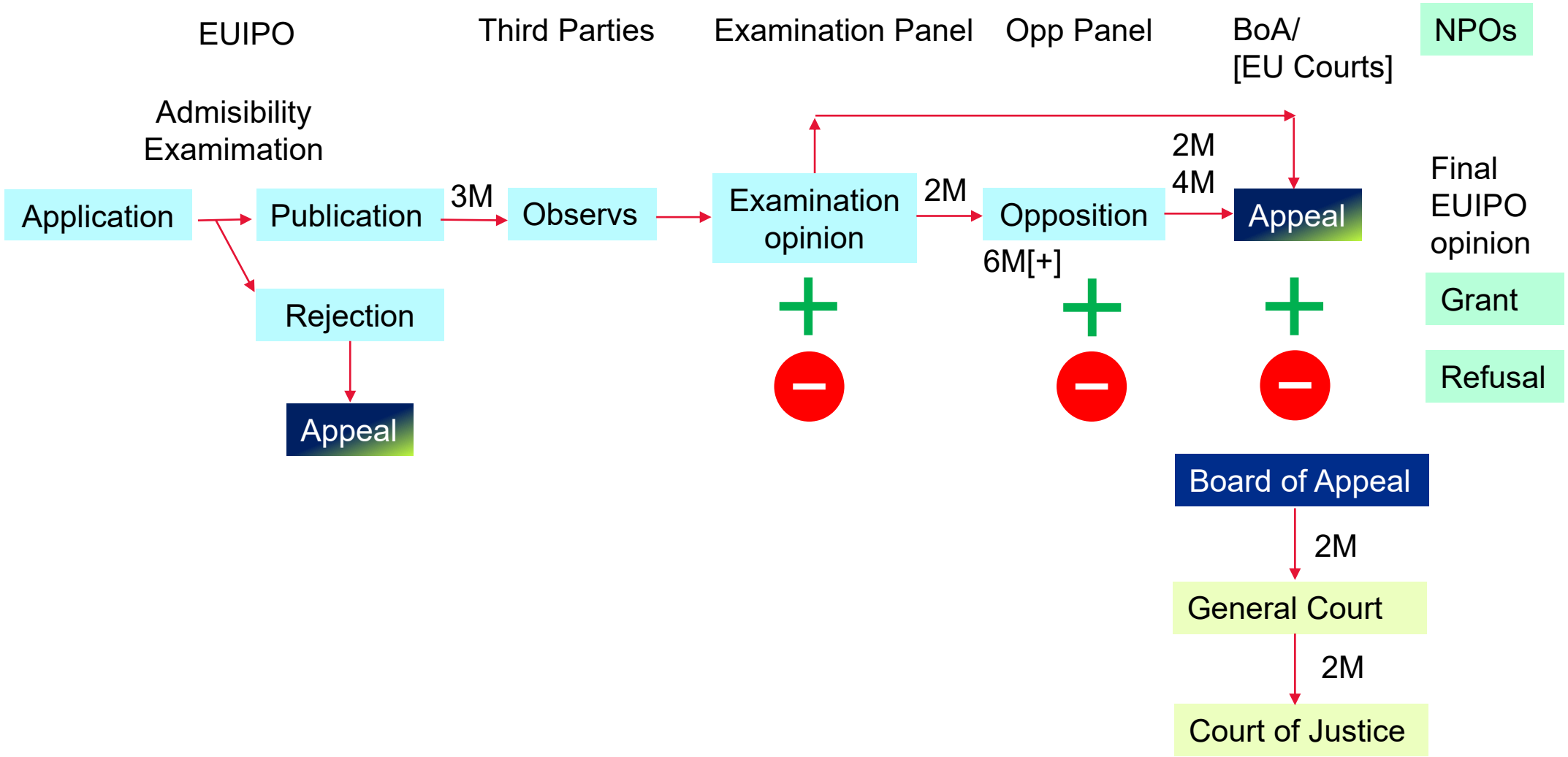
Unitary SPCs for plant protection products

Article 3: Conditions for obtaining a unitary certificate (uSPC Reg for PPP)

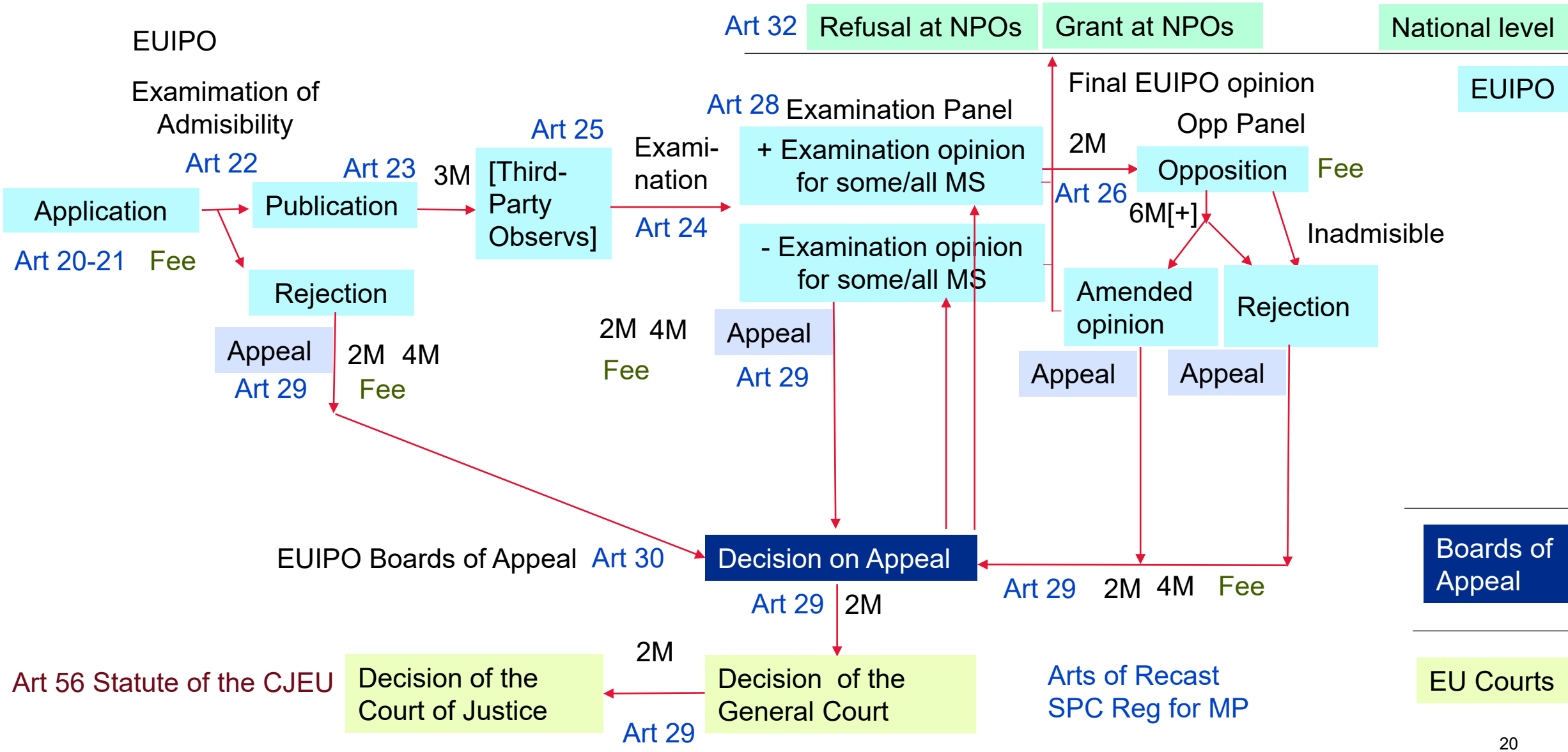
...

3. A unitary certificate shall also be granted for a given plant protection product if the following conditions are fulfilled:
   (a) at the date of the application, in each of the Member States in which the basic patent has unitary effect, an authorisation to place the product on the market as a plant protection product has been applied for in accordance with Regulation (EC) No 1107/2009, but an authorisation has not yet been granted in at least one of these Member States;
   (b) before the examination opinion is adopted, valid authorisations have been granted in each of the Member States in which the basic patent has unitary effect.
4. Where the condition set out in paragraph 3, point (a), is fulfilled, the examination opinion shall not be adopted earlier than 18 months after the application was filed.
5. By way of derogation from paragraph 3, where only the condition set out in paragraph 3, point (a), is fulfilled in respect of a Member State in which the basic patent has unitary effect, a unitary certificate shall be granted, but shall not have effect in that Member State.
   Where a unitary certificate is granted in accordance with the first subparagraph, the applicant may submit to the Office a marketing authorisation subsequently granted in that Member State before the expiry of the basic patent, together with a request for the effect of the unitary certificate to resume in that Member State. The Office shall assess whether the conditions set out in paragraph 1 are fulfilled in respect of that Member State, and shall issue a decision on whether the effect shall resume.

