Master the detail to get the most from SPCs

A flurry of decisions on Supplementary Protection Certificates issued in 2011 has profoundly altered the nature of this important protection for intellectual property. An understanding of these legal changes is crucial since the emerging picture will lead to opportunities for some companies while presenting challenges for others.

By Mike Snodin, Potter Clarkson LLP

Supplementary Protection Certificates (SPCs) are highly valuable European intellectual property (IP) rights that provide an additional monopoly period for use in authorised indications of previously patented active substances. For many innovative medicinal products, 80% or more of total sales will occur during the extended period of protection. Thus, the importance of SPCs cannot be overstated.

SPCs have been around for almost two decades but some fundamental aspects of how the legislation operates are only now beginning to be clarified by the courts.

Background

For human and veterinary medicinal products, SPCs are Europe's answer to patent term extensions (PTEs) under the 1984 Hatch-Waxman Act in the US. Although the two share some features, such as being dependent on the patent and regulatory systems, SPCs are unique. An SPC does not extend patent term, it is a distinct right that comes into force immediately on expiry of the patent on which it is based.

Also, the scope of protection provided by an SPC is usually much narrower than that of the original patent. In essence, an SPC only protects the innovative active ingredient, or combination of ingredients, present in a newly authorised medicinal product. Even then, it only applies to authorised indications.

However, the protection offered is still highly valuable as it covers essentially everything of interest to a generic competitor.

Key provisions

Legislators have tried to set up a balanced system that provides adequate protection for innovators but prevents 'evergreening' of protection arising from minor modifications of existing medicines.

For this reason, there is a distinction between:

- A 'medicinal product', which is essentially the complete formulation taken by patients.
- A 'product', which is an active ingredient or combination of active ingredients.

For human and veterinary medicinal products, this is put into effect by Article 3 of European Parliament Regulation 469/2009, which states that an SPC will be granted if the following criteria are satisfied at the time the application is made:

(a) The product is protected by a basic patent in force in the member state.
(b) A valid authorisation to place the product on the market has been granted in accordance with a relevant EU Directive.
(c) An SPC for the product has not already been granted in the member state.
(d) The authorisation referred to above is the first to place the product on the market as a medicinal product.

The first two criteria above primarily function to tie SPCs to both the patent and regulatory systems; the latter two are designed to prevent evergreening of protection.

Recent developments

During the 19 years that SPC legislation has been in force, the national courts of various member states have regularly sought clarification of its provisions from the EU Court of Justice (ECJ). However, 2011 saw a particularly high number of such rulings, including in relation to fundamental provisions such as Article 3(a) and 3(b).

From the recent ECJ rulings, the following has become clear:

1 It is not possible to obtain an SPC for a product that was on sale in the EU as a medicament before being subjected to clinical trials under modern standards (for example, under Directive 65/65/EEC or its successor, 2001/83/EC).[1]
2 The product defined in the SPC application must be "specified (or 'identified') in the wording of the claims of the basic patent relied on".[2] This interpretation by the court of Article 3(a) means, for example, that a basic patent containing only claims directed to active ingredient A cannot be used to obtain an SPC for a product defined as combination of active ingredients A + B.
3 The product defined in an SPC application may be one or more (but not necessarily all) of the active ingredients present in the medicinal product whose authorisation is relied on.[3] This interpretation of Article 3(b) means, for example, that an authorisation for a medicinal product containing active ingredients A + B can support an SPC to A alone or B alone, subject to the provisions of Article 3(a), 3(c) and 3(d) also being met.
4 It is possible to obtain an SPC that has a non-positive (i.e. zero or negative) term.[4] This is in order to provide full effect for the six-month term extension that can be obtained if clinical trials are completed in the paediatric population.[5]

However, the rulings have left open the following questions:

(I) Does an SPC of a product defined as a single active ingredient (A) protect the (medical uses) of all medicaments containing A that are authorised during the lifetime of the SPC?
(II) What is entailed by the requirement for a product to be "specified in the wording of the claims"? That is, what level of specificity is required?

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Box 1: SPCs – the basics

SPCs are governed by Regulations of the European Commission. As such, the law is supposed to be interpreted in a harmonious manner across the whole of the European Union.

SPCs are national rights and must be applied for on a country-by-country basis. They are available in all EU member states. They are also available in Norway, Iceland, Liechtenstein and Switzerland, although the legislation in these territories is not always identical to that in the EU.

An SPC is applied for and granted to the holder of a patent that 'protects' a newly authorised active ingredient or combination of active ingredients.

An SPC application must be applied for while the patent that it is based on is still in force and within six months of the patent grant and issuance of the marketing authorisation (MA) on which the SPC application is based.

The term of an SPC after the patent expiry is x – 5 years, where x is the period from patent filing to MA issuance. However, the term of a normal SPC is capped at a maximum of five years.

A six-month extension of SPC term is possible where clinical trials (on the active ingredient(s) of the SPC) have been completed in accordance with a Paediatric Investigation Plan agreed with the European Medicines Agency. This is to encourage firms to conduct trials in the paediatric population.

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(III) Is it possible to obtain more than one SPC per basic patent (for example, when that patent protects more than one product)?

Given the logic employed by the ECJ in its interpretation of Article 3(b), it is hard to see how the answer to question (I) above can be anything other than 'yes'. However, we must await the ruling in a further case[6] before this can be formally confirmed.

