Recent amendments to the SPC Regulation

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Recent amendments to the SPC Regulation

By Derk Vos, Maiwald Patentanwalts- und Rechtsanwaltsgesellschaft mbH

In the life sciences industry, patent protection for innovative medicinal products is pivotal to the commercial success of new drug products. Before commercially exploiting such an invention, the patentee must obtain a regulatory marketing authorisation for the medicinal product from a competent health authority, such as the European Medicines Agency, which may take several years.

In order to compensate for the reduced time for effective commercial exploitation of such patents and to support innovation in the European Community, supplementary protection certificates (SPCs) were introduced in the European Union in the early 1990s by EU Regulation 1768/92. SPCs can extend the protection conferred by a so-called 'basic patent' covering the marketed medicinal product by a maximum of five years. A further six-month extension on medicinal products for use in paediatrics may also be available under EU Regulation 1901/2006.

Although they are accessory to patents, SPCs are an IP right *sui generis*, which must be applied for on a country-by-country basis and which are granted to the owner of a basic patent by the respective national authority. Even though their implementation by EU Regulation 1768/92 aimed for unitary application at community level, facilitating free movement of medicinal products within the community, it has proven difficult to prevent divergence by granting authorities and courts through different interpretations of the law and European Court of Justice (ECJ) case law, leading to a disharmonised situation contrary to the aims of the SPC Regulation.

The European Commission's efforts for a single market strategy within the community resulted in proposed changes to the existing SPC Regulation in order to address competitive disadvantages of EU-based generic manufacturers regarding their non-EU competitors, as EU-based companies would not be able to manufacture within the European Union during the lifetime of an SPC, either for export to non-EU countries (third countries) or for day-one entry to the EU market. According to the European Commission, this problem has been aggravated by the developments of the generics and biosimilars markets in recent years, whereby, after the expiration of protection of the reference medicine conferred by a patent or SPC, only the first few generics or biosimilars to enter the market are able to gain a significant market share and be financially viable. The situation resulted in moving manufacturing and jobs to third countries outside the European Union, which was considered contrary to the goals of the original SPC Regulation. Therefore, the legislature aimed for an amendment of the respective SPC Regulation to correct the unintended effects for EU-based generic and biosimilar manufacturers.

This chapter highlights the most important amendments to the SPC Regulation recently introduced by EU Regulation 2019/933 and discusses where further clarification of the amended regulation may be required. Further, recent ECJ decisions are discussed regarding Article 3(a) of the SPC Regulation relating to one of the core aspects of SPCs – namely, the products considered to be protected by a basic patent and the implications for patentees and generics companies.

Amendments to EU Regulation 469/2009

The new EU Regulation 2019/933 (20 May 2019) (known as the 'Waiver Regulation'), amending EU

Regulation 469/2009 (the 'SPC Regulation'), will no longer confer protection against the making of a product or a corresponding medicinal product containing that product for export purposes to third countries, or against the manufacture and stockpiling for day-one entry into the EU market after the SPC has expired. The amendments are effective for any SPC applied for in an EU member state on or after 1 July 2019. While the making of the product for export purposes is permitted during the SPC's lifetime, stockpiling for EU day-one entry must not take place earlier than six months before expiry of the SPC (Article 5(2)(a)(iii) of the Waiver Regulation). The Waiver Regulation requires that the maker of the product inform the granting authority in the respective member state, as well as the SPC holder, where the making will take place, by appropriate and documented means no later than three months before the start of the making or the first related act, prior to making, that would otherwise be prohibited by the protection conferred by the SPC. If making or the first related acts take place in more than one member state, a corresponding notification for each of the member states is required. In case the maker does not produce the product itself, the maker must inform persons within its supply chain that the product is covered by the exception of the manufacturing waiver and its consequences. Failure to comply with this information requirement entitles the SPC holder to enforce its rights under the SPC (eg, Item 20 of the Waiver Regulation).

Even though the Waiver Regulation does not explicitly address the issue, it should be clear that for SPCs granted with a term of less than six months (or even with a negative term), the six-month deadline for stockpiling cannot pre-date the patent expiry.

The Waiver Regulation further imposes a labelling requirement on the maker in respect to the products or medicinal products containing those products to be exported (Item 21). By such labelling, re-import or usage of the product within the European Union that has been produced for export purposes only should be prevented. The Waiver Regulation does not allow for the making of the product within the European Union for export to another EU member state, wherein the said product is not subject to SPC protection. Despite the lack of SPC protection in such markets, it would be necessary to pursue either production in the respective member state itself or import of the product produced in third countries.

The exception provided by the regulation will not apply to SPCs that have already taken effect at the date of entry into force of the new Waiver Regulation (1 July 2019). For those SPCs that were applied for before this date, but take effect only afterwards, the exception will apply from 2 July 2022, to allow the holder a reasonable transition period to adapt to the changed legal context.