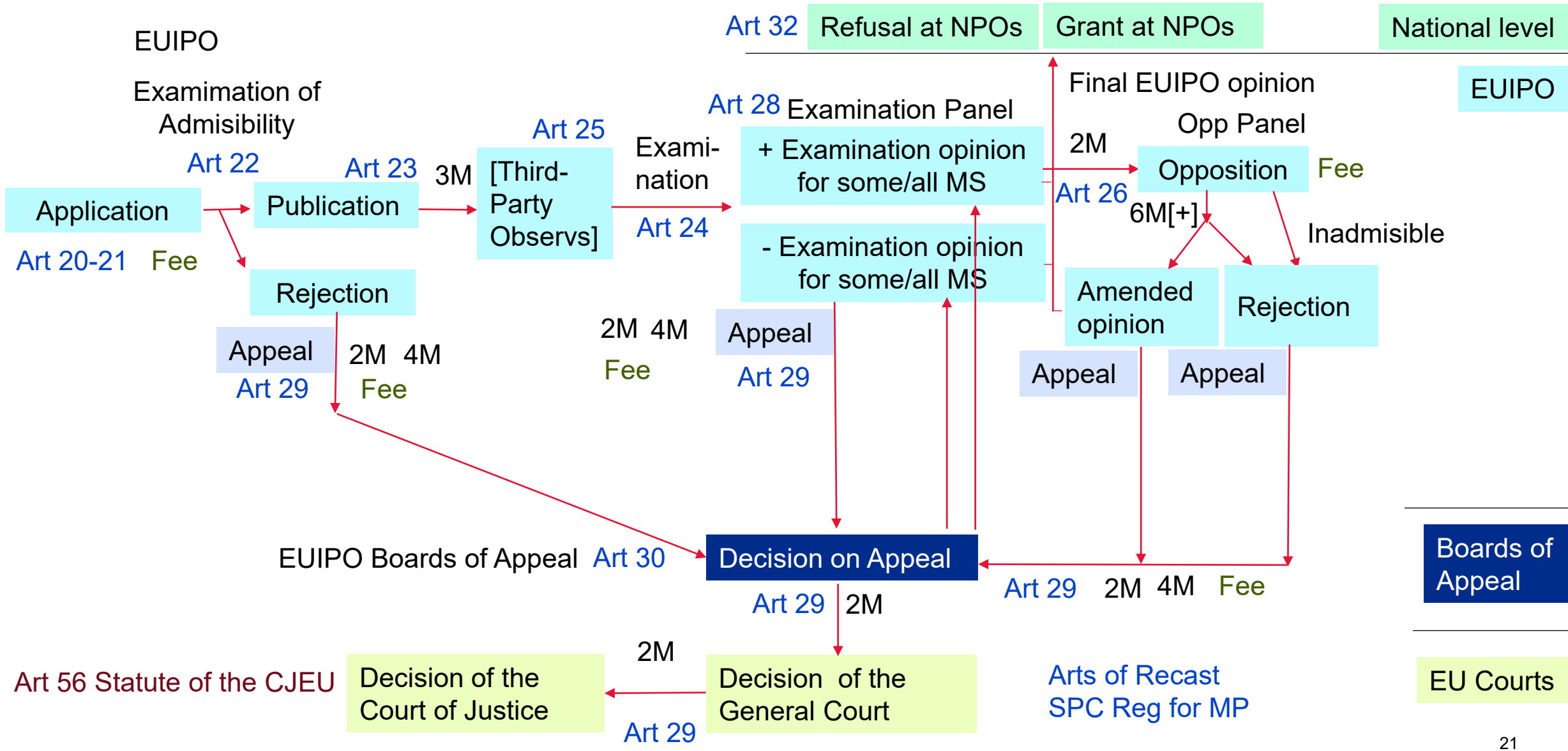
Centralised SPC application procedure



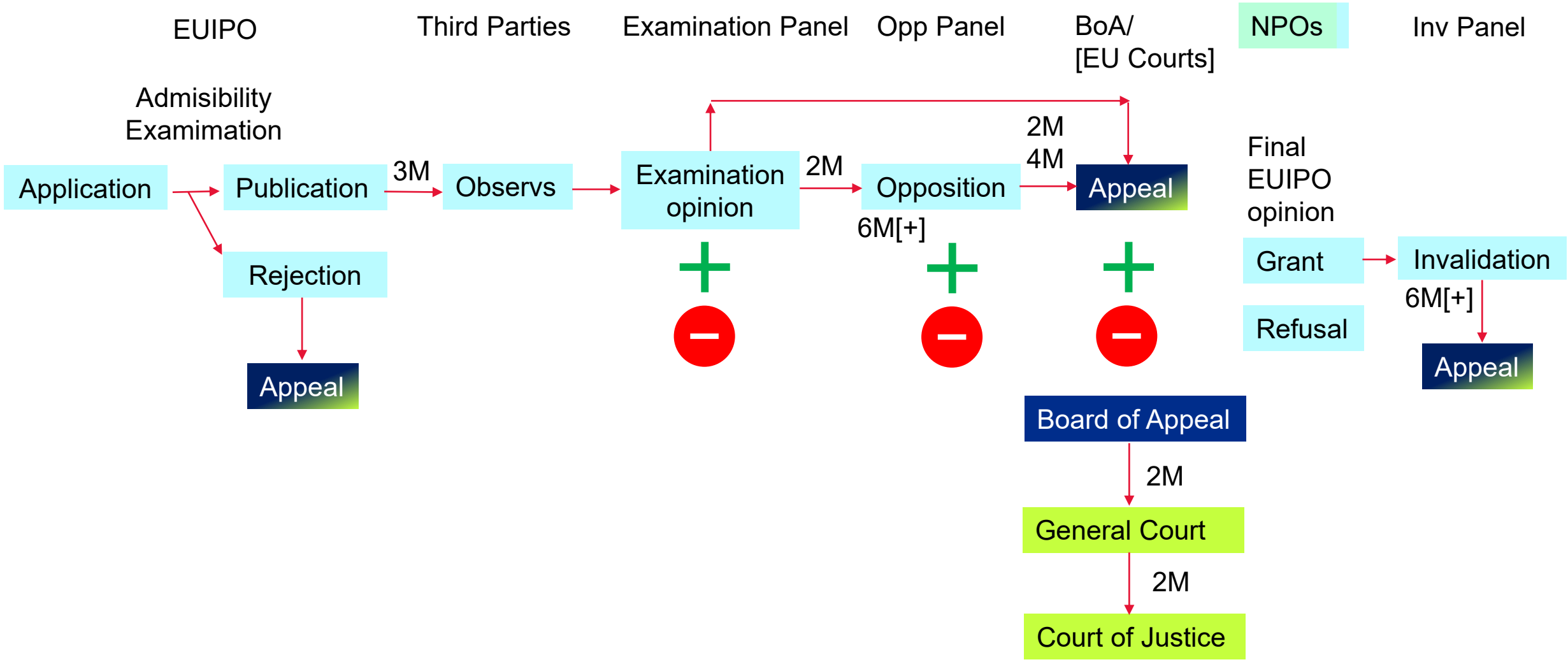
Centralised SPC application procedure



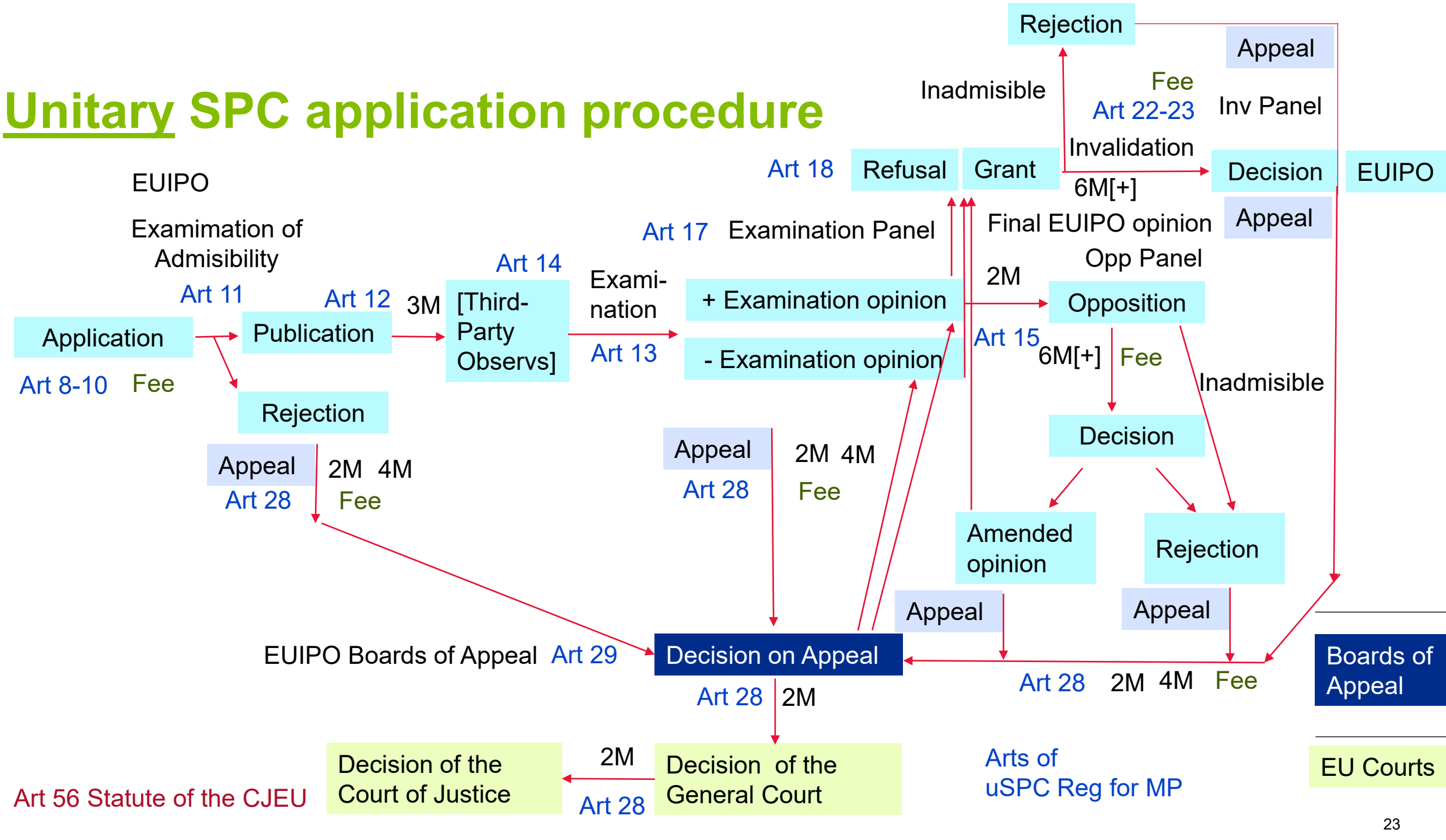
Centralised SPC application procedure



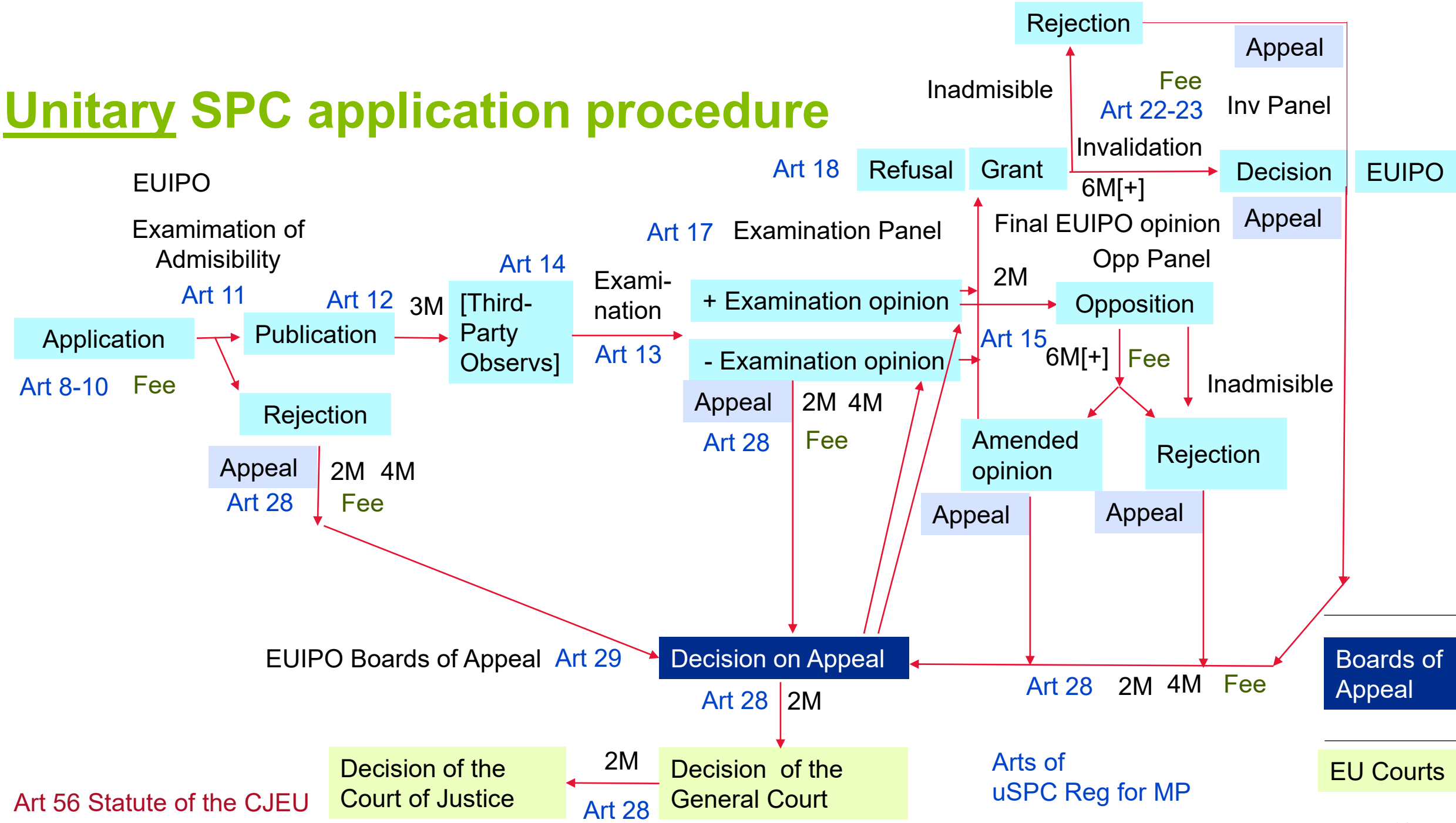
Unitary SPC application procedure



Unitary SPC application procedure



Unitary SPC application procedure



European Union Intellectual Property Office (EUIPO)

The EUIPO is named as the 'Office' in the regulations.

Tasks:

- Examination (including possible oppositions) of:
  - centralized SPC applications,
  - extensions of the duration for certificates granted through the centralised procedure (for medicinal products only)
- Examination (including possible oppositions, invalidations) and **grant**:
  - of unitary SPCs,
  - extensions of their duration (for medicinal products only).

National SPCs will be granted by National Patent Offices (NPOs) after issuance of positive examination opinion by EUIPO at the end of the centralized examination procedure. NPOs will be bound by the opinion from the EUIPO, unless certain exceptional circumstances apply (e.g., if the basic patent has meanwhile been revoked or allowed to lapse before the end if its maximum 20-year term).

The EUIPO will establish a new SPC Division and will partially rely on SPC examiners from the national patent offices.

Panels and Boards of Appeal

Supplementary Protection Certificates Division of EUIPO

Examination panels

Tasks:

- Examination of centralised application for certificates or extensions of duration
- Opposition
- Invalidations

1 member of EUIPO

2 members from 2 different NPOs

Opposition panels

No examiner that examined the centrallised application to be included

Invalidation panels

No examiner that examined the centrallised application, or intervened in related opposition or appeal proceedings to be included

Board of Appeal

3 Members, at least 2 legally qualified
2 further members can be called up
National examiners can be appointed as Members of a BoA
Members of the BoA cannot be involved in examination, opposition or invalidation panels

National examiners as Members of Boards of Appeal

National examiners can be appointed as Members of a Board of Appeal (BoA).
See uSPC Reg for MP, Explanatory Memorandum, 5. Other Elements, Detailed explanation of the specific provisions of the proposal, under 'Appeals' (also in Recast SPC Reg for MP, idem paragraph).

…The appeal would take place before the Boards of Appeal of the EUIPO. Members from the Boards of Appeal should be appointed in accordance with Article 166 (5) of Regulation 2017/1001. These members may also be national examiners, but they may not be the same examiners already involved in the examination of the centralised applications or applications for unitary certificates.

