NEW

SPC

Supplementary Protection Certificate

The »new« SPC system for medicinal products

Part II – The invalidation proceedings

Previously, Vol. 2 of MAIinsight reported on the reform of the Supplementary Protection Certificate (»SPC«) system and the new SPC grant procedures[1]. The following article now sheds light on the fragmented system for SPC invalidation proceedings that may result from the currently pending proposals. We summarize and contrast current and new invalidation proceedings regarding nationally granted SPCs based on the centralized application procedure and examine the various options of attacking a granted unitary SPC.

What options will be available to third parties who wish to take action against a granted SPC in the future? As perfectly summarized by the Presidency of the Council of the European Union, *»the Commission proposals for reforming the SPC regime regarding medicinal products present a **bifurcation**, with, on the one hand, national courts including the Unified Patent Court (UPC) handling invalidity actions relating to national SPCs obtained via the new centralised procedure, and, on the other hand, the European Union Intellectual Property Office (EUIPO) and the General Court of the EU being in charge of direct invalidity actions relating to unitary SPCs«.*[2] With regard to the latter in particular, the current unitary SPC-Proposal (referred to in the following as the »uSPC-Proposal«) is very complex, as it establishes the jurisdiction of the UPC in addition to that of the EUIPO, if the legal status of the unitary SPC is challenged in infringement proceedings by means of a counterclaim.

[1] MAIinsight Vol. 2, 2025, p.16-19
[2] Cf. Note from the Presidency of the Council of the European Union of 23 May 2024 regarding the Unitary SPC

Background

In April 2023, the European Commission submitted two regulatory proposals for reforming the SPC regime regarding medicinal products[3]:

- **Proposal for a Regulation on the SPC for medicinal products (COM(2023) 231):** This proposal is a recast of EC No 469/2009 (referred to in the following as the »Recast-Proposal«). Chapters I and II mainly contain the Articles of the current Regulation including some amendments regarding substantive aspects such as third party marketing authorizations (MAs) and several SPCs for one product. Chapter III contains rules defining a centralized grant procedure and the according granting bodies.
- **Proposal for a Regulation on the unitary SPC for medicinal products (COM(2023) 222):** This proposal contains all regulations defining the procedure regarding unitary SPCs.

In February 2024, the European Parliament approved the two proposals with some amendments. Trilogue negotiations are currently ongoing regarding the design of the system of legal remedies and the designation of the authority responsible for granting unitary SPCs. If successful, these trilogue negotiations will be followed by a second reading and final adoption before the new SPC regulations can enter into force.

