In search for harmony – the European Commission's proposals for centralised SPC examination and unitary SPCs

The European Commission recently published a series of legal proposals that could reshape the European Union's (EU's) pharmaceutical market for years to come (see our related article on the overhaul of the regulatory data protection system).

These include a set of proposals that seek to simplify the EU's system of supplementary protection certificates (SPCs) for medicinal and plant protection products. They intend to establish a new process of centralised SPC examination, as well as a unitary SPC. The proposals are aimed at improving transparency, consistency and efficiency of the process of issuing SPCs across the EU member states.

The proposals have several attractive aspects. For example, they provide the possibility of filing a "combined" SPC application that includes both a request for the grant of a unitary SPC and a request for the grant of national SPCs based on designations of a European patent that fall outside the jurisdictions of the Unified Patent Court. They also provide the option for bringing a central challenge against an SPC application. Under the proposals, the European Union Intellectual Property Office (EUIPO) would be tasked with centrally examining SPC applications and issuing grant and refusal opinions or decisions. Another positive is that the EUIPO would draw on the expertise of SPC examiners from national patent offices from across all EU member states.

Yet the prospect of making the Court of Justice of the European Union (CJEU) the final arbiter on grant and refusal opinions or decision as well as oppositions will likely be far less appealing for many SPC practitioners, given the chequered history of the court in "clarifying" the interpretation of the EU SPC Regulation.

The article summarises the current system, highlights some important changes in the "recast" SPC regulation, and then briefly discusses the proposed unitary SPC.

Background

Pharmaceutical and plant protection products require authorisation before they can be placed on the EU market. Acquiring such authorisations is typically a lengthy regulatory process that can significantly erode the effective term of patents protecting such products.

In the European Economic Area, SPCs were introduced to compensate patent proprietors for the loss of term resulting from the regulatory approval process. Instead of extending the patent term, the EU SPC Regulation establishes SPCs as *sui generis* intellectual property rights that come into force following the expiry of patents protecting authorised pharmaceutical or plant protection products.

Rather than providing EU-wide protection, SPCs are national rights. SPC applications must therefore be filed in each EU member state. As highlighted by the European Commission, such an approach entails significant drawbacks in the context of the EU single market and has led to legal uncertainty and unnecessary expenses.

For example, a national route incurs higher costs for applicants, for what is essentially duplicated work performed by each national patent office. Furthermore, discrepancies frequently arise between EU member states during the examination of SPC applications. Indeed, inconsistencies in decisions to grant or refuse SPCs is the reason most often cited by national courts for referring questions concerning the application of the EU SPC Regulation to the CJEU. It can also be difficult to determine what protection exists for a given product in each EU member state. Such difficulties affect both SPC holders and generics manufacturers.

Content of the proposal relating to EU national SPCs

The European Commission considered various options for addressing the drawbacks of the current SPC regime. These included issuing guidelines for the application of the EU SPC Regulation, as well as establishing a process of mutual recognition whereby the patent office of a reference member state would examine an SPC application and its decision would subsequently be adopted by the national patent offices of other member states for corresponding national SPC applications. The current proposal adopts a third approach of **centralised filing and examination of national SPC applications**. In this proposal, the EUIPO would act as the central examination authority, supported by the national patent offices of EU member states.

Under this proposal, EU SPCs based on nationally validated European patents remain national rights, but the EUIPO would draw up an opinion concerning the grant or refusal of an SPC application. This opinion would be binding on the national patent offices of designated EU member states. The grant of SPCs would be effected by the respective national offices of these states, following a positive opinion from the EUIPO. For non-EU member states such as the UK, SPCs would, of course, continue to be examined nationally.