To assess whether the amendments introduced meet the intention of the legislature, a five-year period for evaluation of the manufacturing waiver is anticipated.

It remains to be seen whether the amendments introduced will have the intended effect. In any case, it is to be expected that disputes between SPC holders and makers on various aspects of EU Regulation 2019/933 (eg, the information obligation) will arise. On the one hand, the Waiver Regulation requires that the maker inform the SPC holder of the necessary and appropriate information to assess whether the SPC holder's rights are respected (Item 15). On the other hand, the respective form annexed to the Waiver Regulation (eg, Form P2041 of the German Patent and Trademark Office) provides only basic information, which may not be considered sufficient by the SPC holder to allow for such an assessment in every case. Moreover, clarification may be required on the consequences when the appropriate and documented means are considered insufficient or incomplete by the SPC holder, but no confidential or commercially

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sensitive information should be provided by the maker. Since the provision of information to the national authority of the member state and to the SPC holder is a prerequisite for benefiting from the exception, and non-compliance with the requirements may lead to a loss of said benefit, it is to be expected that the level of information to be provided will require clarification and may need preliminary ECJ rulings. Further, the method of notification or service of the information to the SPC holder may result in controversy, since the information is not officially served to the SPC holder by the national authority but by the maker. Such service may, in particular, be difficult for third-country SPC holders and it is unclear whether service to the agent of record is considered sufficient for such notification. In any case, it appears advisable for SPC holders to keep the register updated to receive a corresponding notice without delay.

The amendments introduced will likely require further clarification and SPC holders will need to develop strategies to assess whether their rights are respected and how to tackle any possible lack of information from the maker. Makers should carefully assess which information must be provided to the national authorities and the SPC holder to meet the obligations of the Waiver Regulation, but avoid giving away more information than necessary.

Recent ECJ case law on Article 3(a) of the SPC Regulation

Article 3 is the central provision of the SPC Regulation. It provides for the four cumulative requirements for granting an SPC for a respective product. According to Article 3(a), a product is eligible for an SPC only if the product is "protected by the basic patent in force". Article 3(a) has been subject to various preliminary ECJ rulings in the past decade, in order to clarify the conditions to be met for a product to be protected by a basic patent in force.

In *Teva* (Case C-121/17), the ECJ was asked by the High Court of Justice of England and Wales to clarify the conditions under which a product is protected by the basic patent in force. The referring court also intended to clarify whether the so-called 'core inventive advance' approach is applicable for Article 3(a) of the SPC Regulation, according to which it is assessed whether the product is covered by the 'core of the invention' of the basic patent, but does not only relate to further variants thereof.

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Derk Vos is a partner at Maiwald. His work focuses on patents in the pharmaceutical and chemical fields, particularly opposition and appeal proceedings before the EPO and nullity proceedings before the German Federal Patent Court, including various cases where there is a co-pending litigation. Dr Vos provides counselling on patent portfolio strategies and portfolio management across a wide range of industries. He advises his clients on IP-related matters including validity, infringement and nullity proceedings, supplementary protection certificates, due diligence and freedom-to-operate issues. He has extensive expertise in litigating (both national and cross-border) in several technical fields, including polymers, diagnostics and pharmaceuticals (eg, oxycodone, tenofovir/emtricitabine, latanoprost, ezetimibe/simvastatin and sitagliptin/metformin).

The underlying case in C-121/17 involved an anti-HIV combination drug marketed by Gilead as 'Truvada', comprising the two active ingredients tenofovir disoproxil and emtricitabine. The first active ingredient, tenofovir, was explicitly disclosed in the basic patent. However, for the combination, the patentee had to rely on a claim that covered tenofovir but did not mention the second active ingredient, emtricitabine, but instead referred to the rather general expression of 'other therapeutic ingredients', which was an optional feature only. Neither emtricitabine nor its compound class was mentioned in the claims or description of the basic patent. Therefore, it must be clarified whether the optional term 'other therapeutic ingredients' is considered to necessarily fall

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under the invention covered and is a specific enough functional term for emtricitabine.

The ECJ confirmed that active ingredients do not need to be expressly mentioned in the claims to be protected, and set out criteria that a basic patent must meet in order to 'protect' a combination of several active ingredients with a combined effect.

In its decision the ECJ defined that the claims of the basic patent must necessarily and specifically relate to the combination in question. For that purpose, the ECJ stated that for a person skilled in the art, and on the basis of the prior art at the filing date or priority date of the basic patent, the combination of those active ingredients must necessarily, in light of the description and drawings of that patent, fall under the invention covered by that patent. Further, each of those active ingredients must be specifically identifiable, in light of all the information disclosed by that patent (see C-121/17, Order).