Members of the BoA cannot be involved in examination, opposition or invalidation panels. See Art 166(9) of Reg 2017/1001

> *Article 166: Independence of the members of the Boards of Appeal*
> *…9. The President of the Boards of Appeal and the chairpersons and members of the Boards of Appeal shall not be examiners or members of the Opposition Divisions, the Department in charge of the Register or Cancellation Divisions*

The inclusion of national examiners in the BoA is not explicitly mentioned in Art 27 of Recast SPC Reg for MP or equivalent Art 16 of uSPC Reg for MP entitled 'Role of competent national authorities', but is not discarded either.

Actions of third parties against national/unitary SPCs

New

- For national SPCs under the centralized procedure or for unitary SPC applications:
  - Third party observations
  - Oppositions
- For granted unitary SPCs at any time :
  - Declaration of invalidity action at the EUIPO
  - Revocation for extensions at the EUIPO

Existing

- Counterclaims for revocation (in Spanish, *acción reconvencional de nulidad*) after an infringement action is started at a national court or the UPC.
- For national SPCs: invalidity actions against SPCs at national courts (also including the UPC).
  I understand that invalidity actions at national courts are not available for unitary SPCs, which must be challenged only at the EUIPO or through a counterclaim for revocation.

Substantive changes to SPC Regulations: # of SPCs per product

Explicitly stated that the grant of more than one SPC for the same product will only be allowed if SPCs are filed by different patent holders "not economically linked".

Current situation

- Art 3.2. 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 this product may be issued to each of these holders.

According to Recital 17 of Regulation (EC) 1610/96, on SPCs for PPPs, Art 3.2 is applicable to medicinal products.

Proposal

- Art 3.3. 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**.

Art 3.3 Recast SPC Reg for MP
Idem Art 3.2 uSPC Reg for MP

Substantive changes to SPC Regulations: entitlement

An SPC shall only be granted *with the consent of the marketing authorization holder*

Current situation	Proposal
▪ No limitation	▪ Art 6.2. Notwithstanding paragraph 1, where a basic patent has been granted in respect of a product that is the subject of an authorisation held by a third party, a certificate for that product shall not be granted to the holder of the basic patent without the consent of that third party.

Art 6.2 Recast SPC Reg for MP
Art 6.2 uSPC Reg for MP

Substantive changes to SPC Regulations: recitals

New recitals have been introduced, some existing recitals have been amended or deleted.
Example: recital 14 of Recast SPC Reg for PPP also affecting medicinal products has been amended.
Amended recital 14 has also been included as recital 11 of Recast SPC Reg for MP (see also recital 9 of Recast SPC Reg for MP).

Current situation

(14) The issue of a certificate for a product consisting of an active substance does not prejudice the issue of other certificates for derivatives (salts and esters) of the substance, provided that the derivatives are the subject of patents specifically covering them.

Active substance → First SPC

Derivative of active substance protected by a specific patent → SPC for derivative

Proposal

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

Appeals against incorrect date of the first authorisation to place the product on the market in the Union

New paragraph 2 of Art 18 in Recast SPC Reg for MP

2. The decision to grant the certificate shall be open to an appeal aimed at rectifying the duration of the certificate where the date of the first authorisation to place the product on the market in the Union, contained in the application for a certificate as provided for in Article 8, is incorrect.

Third-party observations under the centralised procedure

Summary of Art 25 Recast SPC Reg for MP

1. Any person may submit observations
2. This person shall not be a party to the proceedings.
3. Submitted within 3 months after publication of the centralised application in the Register
4. in one of the official languages of the Union and state the grounds on which they are based.
5. notified to the applicant, who may comment on them within a time limit set by the Office.

Third-party observations under the centralised procedure

Art 25 Recast SPC Reg for MP/Art 14 uSPC Reg for MP

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 designated therein.
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 centralised application in the Register.
4. Any observations by a third party shall be submitted in writing 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.

Opposition against examination opinion

Summary of Art. 26 of Recast SPC Reg for MP/ Art 15 uSPC Reg for MP

- Any person may file a Notice of opposition within 2 months after the publication of the examination opinion
- Grounds: conditions of Article 3 are not fulfilled for one or more of the designated Member States.
- Fee to be paid
- Opposition panel shall not include examiners involved in the examination panel
- The opposition panel may reject the opposition as inadmissible if some formal conditions are not met
- The Office shall issue a decision on the opposition within 6 months, unless the complexity of the case requires a longer period
- Results:
    - Rejection of the opposition
    - Amended opinion

Opposition against examination opinion

Art. 26 of Recast SPC Reg for MP/ Art 15 uSPC Reg for MP

1. Within a period of 2 months following the publication of the examination opinion in respect of a centralised application, 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 designated Member States.
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 centralised 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.
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 28. However, the opposition panel shall not include any examiner previously involved in the examination panel that examined the centralised application.

Opposition against examination opinion

Art. 26 (Recast SPC Reg for MP)

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.
7. The decision to reject an opposition as inadmissible shall be communicated to the holder of the centralised application, together with a copy of the notice of opposition. 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.
8. 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. The Office shall issue a decision on the opposition within 6 months, unless the complexity of the case requires a longer period

Opposition against examination opinion

Art. 26 (Recast SPC Reg for MP)

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.
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.
12. The Commission is empowered to adopt delegated acts in accordance with Article 55 to supplement this Regulation by specifying the details of the procedure for filing and examining an opposition.

Role of competent national authorities

- EUIPO may appoint any competent national authority (NPO) as a participating office in the examination procedure. NPO shall designate one or more examiners to be involved in the examination of one or more centralised applications.
- EUIPO and NPO shall conclude an administrative agreement before that competent national authority is appointed as participating office
- EUIPO appointment of NPO for 5 years, extendible for further periods of 5 years.

Article 27: Role of competent national authorities (Recast SPC Reg for MP)

Art 27 Role of competent national authorities

Article 27 Role of competent national authorities (Recast SPC Reg for MP)

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.
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 centralised examination procedure.
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 and opposition proceedings. Each such competent national authority shall update that list in the event of a change

Examination panels

Article 28 Examination panels (Recast SPC Reg for MP)

1. The assessments under Articles 24 [Examination], 26 [Opposition] and 33 [Centralised application for an extension of the duration of certificates] shall be conducted by an examination panel including one member of the Office as well as two examiners from two different appointed NPOs.

Article 17: Examination panels (uSPC Reg for MP)

1. The assessments under Articles 13 [Examination], 15 [Opposition], 19 [Grant of extensions] and 23 [Applications for declaration of invalidity] 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.

Art 28: Examination panels

Article 28 Examination panels (Recast SPC Reg for MP)

1. The assessments under Articles 24, 26 and 33 shall be conducted by an examination panel including one member of the Office as well as two examiners as referred to in Article 27(1) from two different participating competent national authorities.
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
   (b) the respective workload of the examiners is taken into account;
   (c) no more than one examiner employed by a competent national authority making use of the exemption laid down in Article 10(5).
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.
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 56.

Appeals

Summary of Article 29 Appeals (Recast SPC Reg for MP)

- Under the centralized procedure any party to proceedings adversely affected by a decision of the Office, including the adoption of an examination opinion, may appeal the decision to the Boards of Appeal.
- Appeal period: 2 months of the date of notification of the decision
- Suspensive effect of the appeal.
- Mandatory fee
- Decisions of the Office not contested shall take effect after expiry of the appeal period
- Grounds of appeal within 4 months of the date of notification of the decision.
- If the appeal is admissible, the Boards of Appeal shall decide on the merits
- Where an appeal results in a decision which is not in line with the examination opinion the decision of the Boards may annul or alter that opinion before transmitting it to the NPOs of the designated Member States.

Art 28 of uSPC Reg for MP (similar provisions for unitary SPCs)

Appeals

Summary of Article 29 Appeals (Recast SPC Reg for MP) (Continuation)

- Any party to proceedings before the Board of Appeal adversely affected may bring an action before the General Court of the European Union against a decision of the Boards of Appeal.
- Period for action: 2 months of the date of notification of decision.
- Grounds:
  - 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 General Court shall have jurisdiction to annul or to alter the contested decision.
- The decisions of the Boards of Appeal shall take effect after the expiry of the 2 months period to take action before the General Court or, if an action has been brought before the General Court within that period, after the dismissal of such action or the dismissal of any appeal filed with the Court of Justice of the European Union against the decision of the General Court.

Art 28 of uSPC Reg for MP (similar provisions for unitary SPCs)

Art 29: Appeals

Article 29 Appeals (Recast SPC Reg for MP)

1. Any party to proceedings under this Chapter, 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 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.
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 before the Boards of Appeal of the Office results in a decision which is not in line with the examination opinion and is remitted to the Office, the decision of the Boards may annul or alter that opinion before transmitting it to the competent national authorities of the designated Member States.

Art 29: Appeals

Article 29 Appeals (Recast SPC Reg for MP)

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.

