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The need-to-know facts 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 chapter provides up-to-date answers to the most frequently asked questions 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 previously it automatically extended to Liechtenstein, an EEA member (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 recently confirmed that medical devices, even if they comprise active ingredients, cannot be the subject of an SPC. The question of whether new formulations of known active ingredients could give rise to SPCs after all is open once again given the *Abraxis Bioscience* (C-443/17) referral pending before the ECJ.

What are the conditions for obtaining an SPC?

SPC applications must be filed with each national 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.

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A general question on the interpretation of Article 3(a) was again referred to the ECJ in the recent *Gilead* 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.

As regards the first criterion, the ECJ in *Gilead* 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)). Given the referring court's and the advocate general's controversial discussion of an allegedly additional 'core inventive advance' test under Article 3(a), the ECJ's silence on such a test in *Gilead* should be interpreted as a rejection thereof, at least regarding its relevance for determining what is protected pursuant to Article 3(a).

Two further referrals concerning Article 3(a) are currently pending with the ECJ. Both relate to mono-products. In *Sitagliptin* (C-650/17), the question is whether the active ingredient (Sitagliptin) is protected despite a purely functional claim language (a dipeptidyl peptidase IV inhibitor) and a lack of explicit disclosure in the basic patent. In *Sandoz* (C-114/18) the active ingredient (darunavir) falls under the claimed

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general Markush formula, but neither the compound nor the specific substituent required to arrive at the compound is concretely disclosed in the basic patent. Given the importance of Markush-type claims for the pharmaceutical industry, the *Sandoz* case has significant practical relevance.

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 in order to avoid any later Article 3(a) discussions.

What is the scope of protection afforded by an SPC?

The protection conferred by an SPC shall – 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.

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 3(c) 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. As the Grand Chamber in the more recent *Gilead* decision was silent on an additional core inventive advance criterion with respect to Article 3(a), it must be assumed that this criterion applies only to Article 3(c).

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.

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 may be advisable to split up subject matters (eg, mono and combination products) into patent applications owned by different legal entities.

Can second medical use patents give rise to SPCs?

According to earlier ECJ case law, a first marketing authorisation for a product in the EEA for any given indication prevented SPCs to be granted for a different indication later on. This was overruled in *Neurim* (C-130/11), where the ECJ held that the mere existence of an earlier marketing authorisation obtained for a veterinary medicinal product does not preclude the grant of an SPC for a different application of the same product (in that case, a human therapeutic application unrelated to the earlier veterinary indication).

The applicability of this decision and its implications are controversial. Some argue that it may have opened up the possibility of obtaining SPC protection for second medical uses or even new formulations. There are two referrals pending before the ECJ in this respect. In *Abraxis Bioscience* (C-443/17) the question is whether an SPC can be granted for a new formulation (albumin bound nanoparticles) of an old active ingredient (paclitaxel). However, the advocate general's non-binding opinion answers in the negative. The latest referral, *Santen* (C-673/18), more broadly asks whether *Neurim* should be limited to cases with prior veterinary applications or applied more broadly also to new therapeutic indications in general or to new formulations, dosages and/or modes of administration.

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). SPCs can be invalidated by third parties in national nullity proceedings before the competent national courts.

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. Regarding the planned unitary patent system, the currently envisioned legal framework already provides for SPCs derived from European patents to fall under the jurisdiction of the Unified Patent Court if no opt-out is declared. However, a legal framework for a unitary SPC still needs to be drafted and negotiated. A key area of dispute in this respect is the nature and identity of the granting authority. Given the abovementioned uncertainties in existing SPC law, it may be advisable, instead of drafting a new unitary SPC regulation, to make use of the opportunity and expand, reword and clarify the existing SPC regulations. The EU commission asked the Max Planck Institute for Innovation and Competition to carry out a comprehensive study on the SPC system, which was published in May 2018. The study elaborates many good reform proposals, but also troubling ones such as the recommendation of an SPC manufacturing waiver. It remains to be seen which if any of these proposals will give rise to new legislation in the future. One thing is certain, exciting times lie ahead. *iam*

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