The ECJ emphasised that the protection conferred by the SPC should not extend beyond the invention covered by the patent. According to the ECJ, this could be the case if the SPC did not relate to research results claimed under that patent (C-121/17, Item 40). For the determination of a product to be specifically identifiable, the skilled person may use the information disclosed in the basic patent itself and that in the prior art at the relevant effective date of the patent.

The ECJ did not, however, explicitly address the aspect of the core inventive advance approach in view of Article 3(a) of the SPC Regulation in its decision, so it remained unclear whether the ECJ rejected the concept itself or just used different terminology in this context.

It was hoped that the subsequent referral to be decided by the ECJ on Article 3(a), in *Royalty Pharma* (Case C-650/17), would shed more light on the open aspects. In fact, the referring court explicitly maintained the referral after the issuance of C-121/17, emphasising the need for continued clarification on the core inventive advance concept. Therefore, it may not come as a surprise that the recently issued decision C-650/17 (at least) provides clarity on this aspect, but it may give rise to further issues, in the context of Article 3(a).

The case underlying C-650/17 (*Royalty Pharma*) was concerned with the new use of DPIV-inhibitors in the treatment of *diabetes mellitus* – a treatment method for the disease that had not been previously described in the prior art. The basic patent discloses individual DPIV-inhibitors and points out that, based on the data provided, the new treatment concept can be generally extended to the whole class of DPIV-inhibitors. Sitagliptin, a DPIV-inhibitor marketed for the treatment of *diabetes mellitus*, is not individually disclosed in the basic patent. The active ingredient was, however, developed by a licensee of the basic patent after its filing. Sitagliptin is also protected by a later filed composition of matter patent to the licensee. The German Federal Patent Court referred the case for a preliminary ruling to the ECJ, requesting answers to the question whether it is sufficient that the product meets the general functional definition of a compound class mentioned in the claims, but apart from that is not individualised as a specific embodiment in the basic patent. Further, the Federal Patent Court wanted to know if it matters whether the product in question was developed only after the filing date of the basic patent based on independent inventive activity.

The ECJ re-emphasised the pivotal importance of the claims for the interpretation and that the SPC would be limited to the technical features of the invention claimed in the basic patent, but may not be extended to the 'core of the inventive activity' (see C-650/17, Item 31). Following the referring Federal Patent Court's interpretation, the ECJ rejected the application of the 'core inventive advance' concept under Article 3(a) (its application under Article 3(c) remains unaffected).

Regarding the Federal Patent Court's referral questions directed to the degree of specificity of the disclosure for the product in question, the

ECJ again confirmed that the grant of an SPC is not prevented by the fact that the product in question is not disclosed in individualised form in the basic patent. In this context, the ECJ stated that the skilled person must be able to directly and unambiguously conclude that the product is covered by the subject matter protected by the patent (see C-650/17, Item 42). On the issues of the timing of the development of the product, the ECJ clarified that if the possibility were provided to include results from research conducted only after the effective date of the patent, the SPC holder would unduly benefit from protection of results that were not available on the effective date. Therefore, the ECJ concluded that a product that is only developed after the effective date on the basis of 'independent inventive activity' is not covered by the protection provided by the subject matter of the patent (see C-650/17, Items 44-49).

It remains to be seen how the national granting authorities and courts will interpret the criteria set by the ECJ. Whether a product that is not individualised in the basic patent requires an 'independent inventive activity' may be difficult to assess for a national authority examiner or by a court. For example, in cases where no later patent for the individualised product in question exists, does the examiner have to assess on his or her own motion whether the product is – in view of the prior art at the effective date – to be based on independent inventive activity? Such an approach may require the assessment of inventive activity for the product in question in view of a basic patent and may include patentability assessments. Even where a later separate patent exists that individualises the product in question, this new criterion may still be problematic since it must be assessed whether the product is to be considered to be based on independent inventive activity. How the term 'independent' should be interpreted in this context will certainly be the subject of future discussions.

If, however, in this context, the sole existence of a later patent individualising the product is considered sufficient to deny the fulfilment of the requirements of Article 3(a), this may question the validity of various SPCs granted in the past. For example, it is common practice that new compounds are disclosed and claimed in an initial application, as well as individually in their respective pharmaceutically acceptable salts. Later studies on the compounds may show that a specific salt, not individualised in the initial application, exhibits beneficial properties, which result in additional (later) patent filings covering the specific salt. Would an SPC for a specific salt be considered invalid if that specific salt of the said compound is not individualised in the earlier basic patent, but in the later one?

In case the courts pursue a narrow interpretation of the term 'independent inventive activity', it may well be that the granting practice of the national authorities will have to be adapted for such an interpretation. Therefore, patentees should carefully select suitable basic patents for their SPC applications. In view of the present decisions, generics companies should analyse whether the new criteria set by the ECJ will open new opportunities for early market entry. *iam*

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