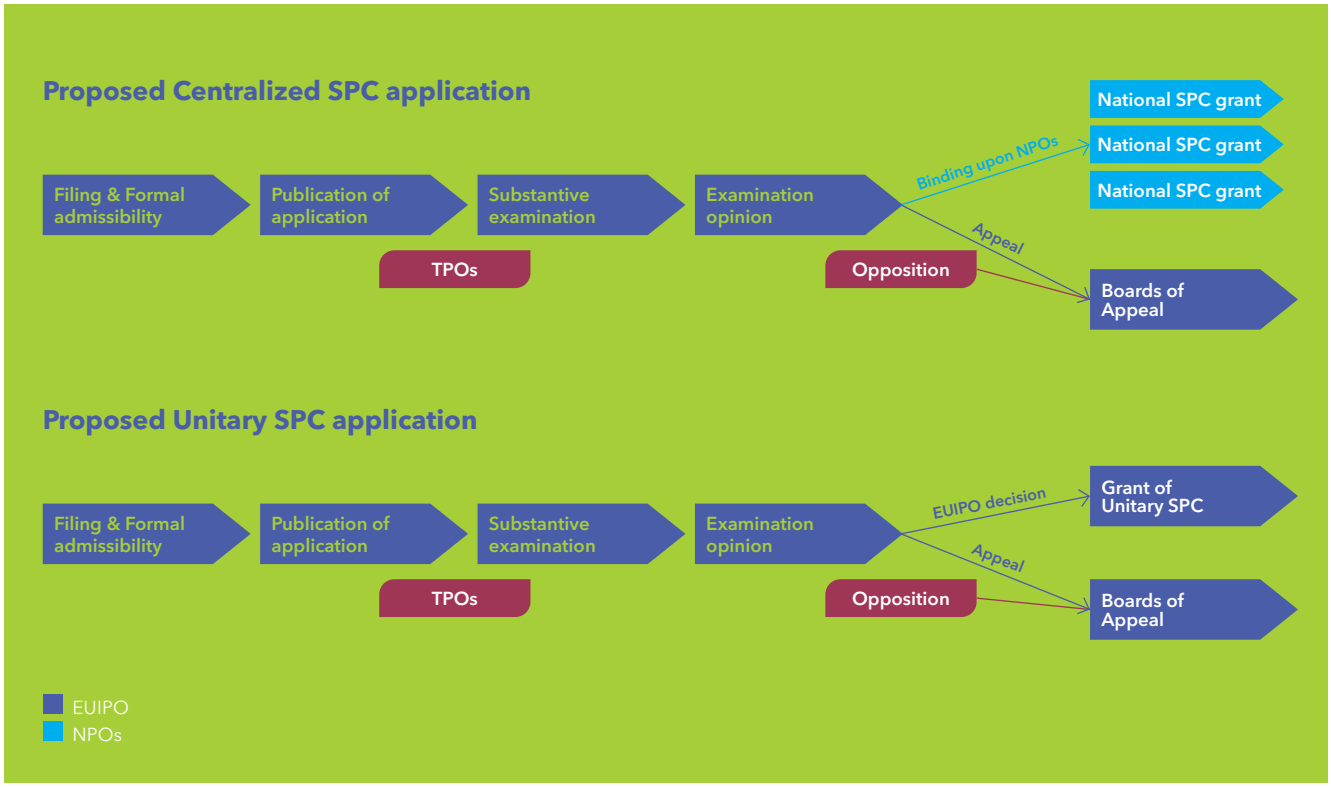
The current system for SPC invalidation proceedings

National bodies and courts

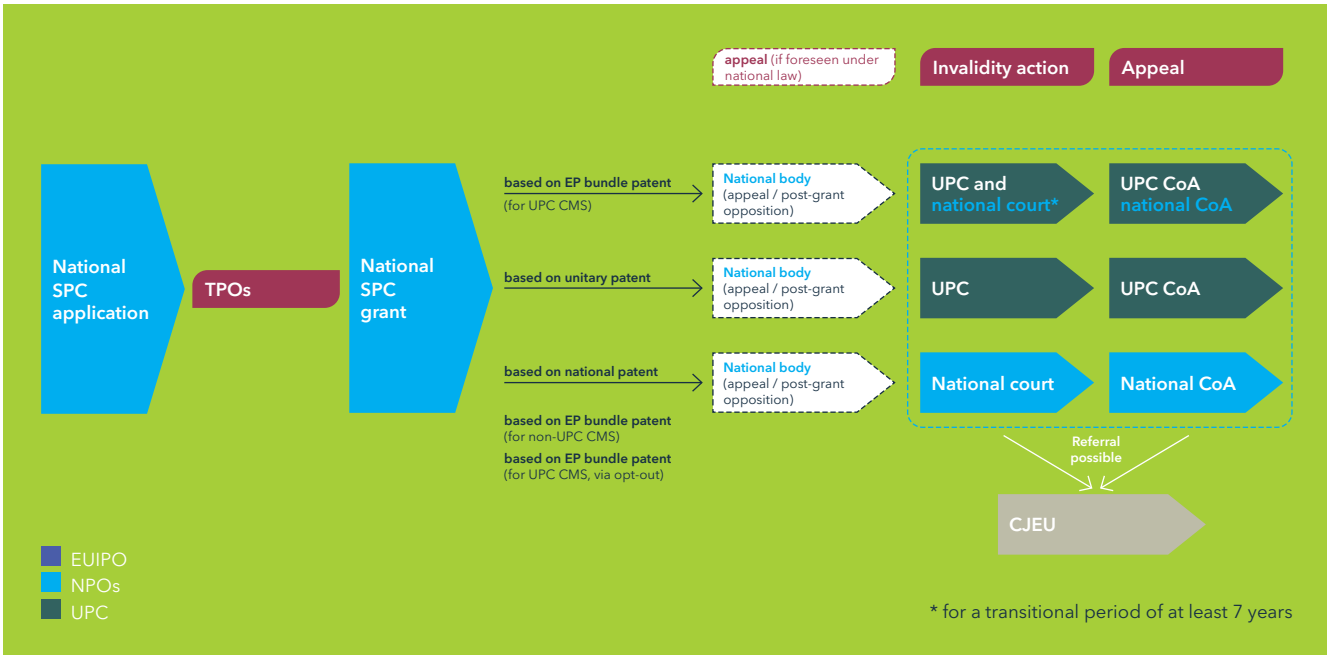
According to Art. 15(2) of current Regulation 469/2009, any person may submit an application or bring an action for a declaration of invalidity of an SPC granted by the national patent offices (NPOs) before the body responsible for the revocation of the corresponding base patent under national law. *(See figure on opposite page.)*

