EU SPC Reform – A Marathon Not A Sprint

Introduction

A few months after the European Commission released its long-awaited proposals for reform of Supplementary Protection Certificates (SPCs)[1], most interested readers will not be surprised to hear that it may still be some time before we see any enactment of reform.

The proposals themselves arise from consultations which date back many years, notably including a study published in 2018 from the Max Planck Institute[2]. Now, under the EU's ordinary legislative procedure, both the European Parliament and the European Council will consider the proposals. Interested parties will have the opportunity to make submissions, and both EU institutions will have the opportunity to propose amendments. Ultimately both must approve a final text before it is adopted. At present there is no clear timetable for any of these processes to occur.

On the other hand, the most recent previous reform of SPCs (the introduction of the so-called "manufacturing waiver"[3]) took 14 months from proposal by the Commission to entry into force, so it is certainly worth giving the current more wide-ranging proposals serious consideration now. The proposals concern SPCs for both medicinal products and plant protection products. We focus here on the former, as likely of wider interest.

The Problems

The Commission proposals identify a number of issues with the existing SPC system, all of which arise from the handling of SPC applications at the national level. At present, individual SPC applications must be filed at the patent office of each country in which a certificate is sought. The Commission see this as increasing both costs (each country carries its own official fees, local agent charges etc.) and complexity, given that the different patent offices (and their respective national courts) have demonstrated a willingness to diverge from each other when examining what should be effectively identical cases under identical law. Few would disagree that the binding effect of numerous CJEU judgments relating to SPCs has had limited success in enforcing uniform interpretation between member states.

The Solutions

The current proposals aim to address these issues via two key reforms:

- Introduction of a centralised examination procedure for SPCs (by recasting the existing SPC regulation)
- Introduction of a unitary SPC (via an additional regulation)

Both procedures will be the responsibility of the EUIPO, initially drawing upon the expertise of experienced SPC examiners from national patent offices.

Centralised Examination

The new route replaces the existing national route for all SPC applications based upon a European patent (i.e. a patent granted by the EPO) and a centralised marketing authorisation issued by the EMA. In practice, this means it will apply to most SPC applications. The vast majority of pharmaceutical inventions seek patent coverage via the EPO, rather than individual national offices, and the categories of medicine that are obliged to use the centralised EMA procedure are relatively broad[4]. If an applicant files via a national office when the conditions for centralised examination are met, the national office will reject the application.

In the centralised examination procedure, after a check for formal admissibility, substantive examination will be conducted by a panel of three examiners, one from the EUIPO and two SPC-qualified examiners drawn from the patent offices of different member states. The panel issues an opinion on validity. This opinion is binding on the national offices, which will respond to a positive opinion by granting a national SPC.

In the case of a negative opinion, the applicant can appeal to the Boards of Appeal of the EUIPO, and ultimately to the General Court and the CJEU (for review of legal principle).

Third parties can also submit observations within 3 months of publication of the SPC application and can file oppositions to a positive validity opinion within 2 months of publication of the opinion.

Unitary SPC

The new unitary SPC would be examined in essentially the same way as the centralised examination procedure above, except the SPC application must be based on a unitary patent. In this case, a positive EUIPO opinion will lead to grant of a unitary SPC having uniform effect in member states in which the basic patent has unitary effect (currently 17 states).

Anticipating a likely ongoing split between EU member states which are UPC participants and those which are not, the proposals permit the applicant to request a "combined application". This would lead to a grant of both a unitary SPC and national SPCs, via the centralised examination route for the additional member states not covered by the unitary patent. This mixed procedure will likely feel familiar to those who have recently gotten to grips with the unitary patent route for validation of a granted European patent, including the sense that it is not quite as unitary as one might wish.

The unitary SPC will be litigated before the Unified Patent Court, in the same manner as unitary patents[5]. This means that after a grant, a third party could bring an action for declaration of invalidity before the court. The Commission proposals make it

clear that such a party would need to choose between filing such an action or instead an (earlier) pursuit of opposition before the EUIPO. A claim for invalidity in the court cannot be brought if the EUIPO has already made a decision on the same subject matter between the same parties.

Substantive Changes?

