



# The Guide to Life Sciences: Key issues for senior life sciences executives

2024

**What rights holders need to know  
about patent-term extensions in  
Europe**

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The fourth edition of the Guide to Life Sciences delivers key analysis designed to help senior life sciences executives better understand the strategic and legal IP challenges that they face around the world. This specialist intelligence will help them to protect, enforce and monetise the IP rights that are so crucial to businesses in the space.

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# What rights holders need to know about patent-term extensions in Europe

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Patent term extensions via supplementary protection certificates (SPCs) play a key role in the protection of drugs and plant protection products in Europe. Understanding their complex legal framework is just as crucial.

As the European Court of Justice (ECJ) has seen an overwhelming number of referrals regarding patent term extensions in recent years, the interpretation of the law in this area has become increasingly complex. This article provides up-to-date answers to the most frequently asked questions on SPCs and elucidates the impact of the entry into force of the Agreement on the Unified Patent Court (UPC) on SPCs.

### **WHAT IS AN SPC?**

SPCs can provide a patent term extension of up to five years and compensate patent owners for the regulatory delays caused by marketing authorisation procedures for medicinal and plant protection products.

### **FOR WHICH COUNTRIES CAN SPCS BE OBTAINED?**

SPCs for medicinal products in the European Union are governed by EU Regulation 1768/92, which came into force on 2 January 1993 and was codified and replaced by EU Regulation 469/2009. A similar legislative framework is in place for SPCs for plant protection products. These regulations apply in all EU member states. Of the non-EU countries for which European patents can be granted, only some (eg, Switzerland but not Turkey) have SPC legislation in place. Only SPCs within the European Union are discussed here.

### **WHAT IS THE DURATION OF AN SPC?**

SPCs extend the patent term for a period that is equal to the time that elapsed between filing the patent application and the first EU marketing authorisation, minus five years. The overall term of an SPC may not exceed five years. In calculating the duration of SPCs, the first marketing authorisation in the European Economic Area (EEA) (ie, the European Union plus Iceland, Liechtenstein and Norway) is important (article 13). In *Seattle Genetics* (C-471/14) the ECJ clarified that the date of the first marketing authorisation is the date of notification of the decision granting the marketing authorisation. SPCs can be corrected accordingly on request, as clarified by the ECJ in *Incyte* (C-492/16). A first marketing authorisation in non-EEA country Switzerland can also count as a first authorisation in the EEA because, up to 1 June 2005, it automatically extended to Liechtenstein (an EEA member) on the same day (see *AstraZeneca*, C-617/12). Today, this extension applies only with a certain delay but may still be important for calculating the SPC term.

According to EU Regulation 1901/2006, the SPC term can be further extended by six months if the marketing authorisation preparations included clinical trials specifically addressing paediatric use of a drug. The ECJ clarified in *Merck* (C-125/10) that an SPC can also be granted with a zero or negative term. This can be desirable, as paediatric extensions are possible only if an SPC is in place. A six-month extension of a six-month negative-term SPC will result in a positive term extension.

### **WHAT SUBJECT MATTER IS ELIGIBLE FOR SPC PROTECTION?**

For pharmaceutical SPCs, only active ingredients (including derivatives thereof – eg, salts or esters (*Farmitalia/Idarubicin*, C-392/97)) or (fixed-dose) combinations of active ingredients

protected by a basic patent and having marketing authorisation as a medicinal product can be the subject of an SPC. 'Basic patent' means (article 1):

- a patent protecting the active pharmaceutical ingredient as such;
- a process to obtain the product; or
- an application of the product.