However, since its entry into force on 1 June 2023, the UPC Agreement (UPCA) stipulates a different jurisdiction for the currently 18 Contracting Member States of the UPCA (referred to in following as »UPC-CMS«).

Proposed Combined SPC application (recap of Part I, MAIinsight Vol. 2)



SPC-invalidation under the current system



Jurisdiction of the UPC

As a rule, SPCs granted under Regulation 469/2009[4] fall within the scope of the UPC Agreement (Art. 3(b) UPCA) and shall have the same effect as the patent (Art. 30 UPCA). Accordingly, the **exclusive** jurisdiction of the UPC covers all legal disputes regarding granted SPCs, in particular actions and counterclaims for declaration of invalidity of an SPC (Art. 32(1) lit. (d) and (e) UPCA).

› *This jurisdiction currently does **not** cover appeals against national decisions granting or rejecting national SPCs and would not seem to cover unitary SPCs once such rights are established in EU law.*

Thus, since 1 June 2023, the UPC has generally held the exclusive jurisdiction over decisions regarding the validity of SPCs based on a European patent. During the transitional period, however, national courts may also be seized instead of the UPC (Art. 83(1) UPCA).

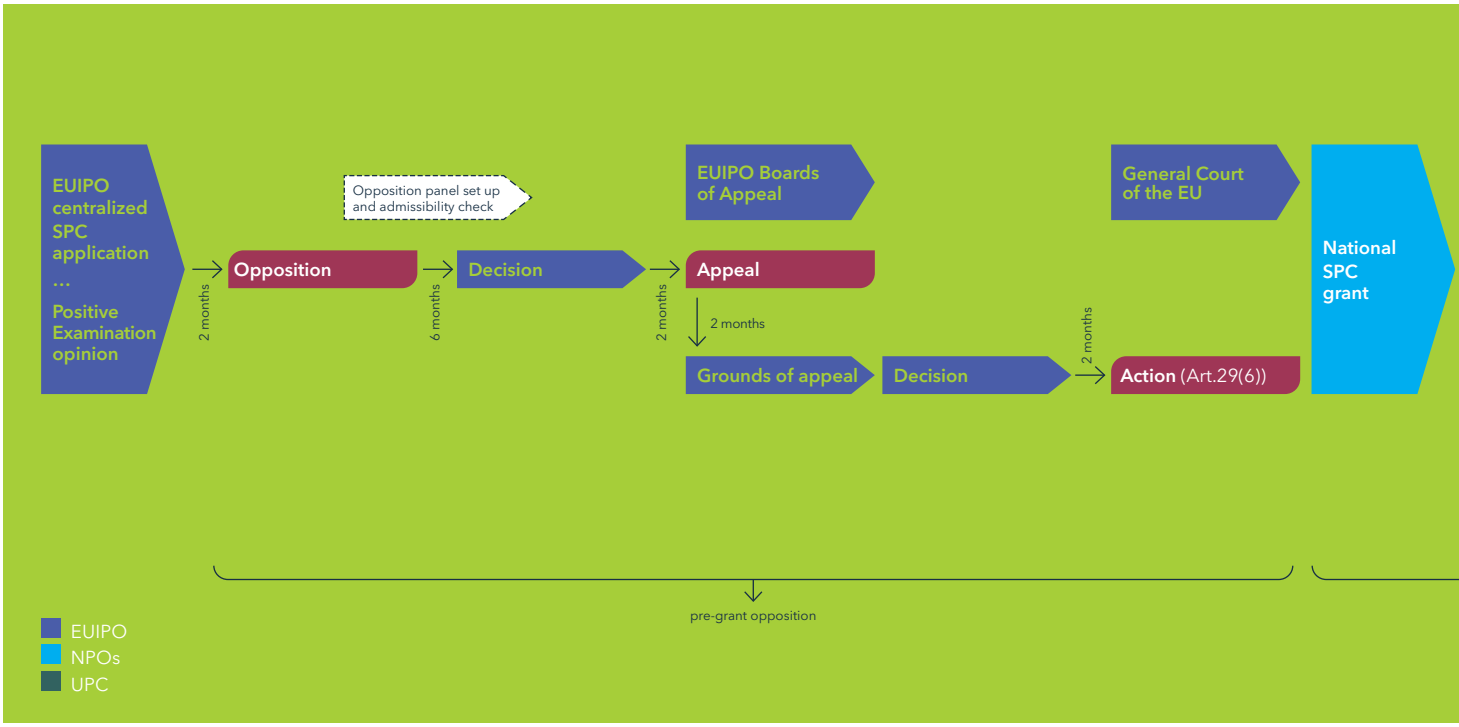
For SPCs, just as for patents, the only possibility to avoid the jurisdiction of the UPC and to have the SPC based on a European patent assessed solely by the national courts is to opt out the base (European) patent from the exclusive jurisdiction of the UPC (Art. 83(3) UPCA).