The Commission proposals stress at various points that there is no intention to modify the substantive aspects of the existing SPC Regulation. This is a little disingenuous. The proposals make explicit some aspects that currently rely upon CJEU case law, impose some additional limitations that go against CJEU case law, and include certain new recitals which address gaps and/or seek to "assist in the interpretation" of various points.

For example:

An effective addition to Article 3 of the current SPC regulation recites that:

"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."

This is largely based on wording that appeared in the Plant SPC Regulation, and that has been applied to human medicines based on a recital of the Plant SPC regulation indicating that it should also apply to human medicines. This has also been confirmed by CJEU case law. However, the closing phrase "where they are not economically linked" is new and may make this provision difficult to interpret.

An effective addition to Article 6 of the current SPC regulation recites that:

"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"

The requirement for consent of the marketing authorisation holder goes against C-181/95 Biogen V SKB, which explicitly endorsed the view that no such consent (or even a relationship) is required. It may be desirable to remove the option to apply for an SPC without the consent of the marketing authorisation holder (a so-called "squatter SPC"), but it would be a departure from established practice to remove the possibility.

There are also recitals which seek to address a widely-acknowledged gap in the CJEU case law. It has long been established that an SPC for a small molecule drug encompasses therapeutically equivalent salts and esters[6], but no equivalent judgment exists for biologics. It is therefore welcome to see that the Commission believe the scope of an SPC should encompass:

"therapeutically equivalent derivatives of that product, such as salts, esters, ethers, isomers, mixtures of isomers or complexes, as well as biosimilars"

and that:

"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."

Finally, and perhaps most significantly, various recitals appear to be seeking to remedy the absence in the current SPC Regulation of guidance to the interpretation of Article 3. The Commission's answer to this appears to take the form of an attempt to summarise the most recent relevant CJEU judgements, particularly with respect to Article 3(a) (the product must be protected by the basic patent) drawing on C-650/17 Royalty Pharma, and Article 3(c) (the requirement that the product should not have been subject of a prior certificate) drawing on C-673/18 Santen. However, the judgments in each case are complex, and are widely regarded as having left questions unanswered. As such, any distillation risks imposing a particular interpretation that may not be a complete picture. The impact of these recitals could therefore be particularly far-reaching and we do not propose to analyse the implications in full here.

Other Considerations

The Commission proposals make it clear that paediatric extensions of unitary SPCs or SPCs granted via the centralised examination route should be available based on essentially the same requirements as now, except requests for extensions will be filed at the EUIPO.

The Commission proposals acknowledge a perhaps surprising discrepancy in national practices, which concerns the calculation of expiry dates of patents and SPCs. Depending on whether a national office interprets expiry to occur at 0:00 on the relevant anniversary, or at 23:59, there can be a difference in the effective expiry date. The proposals express a desire that any new Regulation state explicitly when expiry occurs, at least for a unitary SPC, to ensure that it has uniform term across the applicable member states.

Final Remarks

Whether the Commission proposals survive in their present form or are subject to substantial amendments, and regardless of when progress towards their final adoption and entry into force is made, it seems clear that substantial reform of SPCs is coming. The SPC team at J A Kemp LLP will be ready to assist you when that marathon finally comes to an end. Please feel free to contact any of the team or your usual J A Kemp contact with any questions.

Footnotes

1. Published 27 April 2023 – https://single-market-economy.ec.europa.eu/publications/proposals-regulations-supplementary-protection-certificates_en

2. https://ec.europa.eu/docsroom/documents/29524

3. See our briefing here: https://jakemp.com/en/briefings/spc-manufacturing-waiver/

4. All human medicines derived from biotechnology and other high-tech processes … all advanced therapy medicines and medicinal products containing new active substances intended for the treatment of HIV/AIDS, cancer, diabetes, neurodegenerative diseases, auto-immune and other immune dysfunctions, and viral diseases, as well as to all designated orphan medicines intended for the treatment of rare diseases. Taken from:

https://www.ema.europa.eu/en/documents/leaflet/applying-european-union-marketing-authorisation-medicinal-products-human-use_en.pdf

5. It is expected that the Agreement on a Unified Patent Court (UPCA) will be amended to include unitary SPCs explicitly.

6. C-392/97 Farmitalia

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