In *Boston Scientific* (C-527/17), the ECJ confirmed that medical devices, even if they comprise active ingredients, cannot be the subject of an SPC. In *Abraxis Bioscience* (C-443/17), the ECJ held that an SPC cannot be granted for a new formulation of an old active ingredient in case that active ingredient has already been the subject of a marketing authorisation. Finally, according to *Santen* (C-673/18), an SPC cannot be granted for a different therapeutic application of an active ingredient. In particular, the ECJ ruled that a marketing authorisation cannot be considered to be the first marketing authorisation, for the purpose of article 3(d), where it covers a new therapeutic application of an active ingredient, or of a combination of active ingredients, and that active ingredient or combination has already been the subject of a marketing authorisation for a different therapeutic application.

### **WHAT ARE THE CONDITIONS FOR OBTAINING AN SPC?**

SPC applications must be filed with each national intellectual property (IP) office on a country-by-country basis (article 9). The filing deadline is six months from receiving the marketing authorisation for that country (nationally or centrally via the European Medicines Agency) or within six months of obtaining the basic patent, whichever is later (article 7). Calculation of the SPC filing deadline takes into account the notification date of the first market approval in the country of filing, not the first market approval in the EEA. If the marketing authorisation is granted only after expiry of the basic patent, this leads to an irremediable deficiency, as confirmed in *MSD* (C-567/16). In addition to the regular SPC term, a six-month paediatric extension is possible. Paediatric extensions can be applied for together with the SPC application or up to two years before expiry of the SPC. An SPC may be granted only to the basic patent owner or its successor in title (article 6) if the following conditions are met at the SPC application filing date (article 3 (a) to (d)):

- the product is protected by a basic patent in force;
- a valid marketing authorisation has been granted;
- the product has not already been the subject of an SPC belonging to the same person; and
- the marketing authorisation is the first to have been granted for this product in the country for which the SPC application is filed.

### **WHAT CRITERIA SHOULD BE USED TO DETERMINE WHETHER A PRODUCT IS PROTECTED BY A BASIC PATENT?**

What is meant by the product needing to be 'protected' by the basic patent in article 3(a) is one of the most highly debated and open questions in SPC law, despite the many ECJ decisions on the matter. In November 2011 in a quintet of landmark decisions led by *Medeva BV* (C-322/10), the ECJ put an end to the fight between advocates of the infringement test and the disclosure test. The ECJ took the middle ground by setting out a unique criterion – namely, that the product must be 'specified [or identified] in the wording of the claims'.

However, what degree of 'specification/identification in the wording of the claims' is necessary and sufficient remained unclear and is still a major matter of dispute. In *Eli Lilly* (C-493/12), the ECJ provided some guidance, stating that the active ingredient need not be identified in the claims of the patent by a chemical name or structural formula, but that functional claim language (in that case an antibody binding to a specific target) may also suffice. Claims would not have to expressly mention, but would need to 'relate, implicitly but necessarily and specifically' to the active ingredient in question.

A general question on the interpretation of article 3(a) was again referred to the ECJ in the *Teva UK* case (C-121/17), which was heard and decided by the Grand Chamber in 2018. The ECJ held that for combination products that article 3(a) required, at the filing or priority date of the basic patent:

- the combination of active ingredients must necessarily, in the light of the description and drawings of the patent, fall under 'the invention covered by that patent'; and
- each of the active ingredients must be 'specifically identifiable'.

For the latter, all information disclosed by the basic patent and the prior art (ie, not only the common general knowledge) at the filing or priority date of the basic patent can be taken into account.

Regarding the first criterion, the ECJ in *Teva UK* again emphasised the primacy of the claims and their interpretation as governed by article 69 of the European Patent Convention for determining what is protected under article 3(a). That this is a matter of national or European patent law (ie, non-EU law) and must be decided by the national courts, was already the ECJ's position in its first judgment on article 3(a) (*Farmitalia* (C-392/97)). In *Royalty Pharma Collection Trust* (C-650/17), the ECJ decided that a product is not protected by a basic patent in force, within the meaning of article 3(a), if, although it is covered by the functional definition given in the claims of that basic patent, it was developed after the filing date of the application for the basic patent, following an independent inventive step.