› *In this regard, it is to be noted that the SPC and the base (European) patent **cannot be opted out independently from one another**. The application to opt out the European patent **automatically extends to any SPC** whether already granted or granted subsequently (Rule 5.2 RoP). The same applies to the withdrawal of an opt-out (»opt-in«). It is not possible to opt-out SPCs based on a unitary patent (Rule 5.2(d) RoP).*

(See figure on following page.)

[3] In parallel, two regulatory proposals regarding SPCs for plant protection products were submitted.
[4] Or under Regulation 1610/96 concerning the creation of a supplementary protection certificate for plant protection products (OJ L 198, 8.8.1996, p. 30), including any subsequent amendments.

SPC invalidation under the proposed new centralized system



SPC invalidation under the proposed new centralized system

The proposed centralized application procedure would result in the grant of national certificates by NPOs.

Pre-grant opposition

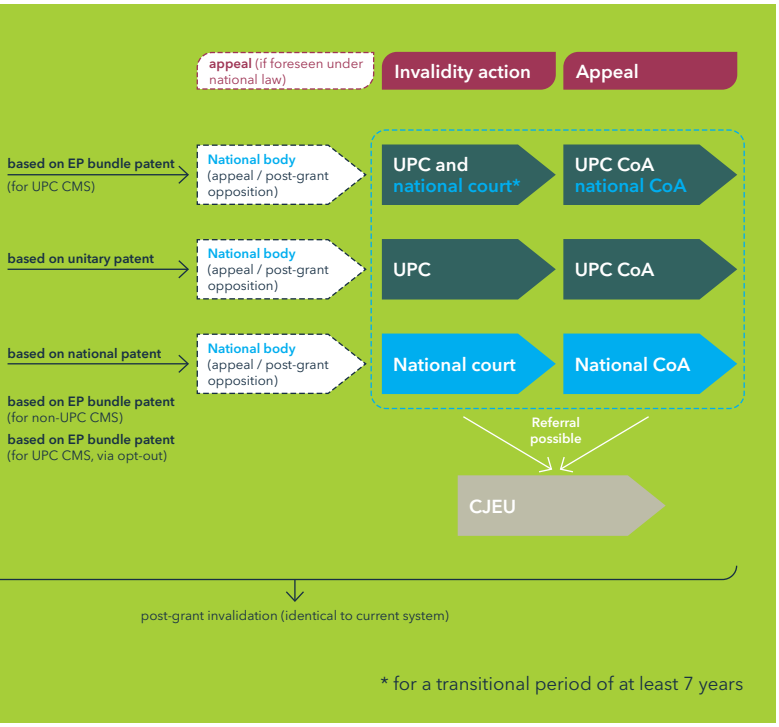
With the centralized procedure for certificates newly introduced in Art. 22 et seqq. of the Recast-Proposal, the Recast-Proposal would implement a pre-grant opposition procedure (Art. 26). This procedure would allow any third party to file a notice of opposition with the EUIPO within two months following the publication of a positive examination by the office (see also Part I).

