



European Commission reforms: SPCs, SEPs and compulsory licences

On 27 April 2023, the European Commission unveiled its blueprint for patent legislative reform. The proposals focus on three key areas: standard essential patents (SEPs), supplementary protection certificates (SPCs) and a compulsory patent licensing scheme for crisis management. The EUIPO is at the centre of administering these proposed regimes.

The proposals arise out of the Commission's November 2022 IP Action Plan,¹ which aims to harmonise the approach to Intellectual Property law across EU Member States. The proposals are only the first step in the process and will now be considered and agreed by the Council of the European Union and European Parliament.

1. Supplementary Protection Certificates (SPCs)

SPCs extend the 20-year term of patent protection for medicinal or plant protection products by up to 5 years² to compensate a patentee for the loss of the patent term while awaiting regulatory approval of the product.

Patentees currently seek SPCs on a country-by-country basis through national applications. This requires separate national examination, often resulting in duplication of work, inconsistent results and legal uncertainty for patentees and other stakeholders. The Commission's report³ notes that discrepancies between national office decisions are often cited as the primary reason that a decision to grant or refuse an SPC is referred to the Court of Justice of the European Union (CJEU). In practice, much of the CJEU referral practice is because of the underlying ambiguity in the SPC Regulation itself, coupled with inconsistent and unclear CJEU case law.

The Commission aims to simplify the procedure by which patentees can obtain SPCs in Europe, also improving transparency and efficiency by introducing:

1. a new centralised procedure for examination and grant of SPCs; and
2. a Unitary SPC to complement the Unitary Patent and Unified Patent Court system.

The proposed process is intended to complement the existing centralised procedures which exist for the grant of European patents (EP) and marketing authorisations. The reforms are expressly not intended to change the conditions for obtaining SPCs or their effect. However, the proposed draft regulation nonetheless appears to contemplate a change in the conditions for obtaining SPCs. James Horgan has authored an article in this Review on SPC policy issues over the last year which provides a more detailed commentary regarding some of these proposed changes. The key points to note on the proposed SPC regulations are as follows:

¹ [Commission adopts Action Plan on Intellectual Property](#)

² Plus a potential additional 6 month paediatric extension

³ https://single-market-economy.ec.europa.eu/system/files/2023-04/COM_2023_231_1_EN_ACT_part1_v10.pdf

- The centralised procedure will be available to medicinal products with a centralised marketing authorisation. For plant protection products, national marketing authorisations will be allowed as a basis for a centralised application. In either case, the application may be based on an EP or unitary patent.
- A central examination authority shall carry out the examination of the application, currently proposed to be a panel at the EUIPO.
- Decisions made by the panel may be appealed to the Board of Appeal of the EUIPO, followed by the General Court and CJEU.
- Following the application procedure, the applicant chooses which member states to designate for the bundle of SPCs sought (including, should it wish to acquire one, a Unitary SPC).

The centralised procedure will also afford Unitary patent holders a mechanism to obtain a Unitary SPC, subject to the same conditions for obtaining an SPC based on an EP.

It is also possible to use the central procedure to file a combined application requesting a unitary SPC for the applicable UPC member states, while also designating non-UP member states where a national SPC will be required. Unlike patents, where certain jurisdictions now allow double patenting, it will not, be possible to obtain a unitary SPC and a national SPC covering the same jurisdiction.

2. Standard Essential Patents (SEP)

SEPs are patents that protect technology declared as being essential for the implementation of a technical standard adopted by a standard developing organisation (**SDO**). Typically, SDOs require holders of SEPs to commit to licence SEPs on fair, reasonable and non-discriminatory (**FRAND**) terms to those who require use of the technology (referred to as “**implementers**”).

The Commission’s proposals aim to harmonise and improve the current SEP licensing regimes by targeting concerns regarding licensing transaction costs and uncertainty about the SEP royalty burdens.

The Commission proposes to address these problems through the creation of a centralised Competence Centre, which will be involved in maintaining SEP and knowledge databases to provide more clarity on SEP ownership (including whether the patents are essential) and FRAND terms, including licence fees. The Competence Centre will also be involved in facilitating resolution of SEP disputes.