Boards of Appeal

Summary of Art 30 (Recast SPC Reg for MP)

- A Board of Appeal in matters regarding centralised applications for 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.
- In matters regarding centralised applications for certificates:
  - There shall be no Grand Board
  - Decisions taken by a single member shall not be possible.

  [options possible in EU trademarks BoA]
- 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 [on European Union trade mark].

Article 166 (5) of Regulation (EU) 2017/1001: The members of the Boards of Appeal shall be appointed by the Management Board for a term of five years. Their term of office may be extended for additional five-year periods, or until retirement age if that age is reached during the new term of office after a prior positive evaluation of their performance by the Management Board, and after consulting the President of the Boards of Appeal.

Art 30: Boards of Appeal

(Recast SPC Reg for MP)

1. In addition to the powers conferred upon it by Article 165 of Regulation (EU) 2017/1001 [on the European Union trade mark], 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 29(1).
2. A Board of Appeal in matters regarding centralised applications for 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 referenced in Article 165 (2), (3) and 4, as well as Article 167 (2) of Regulation (EU) 2017/1001 in matters regarding centralised applications for 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 centralised applications for certificates shall be appointed in accordance with Article 166 (5) of Regulation (EU) 2017/1001.

National implementation of a centralised examination opinion

EUIPO shall transmit only final decisions to the NPOs

NPOs bound by EUIPO examination opinions.
NPOs shall grant SPC where there is a positive opinión from the EUIPO unless
material circumstances in that Member State have changed since the filing of the centralised application due to:

- Lapse of the basic patent before its lawful term expires;
- Revocation or limitation of the basic patent to the extent that the product would no longer be protected,
- after the basic patent has expired, grounds for revocation exist which would have justified such revocation or limitation
- product covered by the certificate may no longer be placed on the market following the withdrawal of the authorization

NPOs shall issue a rejection decision if a negative examination opinion has been issued for one or more designated Member State

Legal basis: Art 32 of Recast SPC Reg for MP

Art 32: National implementation of a centralised exam. op.

Recast SPC Reg for MP

1. When a decision is final (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 NPOs of each designated Member State.
2. Positive examination opinion issued for one or more designated Member State => NPOs shall grant a certificate.
3. By way of derogation from the above paragraph 2, a Member State may decide not to grant a certificate, where material circumstances, in that Member State, have changed since the filing of the centralised application in respect of one or more of the conditions laid down in Article 15(1), points

   (b) [the basic patent has lapsed before its lawful term expires] or

   (c) [the basic patent is revoked or limited to the extent that the product for which the 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.],

   or Article 14, first paragraph, point

   (d) [if and as long as the product covered by the certificate may no longer be placed on the market following the withdrawal of the appropriate authorisation or authorisations to place on the market in accordance with Directive 2001/83/EC or Regulation (EU) 2019/6.]. In such a case that Member State shall reject the application insofar as that Member State is concerned.

Art 32: National implementation of a centralised exam. op.

Recast SPC Reg for MP

Comment: The wording of point 3 of Art 32 does not consider that the Office might have made a mistake in assessing that the basic patent was lapsed or revoked, for instance, because it is limited by: 'where material circumstances, in that Member State, have changed since the filing of the centralised application'.

4. A certificate granted by a competent national authority under this Article shall be subject to Articles 4, 5, 11 and 12 to 19, and to the applicable national legislation.

Art 4: Scope of the Certificate
Art 5 Effects of the certificate (incl. SPC manufacturing waiver)
Art 11 Publication
Art 12 Fees
Art 19 Procedure (in the absence of procedural provisions in this Reg, that of natl. law for patents shall apply, unless there are specific procedures for SPCs, except for oppositions)

5. Where a negative examination opinion has been issued for one or more designated Member State, the competent national authority of each of those Member States shall issue a rejection decision according to its applicable national rules and procedures.

Centralised application for an extension of the duration of certificates

Only available for SPCs granted under the centralised procedure for medicinal products.

Application is:

- examined for admissibility,
- published (if admissible),
- subject to third party observations,
- examined by an examination panel issuing an examination opinion and
- granted by
  - the NPO if the extension is for a national SPCs after a positive examination or refused,
  - the EUIPO if the extension is for a unitary SPC

Legal bases: Articles **33**, 10 (examination/grant), 22 (admissibility), 23 (publication), 28 (examination panel), 35.2(m) (examination opinion included in the Register), 40 (adopting examination opinions) and Recital 41 (positive opinion by Examination Panel and grant by NPOs) of the Recast SPC Reg for MP.
Article 19 uSPC Reg for MP.

Art 33: Centralised application for an extension of the duration of certificates

Article 33 (Recast SPC Reg for MP)

1. Where certificates for a given medicinal product have been granted through the centralised procedure, their holder may request an extension of the duration of those certificates by filing a centralised application for an extension of the duration of those certificates with the Office. That centralised application shall specify the designation of the Member States for which the extension is requested.
2. …

3. Articles 10, 11 and 17 shall apply, whereby references to 'the authority referred to in Article 9(1)' shall be understood as references to the Office.
4. Third parties may also submit observations in respect of a centralised application for an extension of the duration of certificates.

Centralised extension only available for SPCs granted under the centralised procedure

Articles 10 [grant of Certificate], 11 [Publication] and 17 [Notification of lapse or invalidity].
'The authority referred to in Article 9(1)' (NPO) understood as EUIPO.
Probably a mistake as NPOs should grant the extension, not EUIPO.

Third party observations are foreseen.

Centralised application for an extension of the duration of certificates

[I understand that no oppositions are available against positive decisions on extensions. While third party observations are mentioned in Art. 33, oppositions are not. Grounds for oppositions are that Article 3 is not met and this article refers to the conditions for grant of SPCs, not extensions. Art 26 mentions oppositions for 'centralised application' and not 'application for an extension of the duration of certificates', while both are mentioned in Art 23].

[It is unclear to me if the national extensions are granted by the NPOs (as stated in Recital 41) or by the Office (EUIPO), according to Art 10, where the authority according to Art 9.1 (the NPO) is substituted by the Office according to Art 33.3. By analogy to centralised SPC application they should be granted by NPOs. Extensions of unitary SPCs are granted by the EUIPO]

Legal bases: Articles **33**, 10 (examination/grant), 22 (admissibility), 23 (publication), 28 (examination panel), 35.2(m) (examination opinion included in the Register), 40 (adopting examination opinions) and Recital 41 (positive opinion by Examination Panel and grant by NPOs) of the Recast SPC Reg for MP.
Article 19 uSPC Reg for MP.

Fees

Actions of the centralised application procedure associated with fees

- Applications: centralised applications for certificates or for their extensions of duration
- Appeals
- Oppositions
- Applications for unitary SPCs or for their extensions of duration
- Applications for a declaration of invalidity and for conversions of unitary SPCs
- Annual maintenance fees of unitary SPCs
- SPC manufacturing waiver notifications to the EUIPO for unitary SPCs

Obviously, NPOs fees also apply to national certificates granted under the centralised procedure.

Art 34 Recast SPC Reg for MP
Art 30 uSPC Reg for MP

Register and Database

The EUIPO shall keep

- an electronic Register on the status of all published centralised applications and their centralised extensions of the duration and unitary certificates, its published applications and extensions; and
- a Database to store all the particulars provided by applicants or any other third party observations.

The Register and Database are common for medicinal products and for plant protection products.

The Register is available in all official languages of the Union.

Art 35 and 36 Recast SPC Reg for MP
Art 35 and 36 uSPC Reg for MP

Representation

Actor/situation	Representation for centralised procedures
Companies (or individuals) OUT of the European Economic Area	Required (except for filing of a centralised application)
Companies (or individuals) IN the European Economic Area	An employee can act as a representative of his/her company and also for other economically linked entities (in or out of the EEA)
More than one applicant/third party	Common representative required
'Universal' representatives	Lawyers and patent attorneys* established in the EU

*Professional representative in patent matters before a NPO or the EPO (national/European Patent attorneys) or lawyers authorised to practise before the courts or tribunals of a Member State

Legal bases: Art 38 Recast SPC Reg for medicinal products
Art 38 uSPC Reg for medicinal products

Art 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 Chapter III of this Regulation, other than the filing of a centralised application.
2. Natural or legal persons having their domicile or principal place of business or a real and effective industrial or commercial establishment in the European Economic Area 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.

Art 38 Recast SPC Reg for medicinal products and Art 38 uSPC Reg for medicinal products

Languages

Regarding SPCs the EUIPO will accept documents in any of the official languages of the Union.

[What would happen in an opposition where parties use different languages? Would the Office translate documents of the parties? Which language will be used in oral proceedings by the Office?]