The opposition panel, consisting of three members differing from those of the examination panel, would issue a decision on this opposition within 6 months only (Art. 26(9)). This timeframe is very ambitious. However, it is already stipulated that the time limit does not apply and can be exceeded in case of »complex« proceedings – which, based on experience, is likely to be very common in SPC cases. Oral proceedings before the opposition panel would not be public (Art. 44(2)).

Depending on the outcome of the opposition, the examination opinion would be maintained or amended. The decision of the opposition panel would be open to appeal before the EUIPO Boards of Appeal within two months of the date of notification of the decision, with grounds of appeal due within another two months (Art. 29(3)). It is envisioned that an action may be brought before the General Court of the European Union against the decision of the Boards of Appeal within two months from its notification as a final recourse (Art 29(6)).

Post-grant invalidation

The Recast-Proposal **does not provide changes** to post-grant judicial procedures applicable to nationally granted SPCs, whether granted on the basis of a national application or of a centralized application. According to Art. 15(2) of the Recast-Proposal, any person would be able to submit an application for a declaration of invalidity of the SPC before the body responsible for the revocation of the corresponding base patent under national law or bring an action for a declaration of invalidity before a competent court of a Member State.



Therefore, invalidity actions regarding SPCs valid in the 18 UPC-CMS could be brought before the UPC (or, during the transitional period, before the national courts) provided that neither the base patent nor the SPC has been opted-out from the jurisdiction of the UPC. In such a case, only the national bodies have jurisdiction.

In all other EU Member States that do not (or not yet) participate in the new patent and court system, jurisdiction regarding invalidity of the SPCs would remain with the national offices or courts as before.

Unitary SPC invalidation proceedings under the proposed new uSPC-system

Pre-grant opposition

Similarly to the provisions in the Recast-Proposal, the uSPC-Proposal foresees the possibility of a pre-grant opposition to be filed within 2 months after the publication of the examination opinion (Art. 15 uSPC-Proposal). We refer to the details of the opposition proceedings described above.

Post-grant invalidation

For post-grant proceedings regarding the validity of the unitary SPC, the uSPC-Proposal suggests another **split system**[5]:

- **Separate invalidity action:** Similar to pre-grant opposition, the post-grant application for a declaration of invalidity of the unitary SPC would have to be filed with the EUIPO (Art. 23(1)).
- **Counterclaim for invalidity:** If the validity of the unitary SPC is attacked in infringement proceedings in the form of a counterclaim for a declaration of invalidity, the national courts, including the UPC (where applicable), would have jurisdiction.

Both an invalidity action and a counterclaim for invalidity would have to be exclusively based on the grounds for invalidity set out in Art. 22 of the uSPC-Regulation.[6]

It must be noted that by now, the UPC has jurisdiction over a number of remedies regarding unitary patents and national SPCs for the participating Member States. However, this jurisdiction currently does not cover unitary SPCs once such rights are established in European Union law. Jurisdiction of the UPC over counterclaims of declaration of invalidity of a unitary SPC thus would require a suitable amendment of the UPCA beforehand.