When prosecuting patent applications for new active pharmaceutical ingredients, it is highly advisable to ensure that all potential products (individually and in combination) are expressly mentioned in the claim language to avoid any later article 3(a) discussions.

### **WHAT IS THE SCOPE OF PROTECTION AFFORDED BY AN SPC?**

The protection conferred by an SPC should – within the limits of protection conferred by the basic patent – extend only to the product covered by the marketing authorisation and for any medicinal use of the product authorised before expiry of the SPC (article 4). In *Novartis* (C-442/11 and C-574/11), the ECJ confirmed that an SPC provides the same protection as the basic patent against unauthorised use of the product in the form of any medicinal product that contains that product. Accordingly, sale of a combination product A+B infringes an SPC for A. SPCs also cover derivatives if they have the same medical effect and are also included in the scope of protection of the basic patent. Paramount is the scope of protection provided by the basic patent.

### **HOW MANY SPCS PER PRODUCT AND PER PATENT?**

As a rule, an SPC can cover only a single product. The ECJ addressed the question of whether a patent protecting different products can also serve as a basis for more than one SPC in *Actavis I* (C-443/12), *Actavis II* (C-577/13) and *Georgetown II* (C-484/12).

In *Actavis I*, the ECJ considered that, in principle, it is possible to obtain several SPCs on the basis of a patent protecting several different products, provided that each (combination) product presents a core inventive advance and is protected as such by the basic patent. The additional core inventive advance criterion that the ECJ introduced in its assessment of article 3I makes it necessary to evaluate each case individually. In *Actavis I* and *II*, patents claiming an active ingredient A as the subject matter of the invention, and for which an SPC had already been obtained, were found to contravene article 3(c) and therefore could not serve as the basis for a second SPC on the combination of this active ingredient with another substance.

In *Georgetown II*, the ECJ allowed a basic patent claiming a combination of active pharmaceutical ingredients A+B for which a combination SPC had already been obtained to serve as a basis for a second SPC for one of those active pharmaceutical ingredients if this was also individually protected as such by that patent.

In *Royalty Pharma Collection Trust (C-650/17)*, it was found that the core inventive advance criterion set out in *Actavis I* does not apply to article 3(a). This opened the question whether a reassessment of the prior ECJ case law on article 3(c) would be needed. Two currently pending referrals before the ECJ (*Teva BV (C-119/22)* and *Merck Sharp & Dohme (C-149/22)*) both of which concern the interpretation of article 3(c) in light of the interpretation of article 3(a) in *Teva UK* and *Royalty PharmaCollection Trust*, may help to shed light on this question.

Article 3(c) as interpreted by the ECJ prohibits the grant of a second SPC for the same product only in case of identity of the applicants. Multiple SPCs for the same product based on the same marketing authorisation are possible when the underlying patents are owned by different parties, which is known as a 'third-party SPC' (see *ARP Manufacturing (C-482/07)* and *Biogen (C181/95)*). To avoid any article 3(c) discussions, it is worth exploring the option of splitting up subject matters (eg, mono and combination products) into patent applications owned by different legal entities.

### **HOW CAN SPCS BE FORFEITED OR LOST?**

SPCs can be invalidated if they were granted contrary to the provisions of article 3. In addition, SPCs are linked to the validity of the basic patent for which they were issued. Therefore, an SPC becomes invalid if the underlying basic patent prematurely lapses or is revoked, or if it is limited to an extent that it no longer protects the product for which the SPC was granted (article 15). Depending on the nature of the basic patent and on the opt-out status thereof, SPCs can be invalidated by third parties in national nullity proceedings before the competent national courts or in nullity proceedings before the UPC at least during a transitional period of seven years.