Languages

1. All documents and information sent to the Office in respect of the procedures under this Regulation shall be in one of the official languages of the Union.
2. For the tasks conferred on the Office under this Regulation, the languages of the Office shall be all the official languages of the Union in accordance with Council Regulation No 1.

Council Regulation No 1

…Art 2

Documents which a Member State or a person subject to the jurisdiction of a Member State sends to institutions of the Community may be drafted in any one of the official languages selected by the sender. The reply shall be drafted in the same language.

Article 3

Documents which an institution of the Community sends to a Member State or to a person subject to the jurisdiction of a Member State shall be drafted in the language of such State.

…

Article 8

If a Member State has more than one official language, the language to be used shall, at the request of such State, be governed by the general rules of its law…

[What would happen in an opposition of parties using different languages? Would the Office translate documents of the parties? Which language will be used in oral proceedings by the Office?]

Legal bases: Article 41 SPC Recast Reg and Art 33 uSPC Reg

Oral proceedings

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.

Not public	Public
Oral proceedings before: ▪ an examination panel, ▪ an opposition panel or ▪ invalidity panel for unitary SPCs.	Oral proceedings before the Boards of Appeal unless the Boards decide that admission of the public could have serious and unjustified disadvantages, in particular for a party to the proceedings.

At oral proceedings the decision may be given orally.
Subsequently, the decision or opinion shall be notified in writing to the parties.

Art 43 and **44** Recast SPC Reg for MP
Art **41** uSPC Reg for MP

Costs

The winner takes it all…

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 winner and
- all costs incurred essential to the proceedings, including travel and subsistence and the remuneration of a representative…

Costs

The winner takes it all…

Art 48 uSPC Reg for MP

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. …

Art 51 Recast SPC Reg for MP
Art 48 uSPC Reg for MP

Intention of the reform: not to alter the substantive features of the existing SPC regime

Recast SPC Reg for MP: At the Explanatory Memorandum, 3. Results of ex-post evaluations, stakeholder consultations and impact assessments, Under: 'Fundamental rights'

This proposal will have no impact on fundamental rights, especially since it is not proposed to alter the substantive features of the existing SPC regimes (e.g. conditions for grant, scope, effects).

Intention of the reform: not to alter the substantive features of the existing SPC regime

Recast SPC Reg for MP: At the Explanatory Memorandum, 5. Other Elements, Detailed explanation of the specific provisions of the proposal, Under: 'Substantive features of the SPC regime'

This reform does not intend to modify, nor further clarify in view of the relevant case law of the Court of Justice, the substantive features currently laid down in Regulation (EC) No 469/2009 for the existing national SPC regimes or the new centralised procedure, since:

- the case law on SPCs is progressively converging, and steadily reducing uncertainty about the interpretation of the SPC regime, while further amendments might trigger new fluctuations and uncertainty as regards the proper interpretation of the amended rules;
- respondents to the Allensbach survey did not call for Article 3 of the SPC Regulations to be amended (question 48) even if they consider that the case law is unclear in some respects (question 46).

Intention of the reform: new recitals incorporate case law of the CJEU

Recast SPC Reg for MP: At the Explanatory Memorandum, 5. Other Elements, Detailed explanation of the specific provisions of the proposal, Under: New recitals

It was noted that there were no relevant recitals in Regulation (EC) No 469/2009 that could assist in interpretation of Article 3. Accordingly, certain recitals concern the conditions in Article 3 for the grant of SPCs, and incorporate the case law of the Court of Justice. The aim is to ensure consistency. In particular the judgements in cases C-121/17 and C-673/18 interpret Article 3(a) and 3(d) of Regulation (EC)No 469/2009, respectively, and should be considered settled case law. This is also the case for judgement C-471/14, whereby the date of the first marketing authorisation in the Union, within the meaning of Article 13, is the date on which notification of the decision granting the authorisation was given to the addressee of the decision.

Note: C-121/17: Teva vs Gilead on Truvada® (a combination of tenofovir disoproxil and emtricitabine).
Article 3(a) of the current SPC Regulation for medicinal products was discussed: an SPC may be granted if the authorised active ingredient or combination of active ingredients is “protected” by a patent.

C-673/18: Santen on a ciclosporin eye drop emulsion for the treatment of a type of severe keratitis
Article 3(d) of the current SPC Regulation for medicinal products was discussed: the authorization must be the first to place the product on the market as a medicinal product.

Intention of the reform: keep one certificate per product

Recast SPC Reg for MP. COM(2023) 231 final: At the Explanatory Memorandum, 5. Other Elements, Detailed explanation of the specific provisions of the proposal, Under: New recitals

Many general objectives set out in the Explanatory Memorandum of the proposal (COM(90)101) for what became Council Regulation 1768/92/EEC, i.e. the predecessor of Regulation (EC) No 469/2009, remain fully relevant today and should continue to be used as a guide to interpretation, where relevant. This includes the objective that *only one certificate may be granted for any one product, a product being understood to mean an active substance in the strict sense. Minor changes to the medicinal product such as a new dose, the use of a different salt or ester or a different pharmaceutical form will not lead to the issue of a new certificate*.

As regards the rights conferred by a certificate, and in line with the earlier statements regarding derivatives, it could be appropriate to consider that the protection conferred by a certificate on a product extends to the therapeutically equivalent derivatives of the product.

Intention of the reform: close national route when the conditions of centralized procedure are met

Recast SPC Reg for MP. COM(2023) 231 final: At the Explanatory Memorandum, 5. Other Elements, Detailed explanation of the specific provisions of the proposal, under: Basic patent

In those situations where a centralised application could be filed, namely where the basic patent is a European patent and the marketing authorisation is a centralised one, the choice could have been made to also allow applicants to file national SPC applications. Based on the findings of the evaluation completed in 2020, which revealed discrepancies between the granting practices of various national offices, this might have resulted, however, in applicants applying for certificates in Member States with less strict examination standards, to avoid filing a centralised application that may be rejected due to a stricter examination. Such a situation would be detrimental to consistency and legal certainty, could promote forum shopping, and would result in a higher total workload across the EU from examining applications. To avoid these drawbacks, it is considered preferable to examine applications under the centralised procedure in all cases where the conditions for using this procedure are met. Accordingly, this proposal requires that a national SPC application, filed in a Member State, be rejected where the requirements for filing a centralised application are fulfilled (‘closing of the national route’).

Intention of the reform: close the centralized procedure for national MAs

Recast SPC Reg for MP. COM(2023) 231 final: At the Explanatory Memorandum, 5. Other Elements, Detailed explanation of the specific provisions of the proposal, under: Marketing authorisations concerned

A centralised SPC application based on national marketing authorisations, such as those granted under the decentralised or mutual recognition procedures, would have significant drawbacks. These would include a bigger examination workload, potential differences between the various national marketing authorisations granted for the product concerned in different Member States, including language issues.

Some relevant recitals

Recast SPC Reg for MP

(8) 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 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 is specifically identifiable in the light of all the information disclosed by that patent.

(9) 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.

Some relevant recitals

Recast SPC Reg for MP

(11) To ensure balanced protection, however, a certificate should entitle its holder to prevent a third party from manufacturing not only the product identified in the 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 certificate. There is therefore a need to consider that the protection conferred by the certificate extends to such equivalent derivatives, within the limits of the protection conferred by the basic patent.

(12) 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.

=> Recital 12 incorporated in Article 3.3 and Art 6.2 of Recast SPC Reg for MP (and Art 3.2 and 6.2 of uSPC Reg for MP)

Some relevant recitals

Recast SPC Reg for MP

(13) 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 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.

(14) In order to ensure maximum flexibility and not unduly discriminate between holders of different types of patents, there should be no limitation on the type of patent on which a national certificate can be applied for before a competent national authority. Therefore, this should continue to be possible on the basis of a national patent or of a European patent and, in particular, this should also be possible in respect of a European patent with unitary effect (‘unitary patent’).

Some relevant recitals

Recast SPC Reg for MP

(16) All the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector should nevertheless be taken into account. For that purpose, it should not be possible to grant a certificate for a period exceeding 5 years. The protection granted should furthermore be strictly confined to the product which obtained authorisation to be placed on the Union market as a medicinal product. In addition, the timely entry of generics and biosimilars into the Union market is also important, particularly in order to increase competition, to reduce prices and to ensure that national healthcare systems are sustainable and that patients in the Union have better access to affordable medicines.

(19) There is a centralised procedure for granting European patents, as well as a centralised procedure for obtaining marketing authorisations for medicinal products. In addition, the 'unitary patent' as laid down in Regulation (EU) No 1257/2012 of the European Parliament and of the Council is to enter into force in June 2023 in respect of the Member States having ratified the Agreement on a Unified Patent Court ('UPC').