Separate invalidity action for a unitary SPC

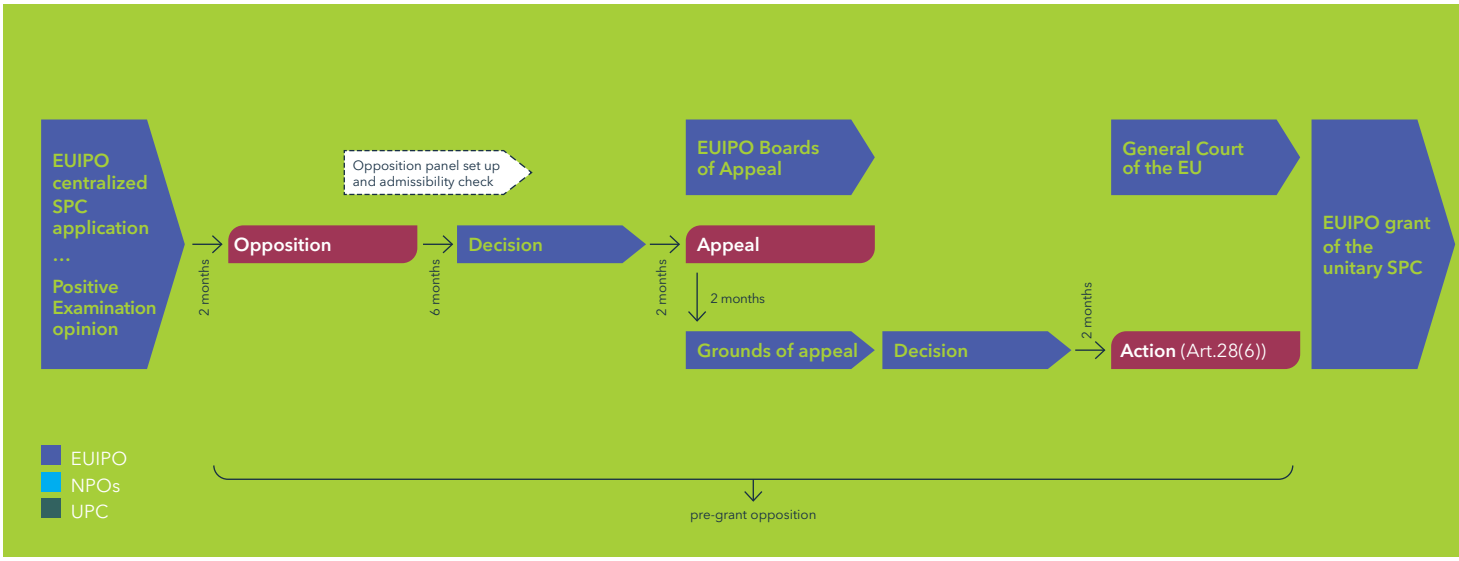
Any third party would be able to challenge the validity of a unitary SPC by lodging with the EUIPO an application for declaration of invalidity according to Art. 23 of the uSPC-Regulation.

However, such an application for declaration of invalidity logged at the EUIPO would be inadmissible if either the EUIPO or a court had issued a final decision in, for example, previous opposition proceedings or national litigation regarding the same unitary SPC and between the same parties (Art. 23 (6)). There would be **no re-litigating a unitary SPC before the EUIPO**.

The EUIPO would set up an **invalidation panel** to decide on the invalidity action. This panel would consist of three members, including one member from the EUIPO and two examiners from two different NPOs, provided these members were not involved in the examination panel or possible related opposition and appeal panels (Art. 23(5)). Oral proceedings before the invalidity panel would not be public (Art. 41(2)).

[5] In addition to the general „bifurcation» between national courts/the UPC with jurisdiction over invalidity actions relating to nationally granted SPCs and the EUIPO with jurisdiction over invalidity actions relating to unitary SPCs, as the Council Presidency calls it, cf. footnote 1.
[6] Grant contrary to Art. 3, base patent lapsed before the 20year term, base patent is revoked or limited in a product relevant manner.