### **WHAT IMPACT WILL THE ENTRY INTO FORCE OF THE UNIFIED PATENT CONVENTION HAVE ON SPCS?**

An SPC can also be granted on the basis of a European patent with unitary effect (unitary patent) if the unitary patent is effective in the respective EU member state in which the SPC application is filed. The SPC applications based on unitary patents must be filed with each national IP office on a country-by-country basis. The territorial scope of protection of such an SPC is limited to the EU member state that granted the SPC, although the underlying unitary patent is uniformly valid in all participating member states. An SPC with unitary effect in

all participating member states does not yet exist (although there are plans to introduce a unitary SPC in the future).

SPCs that have been granted or are being applied for on the basis of a European patent or a European patent with unitary effect fall under the jurisdiction of the UPC, while national courts retain jurisdiction for SPCs that have been granted or are being applied for on the basis of national patents. During a transitional period of at least seven years for SPCs based on classical European bundle patents there will be a competing jurisdiction of both the UPC and the national courts. During this period, it will be possible to opt-out of the jurisdiction of the UPC by filing an opt-out declaration for the respective European patent (thereby automatically including granted or future SPCs based on this patent) as long as no legal action with regard to this European patent is pending at the UPC. Opting out is not possible for unitary patents and, therefore, SPCs granted on the basis of unitary patents fall under the exclusive jurisdiction of the UPC.

### **PROPOSALS FOR A UNITARY SPC AND CENTRALISED SPC EXAMINATION**

Significant changes to the SPC system have been proposed in a draft SPC regulation published on 27 April 2023. The new proposal serves two main goals: (1) to establish a centralised review procedure and (2) create a unified SPC. The new examination procedure is intended to simplify the existing SPC system, reduce fragmentation between member states and provide more legal certainty with regard to the granting and refusal of SPCs.

It is proposed to establish a new SPC unit within the European Union Intellectual Property Office (EUIPO). The examination would be carried out by a new panel composed of one member of the EUIPO and two qualified examiners from the national patent offices of the member states.

The centralised procedure may become mandatory if the basic patent is a European patent (standard EP or unitary patent (UP)) and the marketing authorisation has been granted through the centralised procedure.

Contrary to the present system, the proposal provides the possibility of filing third party observations within three months from the publication of the SPC application and third-party oppositions within two months from the grant of the SPC. Decisions may be appealed (before an EUIPO Board of Appeal) and further contested before the General Court of the EU and ultimately the Court of Justice of the European Union. After grant, a declaration of invalidity may be filed with the EUIPO.

For obtaining the proposed new unitary SPC, the basic patent would need to be a UP and the marketing authorisation a centralised one. The unitary SPC would be effective in all member states where the basic patent has unitary effect. Since the unitary SPC would not cover territory outside the unitary patent system, there may be an option to file a combined SPC application, including a request for grant of a unitary SPC and national SPCs.

Although significant changes to the examination procedure are proposed, the provisions governing the grant, duration and effects of the unitary SPC are proposed to be identical to the existing SPC regime. The proposals for amending the SPC system will be discussed by the European Parliament and the Council and may therefore be subject to change before final adoption.

### **CONCLUSION**



The low number of SPC applications filed annually, coupled with the tremendous economic importance of SPCs and the complexity of parallel filings in potentially all EU member states, calls for appointing an experienced lead counsel in Europe to manage, coordinate and oversee the diverse national SPC examination proceedings.

Although having been in force for more than 20 years and the subject of a plethora of ECJ decisions, the SPC regulation is still one of the most unsettled and controversial areas of European IP law. Many users of the SPC system have been disappointed by the guidance given by the ECJ, which often seems to open up more new questions than it answers.

In regard to the unitary patent system, the currently envisioned legal framework already provides for SPCs derived from European patents to fall under the jurisdiction of the UPC if no opt-out is declared.

On 27 April 2023, the European Union's draft legislation for a reform of the existing legal regime on SPCs was published including the establishment of a centralised SPC filing and examination procedure before the EUIPO as well as the introduction of a unitary SPC. This draft regulation is not yet in force. If adopted into legislation, the proposed reforms will have far-reaching implications for the practicalities of obtaining SPCs in Europe and may also affect the substantive aspects of SPC law.

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