The proposed SPC examination procedure draws many parallels with that of the European patent examination:

- **A central examination authority**
  Examination would be conducted by a panel of three examiners – one member of the central examining authority, and two qualified examiners from two different national patent offices in Member States. Examination would be conducted on the basis of the existing EU SPC Regulation and associated body of case law of the CJEU.
- **Designation of member states**
  Following centralised examination, an applicant would choose in which EU member states to seek SPC protection. The end result would be a “bundle” of national SPCs.
- **Third party observations/oppositions**
  A new feature of the proposal is an option for third parties to centrally challenge an SPC application. Within three months of publication of the centralised application, third parties could submit observations concerning the validity of the application. It would also be possible to challenge a positive opinion, by initiating an opposition procedure within two months of the publication of the opinion on the grounds that one or more conditions for obtaining an SPC have not been met.
- **Appeal procedure**
  Applicants would be able to appeal negative opinions issued during examination. Similarly, any party adversely affected by the outcome of an opposition would be able to appeal the decision. Appeals would initially be handled by the Boards of Appeal of the EUIPO, followed by the General Court and ultimately the Court of Justice. The fact that the General Court has specialised IP Chambers should ensure decisions that will be persuasive throughout Europe without the need to refer questions to the CJEU.

Eligibility

Only SPC applications based on a European patent (including a unitary patent) could be filed via the proposed centralised procedure. SPC applications based on patents issued by national patent offices of EU member states would not be eligible.

Eligibility is further restricted by the type of authorisation on which the SPC application is based:

- **For medicinal products**, only a centralised marketing authorisation issued by the European Commission could be used as basis for a centralised SPC application.

- **For plant protection products**, there is no equivalent central marketing authorisation. Consequently, national marketing authorisation could be used as basis if:
    - at the date of filing of the application, marketing authorisations were applied for in each of the designated Member States, and
    - before the end of the examination process, authorisations were granted in each of the designated Member States.

Finally, the proposal aims to clarify who is entitled to an SPC based on a given authorisation. New Article 3(3) clarifies that more than one SPC can be granted for the same product to different patent holders "*where they are not economically linked*". New Article 6(2) confirms that "*a certificate for that product shall not be granted to the holder of the basic patent without the consent of*" the authorisation holder. It is unclear how consent must be obtained, and authorisation holders will need to consider carefully whether to give consent (and possibly incur royalties) or refuse it (and sacrifice a layer of exclusivity).

A unitary SPC?

In addition to centralised SPC examination, the European Commission further proposes to establish a unitary SPC system available to all EU member states that are signatories of the "Agreement on a Unified Patent Court". An SPC application based on a unitary patent would give rise to a single SPC effective in the same member states as the basic unitary patent. The procedure for the filing and examination of unitary SPC applications would be the same as the centralised procedure defined in the above-mentioned parallel proposal.

The proposals also foresee a "combined" SPC application that includes both a request for the grant of a unitary SPC and a request for the grant of national SPCs based on designations of a European patent that fall outside the jurisdictions of the Unified Patent Court. The "combined" application would undergo a single examination procedure, ruling out any discrepancies and considerably reducing the costs and administrative burden associated with the current SPC regime.

Summary

These proposals are intended to be solely procedural in nature. They are not intended to modify the scope nor the effect of the rights conferred by national SPCs. Nevertheless, the changes for SPC practitioners would be considerable.

A centralised filing system and unitary SPCs appear to be welcome steps toward streamlining applications and harmonising the standards for grant. For opponents, the potential for centralised third-party observations and opposition proceedings is also an attractive prospect. However, establishing the CJEU as the final authority for appeal proceedings will perhaps raise a few eyebrows, given the court's historically inconsistent application of SPC law. In this regard, it is hoped that the establishment of specialist IP chambers at the European General Court would result in more consistent decisions, avoiding the need for referrals to the CJEU.

Drawing on the expertise of national examiners seems a sensible decision that nonetheless raises more questions. Would further training and guidance be provided to achieve a uniform application of the law? Otherwise, inconsistencies at an international level may simply be replicated centrally.

Overall, the proposals appear to be positive, albeit with some important concerns left unassuaged.

For more detailed advice in relation to any of the issues discussed above or for advice relating to other matters regarding European practice please do not hesitate to get in contact with your E+F representative or email us at jens.grabenstein@elkfife.com or andy.nicoll@elkfife.com.

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