Unitary SPC invalidation under the proposed new uSPC-system



Similarly to the pre-grant opposition, in invalidity proceedings decision would also have to be given within six months (Art. 23(10)). If the application for declaration of invalidity of the unitary SPC is successful, the certificate would be declared invalid with retroactive effect (ex-tunc, Art. 23 (12)).

The decision of the EUIPO invalidation panel would be open to appeal before the EUIPO Boards of Appeal within two months, with grounds of appeal due within another two months (Art. 28). The filing of an appeal would have suspensive effect. The Board of Appeal would consist of three members, at least two of which would be legally qualified, and could be enlarged to five members in individual cases (Art. 29). Unlike in lower instance proceedings, oral proceedings before the Board of Appeal would be public (Art. 41(3)).

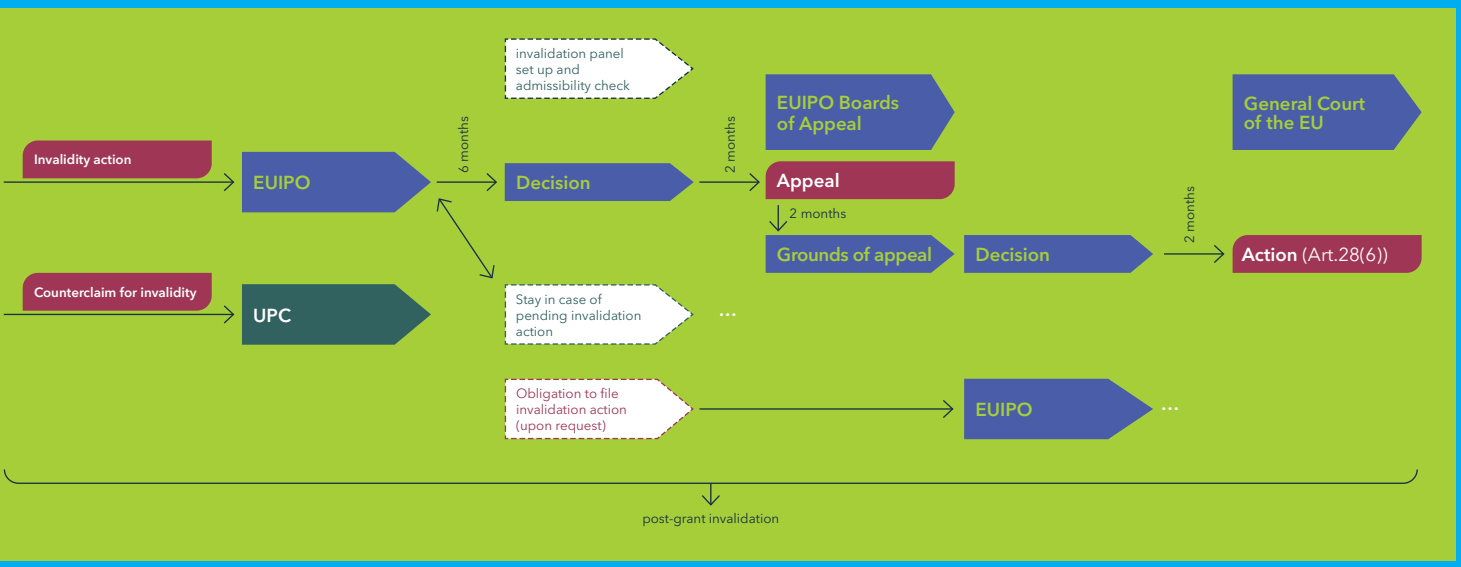
An action against an appeal decision before the General Court of the EU would only be possible on grounds of infringement of a rule of law or misuse of power and would have to be filed within two months(Art. 28(6)).

Counterclaim for invalidity of a unitary SPC

Art. 24 of the uSPC-Proposal, which relates to the counterclaim for a declaration of invalidity of a supplementary protection certificate, provides for detailed rules to avoid parallel or, in the case of identical parties, repeated proceedings on the same unitary SPC, with clear priority given to the jurisdiction of the EUIPO.