Further details of the proposed reforms are detailed below:

1. **A new Competence Centre:** The Competence Centre, established within the EUIPO is proposed to administer the key functions of the proposal.
2. **Creation of an SEP register and essentiality checks:** Establishment of an obligatory register held by the EUIPO where patentees are required to register their SEPs before seeking licenses. Selected SEPs will be independently evaluated as part of an essentiality check regime.
3. **FRAND determination procedure.** The Commission proposes that parties go through a mandated (but not binding unless by consent) 9-month FRAND determination procedure as a precursor to litigation.
4. **SEP aggregate royalty (i.e., a maximum total price).** SEP holders should agree upon and notify the Competence Centre of the expected maximum aggregate royalty for licences to all SEPs applicable to a specified implementation. There is provision for a conciliator to mediate these

discussions in certain circumstances and an ability to request a non-binding expert opinion on the aggregate royalty. The aggregate royalty, although non-binding, would be published on the SEP register.

5. **SME support:** The Commission proposes that SMEs be provided free advisory services, reduced fees and access to the SEP register to improve transparency.

The draft SEP regulation is expressly stated to apply to patents essential to standards that are published after the regulation comes into force, but there is nonetheless provision that allows the EC to pull, at its discretion, existing standards into the regime.

3. Compulsory licensing for crisis management

The current compulsory licensing framework within the EU is only implemented at a national level. While national legislative rules operate within the boundaries of TRIPS, the specific rules of procedure and grant of compulsory licences will differ between states.

The Commission's proposal, which seeks to introduce a new EU-wide compulsory licence right, reflects a broader initiative which the Commission has implemented since the Covid-19 pandemic to ensure that in times of crisis, EU Member States have access to products and inventions that are necessary. The Explanatory Memorandum to the proposed regulation claims that compulsory licences enable the manufacture of critical products needed in times of crisis, whilst also incentivising parties to reach voluntary agreements.

The proposal does not seek to interfere with existing powers in individual Member States, which allow them to grant compulsory licences in their jurisdictions. However, Member States would be under an obligation to notify the Commission when they grant national compulsory licences and explain the purpose of granting the licence, the products it applies to and the scope of the licence.

The key takeaways of the proposed reform are as follows:

1. **Creation of a Union compulsory licence (UCL).** Under the proposal, the Commission has the power to grant UCLs for patents, published patent applications, utility models and related SPCs. The proposal purports to be limited to patents; however, on the current draft the Commission appears to have power to confer the transfer of trade secrets and know-how to enable a crisis relevant product to be made/process to be carried out.
 - i. The power is limited to: (i) crisis and emergency situations; (ii) the EU only – the intention is solely to meet EU needs; and (iii) products which are essential to respond to a crisis, or to address the impact of a crisis – although this in itself is vaguely defined. The Commission has included a list of EU crisis instruments that can trigger a UCL. This includes situations concerning the safeguarding and security of gas supply, health emergencies and the like.
 - ii. The UCL will have a specified scope, duration and application, and be granted in exchange for an “adequate” compensation to the rights holder – although there is a proposed cap (see below).
2. **Rights holders can provide comment on a proposed UCL prior to grant.** Prior to granting a UCL, the Commission will consult an advisory body on whether a licence needs to be issued. The proposals require the Commission to notify the rights holders/patentee, specifically as to whether there is a possibility to reach a voluntary licence agreement, whether the licence

is required and if so on what terms. Whilst a rights holder can provide submissions on a proposed UCL, its consent is not needed to proceed.

3. **Patentee is entitled to receive compensation.** However, compensation cannot exceed 4% of the licensee's turnover covered by the UCL and if the licence is granted in relation to a patent application which subsequently does not grant, the fees paid will be refunded.
4. **Licensee will be bound by obligations.** The proposed regulation imposes obligations on the licensee to counteract any scope for abuse of the licence. For example, a licensee can only manufacture the relevant products or use the invention in way that is relevant to the crisis or emergency that the licence has been granted for. Sanctions may be imposed if the licensee fails to comply with its obligations (such as terminating the licence or financial penalties).

The Commission's suite of proposals has been met with mixed reactions. Critics argue that they could potentially disrupt the balance of power between patent holders and users. Supporters have welcomed the recognition by the Commission that there are important areas which are not functioning efficiently, and which require legislative intervention.. Both critics and supporters nevertheless acknowledge that the detailed drafting needs refinement.

The EC argues that the proposals are necessary to create a more transparent, effective, and future-proof IP framework, thereby contributing to the EU's competitiveness and technological sovereignty.

The EC's proposals will now be considered by the European Parliament and the Council of the European Union. If approved, the new regulations could be in place by 2025.

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