(20) Therefore, it is necessary to complement the existing national procedures for the grant of certificates for medicinal products with a centralised procedure. That procedure should make it possible, where the basic patent is a European patent, including a unitary patent, to request the grant of national certificates for two or more designated Member States through the filing and examination of a single 'centralised' application. Following the grant of certificates under the centralised procedure, those certificates should be equivalent to the certificates granted under national procedures and be subject to the same rules.

Some relevant recitals

Recast SPC Reg for MP

(23) The centralised procedure should apply only to a medicinal product that is based on a centralised marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council or Regulation (EU) No 2019/6 of the European Parliament and of the Council [for veterinary products]. These authorisations refer to human medicinal and veterinary medicinal products respectively. Such an authorisation, unlike national authorisations, relates to the same medicinal product throughout the Union, and will facilitate the examination of centralised applications.

(40) Any person may challenge the validity of a certificate granted following the centralised procedure before a competent court of a Member State, which includes the Unified Patent Court where the conditions are met.

Some relevant recitals

Recast SPC Reg for MP
SPC Manufacturing Waiver

(42) In 2019, the Union introduced an exception in Regulation (EU) 2019/933 of the European Parliament and of the Council from the protection granted to holders of supplementary protection certificates for medicinal products. It noted the absence of any exception to the protection conferred by the certificate has had the unintended consequence of preventing makers of generics and biosimilars established in the Union from making generics and biosimilars in the Union, even for the purpose of export to third country markets in which protection does not exist or has expired or for the purpose of storing with a view to day-one placement on the Union market entry. Those circumstances put makers of generics and biosimilars established in the Union at a significant competitive disadvantage in comparison with makers based in third countries that offer less or no protection. The reasons for the introduction for the waiver and the conditions for its application remain applicable at the present time.

Algunos de los considerandos del Reglamento del *SPC Manufacturing Waiver* se han eliminado o modificado

03

Unitary SPCs

Articles, recitals and parts of the Explanatory Memorandum cited are from the uSPC Reg for MP

Central invalidation or counterclaim for invalidation before the courts

uSPC Reg for MP
COM(2023) 222 final, Explanatory Memorandum, 3. Results of ex-post evaluations, stakeholder consultations and impact assessments, under: 'Fundamental rights'.

After a unitary SPC is granted by the Office, third parties will also be able to challenge its validity before the Office. Counterclaims for a declaration of invalidity could be raised in the competent court of a Member State.

Also:
COM(2023) 222 final, Explanatory Memorandum, 5. OTHER ELEMENTS, Detailed explanation of the specific provisions of the proposal, Examination procedure and remedies

After the grant of a unitary SPCs, third parties will be able to initiate invalidity proceedings (actions for a declaration of invalidity) before the Office. Here as well, related decisions may be appealed to the Boards of Appeal, and may end up before the General Court.

Counterclaims for a declaration of invalidity could be raised in the competent court of a Member State (including the Unified Patent Court where the applicable conditions are met, subject to a suitable amendment of the UPCA).

Litigation at national courts and the UPC

uSPC Reg for MP

COM(2023) 222 final, Explanatory Memorandum, 5. OTHER ELEMENTS, Detailed explanation of the specific provisions of the proposal, Examination procedure and remedies

Litigation

It is intended that a unitary SPC will be able to be litigated before the body responsible under national law for the revocation of the corresponding basic patent. It is expected that the definition of SPCs present in the UPCA will be amended to include unitary SPCs as well. Such amendment may be based on Article 87(2) of the UPCA.

Reasons for the existence of Unitary SPCs and the maintenance of the national route

uSPC Reg for MP

Recital 6

(6) In the absence of a unitary certificate, a unitary patent could only be extended by applying for several national certificates in each Member State where protection is sought, preventing the holder of a unitary patent from obtaining unitary protection during the whole combined protection period conferred by that unitary patent and subsequently by these certificates. Therefore, a unitary certificate for medicinal products should be created, that would allow a unitary patent to be extended in a unitary manner. Such a unitary certificate should be applied for on the basis of a unitary basic patent and a centralised authorisation; it would have the same legal effects as national certificates in all Member States in which that basic patent has unitary effect. The main feature of such a unitary certificate should be its unitary character.

…

(9) Considering that products authorised under procedures other than the centralised one should still be able to enjoy supplementary protection, and that certain Member States have not yet joined the unitary patent system, certificates granted by national patent offices should remain available.

Double national and unitary SPC not allowed

uSPC Reg for MP

Recitals

(15) In such an event, double protection by both a unitary certificate and a national certificate – whether obtained on the basis of a national application or of a centralised application – should be excluded in any Member State.

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 the examination opinion by granting a unitary certificate or rejecting the application, as applicable.

Art 1: Subject matter

uSPC Reg for MP

This Regulation lays down rules on the unitary supplementary protection certificate ('unitary certificate') for medicinal products protected by a European patent with unitary effect and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure as laid down in Regulation (EC) No 726/2004, or Regulation (EU) 2019/6.

Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency:
It regulates the approval of human medicinal products by a centralized procedure only.

REGULATION (EU) 2019/6 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC:

It regulates both the approval of veterinary medicinal products by a centralized procedure or by national procedures (purely national, decentralized or mutual recognition procedures)!

Art 3: Conditions for obtaining a unitary certificate

uSPC Reg for MP

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 Regulation (EU) 2019/6 [veterinary medicinal product], or with the centralised procedure under Regulation (EC) No 726/2004 [medicinal product for humans];

(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.

Unitary certificate => unitary patent + MA for veterinary products (centrally approved only?) OR centralized MA for medicinal products for humans

Art 3 should specify that the MA for the veterinary medicinal product should be centralized:
'the product on the market as a medicinal product has been granted **with the centralised procedure** in accordance with Regulation (EU) 2019/6 or in accordance with Regulation (EC) No 726/2004. See recital 13.

Centralized Marketing Authorisation

uSPC Reg for MP. Recital 13.

(13) A unitary certificate for a medicinal product should be based only on a centralised marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council or Regulation (EU) 2019/6 of the European Parliament and of the Council only. These authorisations refer to human medicinal and veterinary medicinal products respectively. Such an authorisation, unlike national authorisations, relates to the same medicinal product throughout the Union, and this would thus facilitate the examination of applications for unitary certificates.

SPC Manufacturing Waiver Notifications

When the SPC is unitary, in addition to the NPOs, the EUIPO must also receive the same notifications which are subject to fees.

Art 5: SPC Manufacturing Waiver

When the SPC is unitary, in addition to the NPOs, the EUIPO must also receive the same notification which are subject to fees

uSPC Reg for MP

Art. 5.3
(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

(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;

Art. 31.4
The notifications referred to in Article 5(3), points (b) and (c), shall be subject to the payment of a fee to the Office.

Triggering event for requesting a uSPC if the MA is already granted

uSPC Reg for MP

If the MA is already granted, the triggering event for requesting a uSPC is ‘the date on which unitary effect is attributed to the basic patent’, not the date of the grant of the patent!

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.

Art 13: Examination of the application for a unitary certificate…

uSPC Reg for MP

…Office shall issue a reasoned positive examination opinion in respect of the grant of a unitary certificate. OR reasoned negative examination opinion on the grant of a unitary certificate

Comment: As the SPC is unitary there cannot be a positive opinion for some states and a negative opinion for others as in the centralized application procedure.

Duration of unitary SPCs

uSPC Reg for MP

COM(2023) 222 final, Explanatory Memorandum, 5. OTHER ELEMENTS, Detailed explanation of the specific provisions of the proposal, under ‘Substantive features of the SPC regime’, last sentence:

…That being said, considering that there are national discrepancies in the interpretation of the rule defining the duration of a European patents, which may result in a one-day difference, there is a need to clarify that rule insofar as its application to unitary SPCs is concerned.

Duration of [unitary] SPCs

uSPC Reg for MP
Recitals 10 and 11

(10) To avoid discrimination between applicants for certificates under Regulation [COM(2023) 231] [Recast SPC Reg for MP granting national SPCs] and for unitary certificates under this Regulation, and distortions of the internal market, the same substantive rules should apply, with appropriate adaptations, to certificates under Regulation [COM(2023) 231] and to unitary certificates, in particular as regards the conditions for grant of a certificate, as well as the duration and effects of a certificate.

(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.

Duration of unitary SPCs

Article 20: Duration of the unitary certificate (uSPC Reg for MP)

1. The unitary certificate shall take effect at the end of the lawful term of the basic patent, namely on the twentieth anniversary of the filing date of the application for that patent, for a period equal to the period which elapsed between the date on which the application for the basic patent was lodged and the date of the first authorisation to place the product on the market in the Union, reduced by a period of 5 years.
2. The duration of the unitary certificate may not exceed 5 years from the date on which it takes effect.
3. The periods laid down in paragraphs 1 and 2 shall be extended by 6 months in the case where Article 36 of Regulation (EC) No 1901/2006 applies. In that case, the duration of the period laid down in paragraph 1 of this Article may be extended only once.