- **No parallel proceedings involving the same parties:** The counterclaim of the defendant in infringement proceedings would be inadmissible if EUIPO has already made a final decision on an action for declaration of invalidity brought by that defendant (Art. 24(2)).
- **Stay of proceedings in case of lis pendens:** The court with jurisdiction over the counterclaim would only be allowed to pursue it if the EUIPO had been informed of the date of the counterclaim and no action for declaration of invalidity of the unitary SPC were pending at that time. If such an action had already been filed, the court would have to stay the proceedings until a final decision is made on the action for a declaration of invalidity (or its withdrawal) (Art. 24(4)).
- **Obligation to file a separate invalidation action:** The court having jurisdiction over the counterclaim could, at the request of the right holder, stay the proceedings and require the defendant in the infringement action to file a separate action for a declaration of invalidity of the unitary SPC with the EUIPO within a period to be determined. If the defendant in the infringement action were to fail to comply, the counterclaim would be deemed withdrawn (Art. 24(6)).
- **Provisional measures in case of suspended proceedings:** In the event of a suspension of proceedings by the competent court, the latter could order provisional measures in favor of the SPC holder for the duration of the suspension (Art. 24(6) 3rd sentence). *(See figure above.)*

[7] Cf. Note from the Presidency of 23 May 2024 regarding the Unitary SPC proposals, partially published on 5 July 2024); see also VCI-Position on Key legal questions regarding the unitary SPC system dated 10 February 2025: https://www.vci.de/ergaenzende-downloads/vci-position-spc-system-en.pdf.
[8] Cf. Note from the Presidency of 23 May 2024 regarding the Unitary SPC proposals, partially published on 5 July 2024), marginal no. 17.
[9] For regular updates, see for example the Legislative Train Schedule of the European Parliament relating to the unitary SPC for medicinal products, published by rapporteur Tiemo Wölken: https://www.europarl.europa.eu/legislative-train/theme-legal-affairs-juri/file-unitary-supplementary-certificate-for-medicinal-products.



Outlook

Pre-grant opposition, which would become available as a tool for the first time as part of the new, centralized SPC application procedure (if implemented), could open a strategic playground to third parties who want to prevent, or at least delay, the grant of a SPC. Even though decisions are intended to be made quickly, ideally within six months, this new, early possibility of challenging an SPC application could have a significant impact and create additional uncertainties, particularly in terms of time, for everyone involved, but especially for the applicant. Apart from the explicit provision regarding parallel proceedings in Art. 24(2) of the uSPC-Proposal, it is also unclear whether and what implications a pre-grant opposition would have on subsequent nullity actions, especially if filed by the same third party. This would only become clear with practice and the development of case law if and when the Proposals enter into force.

Further, the proposed approach relating to unitary SPC post-grant invalidity proceedings has received copious negative feedback. Some stakeholders and Member States are of the opinion that this approach would create a parallel jurisdiction on the scope of protection of the unitary patent and the interpretation of patent claims, possibly leading to conflicting judgments and legal uncertainty.[7]

According to the uSPC-Proposal, a unitary SPC must be based on and complements a unitary patent. However, in individual cases, if the protection of the underlying unitary patent has already expired, aspects of the validity of the base patent would also be open to discussion in EUIPO invalidity proceedings in order to justify the revocation of the related unitary SPC. There are concerns that this could lead to a central (re)assessment of the legal status of the unitary patent by the EUIPO, which is neither responsible nor experienced in this area. There is therefore broad support among stakeholders and Member States for assigning jurisdiction for unitary SPC invalidity actions to the UPC, which also has exclusive jurisdiction for the unitary patent, instead.

So far, the Commission has merely countered these concerns by stating that Article 263 TFEU requires that actions against acts of bodies, offices, or agencies of the Union – and the EUIPO is such an office – intended to produce legal effects vis-à-vis third parties must be brought before the General Court, and that jurisdiction cannot be conferred to another court, such as the UPC, where the EUIPO is deciding on SPC applications.[8]

Currently, negotiations between the Council of the European Union, the European Parliament, and the European Commission regarding the entire SPC framework are still ongoing.[9] It is therefore not yet clear when and in what form the two SPC regulations presented here will be adopted.

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