Question (II) will no doubt soon be addressed by national courts. Question (III) arises from unclear language used by the ECJ. There are numerous examples of single patents that are associated with multiple SPCs, so this issue is also likely to be subject to consideration by one or more national courts in the near future.

Where are we now?

The ECJ rulings set out above will have surprised some national intellectual property offices. This is because, before the recent rulings, some national offices will have routinely granted or refused SPC applications on the basis of standards that differ from those set out in the ECJ decisions.

As a result, there are now likely to be many granted SPCs that are of questionable validity, especially in view of points 1 and 2 above – and also question (III) , if that is eventually answered in the negative.

On the other hand, points (3) and (4) above provide opportunities for more SPC protection than was previously thought possible (especially if question (I) above is answered in the positive).

Thus, likely consequences in the short to medium term include:

- In view of point 1 above, invalidity of SPCs to certain 'old' active agents. Products already affected by this point include memantine (Ebixa) and galantamine (Reminyl) but there could well be others.
- Invalidity of certain SPCs to combination products – those not granted in accordance with the standard at point 2 above.
- In view of point 3 and question (I) above: generic versions of combination products will be delayed from entering the market until at least the time when SPC protection for all of the individual actives has expired; and there will be more applications for SPCs directed towards one or more, but not all, of the active ingredients present in authorised medicinal products.
- There will be more applications for SPCs that, when granted, will initially have a negative term (i.e. where the authorisation relied on was issued between four and a half and five years after the filing date of the basic patent relied on). However, this will only be in respect of human medicinal products where clinical trials in the paediatric population have been (or will be) completed.

Where are we going?

It is reasonable to predict that the answer to question (I) above will be 'yes'. However, a great deal of uncertainty remains in relation to questions (II) and (III). The eventual answers will directly affect the validity of many granted SPCs. In the meantime, there will be much collective holding of breath in the pharmaceutical industry.

Regardless of what happens on those points, the next few years are likely to see challenges under Article 3(d) of Regulation 469/2009 against SPCs for products that are single enantiomer forms of previously authorised racemates. Such challenges are likely to be based on the following questions based on point 3 above and on the 2006 decision of the ECJ in the MIT case[7]:

- Does the prior authorisation of the racemate count as the first authorisation for each of the enantiomeric forms present in the racemic mixture?
- If only one of the enantiomeric forms has pharmacological activity, does the prior authorisation of the racemate count as the first authorisation for that (active) enantiomer?[8]

The ruling in the MIT case may also be revisited in relation to ingredients where it is unclear that they have a therapeutic effect on their own. The most likely technical area for this issue to arise is in connection with novel vaccine adjuvants.

Other ECJ rulings are certain to be revisited, including Yissum[9] and Pharmacia Italia[10], because of the Neurim case that is pending before the court, in which an attempt is being made to distinguish the previously decided cases by arguing that certain prior authorisations are not relevant to the assessment under Article 3(d). Although those arguments look likely to fail, they have certainly attracted sympathy from various parties, including the UK judge that referred the case to the ECJ.

Finally, there is a discrepancy regarding how different national offices assess the date of a 'centralised' (European Commission/ European Medicines Agency) authorisation. It may be that many offices are basing the term of an SPC on the wrong date, and this could lead to some SPC proprietors being entitled to a few additional days.[11]

Conclusion

Although several questions remain unanswered at this point, it is clear that recent and likely developments present challenges and opportunities for companies with an interest in SPCs. Whatever happens, the chances of withstanding challenges and taking advantage of opportunities will be improved by understanding the intricacies of this niche and complex area of the law. ■

References

[1] Synthon v Merz (C-195/09) and Generics (UK) v Synaptech (C-427/09).

[2] C-322/10 (Medeva), C-422/10 (Georgetown University et al), C-518/10 (Yeda Research and Development Company Ltd, Aventis Holdings Inc), C-630/10 (University of Queensland, CSL Ltd) and C-6/11 (Daiichi Sankyo Co Ltd).

[3] C-322/10 (Medeva), C-422/10 (Georgetown University et al) and C-630/10 (University of Queensland, CSL Ltd).

[4] C-125/10 (Merck & Co) and the analysis of that ruling in Snodin M, "European Court Ruling on SPCs brings relief to industry", Scrip Regulatory Affairs, January 2012, 7-8.

[5] This concept was first proposed in Snodin M and Miles J, "Making the Most of Paediatric SPC Extensions", The Regulatory Affairs Journal – Pharma, 2007, 18(7), 459-463

[6] C-442/11 (Novartis AG v Actavis UK Ltd.)

[7] C-431/04, where the Court of Justice decided that a substance that does not have therapeutic effect on its own and which is used to obtain a certain pharmaceutical form of the medicinal product is not covered by the concept of 'active ingredient', which in turn is used to define the term 'product'.

[8] An SPC to escitalopram has already been held invalid by the Belgian District Court, in view of the decision in MIT and Lundbeck's submission to regulatory authorities that the R-enantiomer in the prior-authorised racemate (citalopram) "does not contribute significantly to the pharmacological effect".

[9] C-202/05, where the Court of Justice ruled that the medical use of an active ingredient cannot form an integral part of the definition of the product.

[10] C-31/03, where the Court of Justice ruled that a prior veterinary authorisation for a product prejudices the grant of an SPC based on the first human authorisation for the same product.

[11] This point is argued in Snodin M, "Every day counts: why pharmaceutical companies in the EU need to make sure that they get the right SPC term", Scrip Regulatory Affairs, October 2011, 6-7.