Despite the intention to unify duration for uSPCs and national SPCs expressed at recitals 10 and 11 of uSPC Reg for MP, Article 13 of Recast SPC Reg for MP does not explicitly include 'namely on the twentieth anniversary of the filing date of the application for that patent'

Art 13: Duration of the certificate (Recast SPC Reg for MP)

1. The certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorisation to place the product on the market…

Art 24: Counterclaim for the invalidity of a certificate

uSPC Reg for MP

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.

…

4. … 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.

…

Art 22

(a) certificate granted contrary to A3;
(b) basic patent lapsed before term;
(c) basic patent revoked or limited so that the product would no longer be protected…

Counterclaim in the court not a second opportunity after final decision at the Office.

Stay of counterclaim in the court if there is a previous ongoing invalidation at the Office.

Art 24: Counterclaim for the invalidity of a certificate

uSPC Reg for MP

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.

Upon request by the holder of the certificate the court may:

- stay the proceedings and
- request the defendant to submit an application for a declaration of invalidity to the Office.

Art 25: Revocation of an extension of the duration of a unitary certificate for a medicinal product

uSPC Reg for MP
1. The Office may revoke an extension of the duration if it was granted contrary to Article 36 of Regulation (EC) No 1901/2006.
2. Any person may submit an application for revocation of the extension of the duration to the Office.

Ataques:
- uSPC: Declaration for revocation of the extension of the duration at the Office or counterclaim for invalidity at the courts

Conversion when the unitary effect of the basic patent is revoked

Conversion

Application for a unitary certificate	→	Centralised application for [national] certificates
Granted unitary certificate	→	National certificates

Legal Basis: Art 27 uSPC Reg

Art 27: Conversion

uSPC Reg for MP

1. Where the unitary effect of the basic patent is revoked while the application for a unitary certificate is still pending, the holder of that application may, subject to a fee, request the conversion of that application into a centralised application for certificates.
2. Where the unitary effect of the basic patent is revoked after the unitary certificate has been granted, the holder of that certificate may, subject to a fee, request the conversion of that unitary certificate into national certificates.
3. A request for conversion may be filed with the Office within 3 months after notification of the revocation of the unitary effect of the basic patent.
4. A request for conversion, as well as its outcome, shall be published in the Register.
5. The Office shall check whether the conversion requested fulfils the conditions set out in this Article, together with the formal conditions specified in the implementing act adopted pursuant to paragraph 8. If the conditions governing the request are not fulfilled, the Office shall notify the applicant of the deficiencies. If the deficiencies are not remedied within a period to be specified by the Office, the Office shall reject the request for conversion. Where the conversion fee has not been paid within the relevant period of 3 months, the Office shall inform the applicant that the request for conversion is deemed not to have been filed.

Art 27: Conversion

uSPC Reg for MP

6. Where a request under paragraph 1 complies with paragraph 5, the Office shall convert the application for a unitary certificate into a centralised application for certificates designating the Member States in which the basic patent had unitary effect. In the event of a combined application, the designation of the Member States in which the basic patent had unitary effect shall be added to the designation of other Member States already included in the combined application.

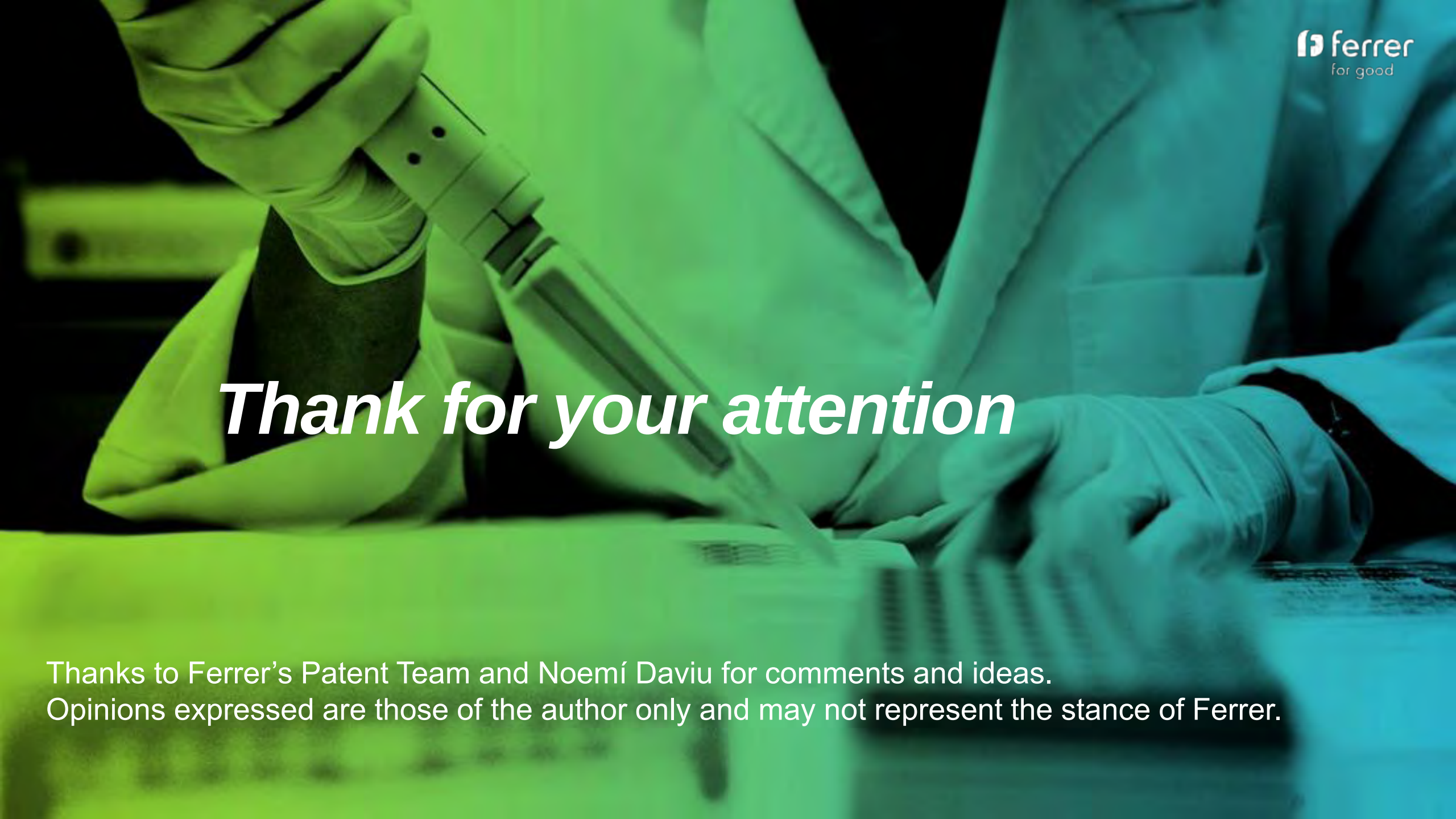
7. Where a request under paragraph 2 complies with paragraph 5, the Office shall transmit the request for conversion to the competent national authorities of each Member State in which the basic patent had unitary effect and for which the request has been found admissible. The competent national authorities shall take decisions accordingly.

8. The Commission shall adopt implementing acts specifying the details to be contained in a request for conversion of the for a unitary certificate or unitary certificate into a centralised application for certificates or national certificates. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55.

Key issues not disussed at the oral presentation

- Conditions for the use of centralised/unitary SPC applications for plant protection products, for which there is no centralised marketing authorisation procedure.
- Triggering event for requesting a unitary SPC if the marketing authorisation is already granted: the date on which unitary effect is attributed to the basic patent (not the date of grant).
- Unification of the exact duration of unitary SPCs at the EU level. What for national SPCs? Will one day differences in the expiry date cease to exist for national SPCs?
- Interactions between counterclaims for a declaration of invalidity of a unitary certificate and applications for a declaration of invalidity at the EUIPO: possible stay of the counterclaim and/or bifurcation of the counterclaim to the declaration of invalidity action.
- Alleged mistake in Article 3 of unitary SPC Reg for medicinal products on the conditions to be met for the grant of a unitary certificate regarding the approval procedure of the medicinal product.
- Conversion of unitary SPCs or its applications into national SPCs or its applications associated with the revocation of their unitary effect.
- New national appeal procedure explicitly incorporated into the Regulation ‘aimed at rectifying the duration of the certificate where the date of the first authorisation to place the product on the market in the Union, contained in the application for a certificate as provided for in Article 8, is incorrect’.

These issues are discussed in the documentation.



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Opinions expressed are those of the author only and may not represent the stance of Ferrer.