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SPCs and the European Jurisprudence on Patent Term Extensions

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I. Importance of SPCs

Patent extensions are vitally important in the life sciences industry. They are highly valuable, as they extend the period of exclusivity in which the patentee can market a medicinal product beyond the expiry of the term of the patent for that product at the point in time where profitability is typically at its highest.

Patents in the life sciences sector can protect products that can generate billions of dollars a year. Compared to the normal 20-year life of a patent the maximum patent extension in Europe of 5 years and 6 months (with paediatric extension) may appear unexceptional, but nonetheless in the life sciences sector this can be commercially very significant.

The exclusivity conferred by a Supplementary Protection Certificate (SPC) operates after the end of the patent's life. This is typically the most valuable period from a patentee's perspective, as the market and reference prices for that product will have been well-established, the product-profit cycle is at its peak, and the patentee can reap the benefit of all the efforts that have already been made to establish the product in the market.

Patent extensions have now been made easier to obtain following a recent series of judgments of the Court of Justice of the European Union. The following is a strategic overview of the key issues arising from this jurisprudence — the prime focus in any SPC litigation is whether they can be unpicked and how.

II. SPCs and the SPC Regulation

The European SPC is a *sui generis* intellectual property right created to compensate life sciences companies for the loss of commercially exploitable patent term caused by the delays inherent in the regulatory approval system. It achieves that by extending the term of the corresponding patent by up to 5 years.[1]

The general rule with patents is that once a patent has been applied for the patentee can immediately start exploiting the invention on the market. This is not the case for patents for medicinal products, where the patentee cannot commence exploiting the invention on the market until an appropriate marketing authorisation (MA) has been granted.

The average time to market for a medicinal product is around 12 years. Because the necessary supporting clinical trials for the MA — and the MA process itself — can take this long, patentees of medicinal products face the potential loss of a substantial period of the exclusivity conferred by the patent before they can market their products; and broadly, the more significant the invention the longer this process takes.

The SPC system is therefore intended to compensate patentees for this regulatory burden given that the length of patentees' effective patent monopolies can be significantly eroded by this regulatory process.

The SPC Regulation[2] is the result of the interaction between the laws and practices of the patent system and of the medical regulation system. The former is a question of national law for member states — no pan-EU system yet being in force — and the latter is the result of the harmonised EU system. The SPC Regulation therefore operates at the interface between what is meant by patent protection of "products" and by authorisation to market "medicinal products".

The practical difficulties encountered with SPCs largely mirror those encountered by life sciences companies when navigating the routes to patent enforcement across Europe — many of the same strategic and tactical considerations that are engaged in developing litigations strategies will apply.[3] Because SPCs are granted by national patent offices (i.e. country by country) the result has been that the SPC Regulation has been applied differently across Europe. Fortunately, the recent series of CJEU judgments will go a long way to redressing this.

III. Legal Issues Surrounding SPCs

The circumstances in which an SPC may be granted — and can therefore be attacked — and the commercial significance this has (especially when faced with multiple generic or competitor entry) is potentially profound. For exactly the same reasons that an SPC is potentially of such significant commercial value to patentees, breaking them to gain access to a valuable market will be of particular interest to competitors and generics. They will therefore be focusing their attack on the validity of the SPC. If it is declared invalid, the market can be prised open.

Under SPC Regulation, Article 5 the grant of an SPC confers the same rights, and is subject to the same limitations and the same obligations as the basic patent. The SPC does not therefore affect the extent of protection conferred by the patent, which is still governed by national law in each applicable country.

The effect of an SPC is not formally to extend the duration of a patent. Instead, protection is given under Article 4 only in relation to the product covered by the MA and for any use of the product as a medicinal product that has been authorised before the expiry of the SPC. But subject to that, the SPC confers the same rights as the basic patent.

The following points will be of crucial significance.

IV. SPC Duration

(a) SPC and Paediatric Extension Standard Terms

The SPC Regulation provides that an SPC shall not be granted for more than 5 years.[4]

The SPC's term is calculated by deducting 5 years from the period that elapses between the patent's filing date and the date of grant of the MA, with the SPC taking effect at "the end of the lawful term of the basic patent".

The term (T) of an SPC can be calculated as follows, where A is the date of first MA in the European Union and B is the application date of the basic patent:

$$T = (A - B) - 5 \text{ years}$$

Thus where a basic patent was applied for on March 31, 2000 and the first MA was granted on March 31, 2007, namely 7 years later, the SPC term will be 2 years.

The commercial matrix changed in 2006 with the introduction of the Paediatric Regulation.[5] This provides for a 6-month extension for an SPC already in place for a medicinal product if it is for paediatric use, the underlying policy rationale being to incentivise research and development of paediatric medicines. This 6-month extension to the SPC is granted in exchange for including all studies conducted in compliance with an agreed paediatric investigation plan in the product information for the SPC application.[6] However — and this must be stressed — a paediatric extension can only be granted if an SPC is already in place.

In the example above, the SPC term with the paediatric extension will be extended to a total of 2 years 6 months.

(b) Negative Terms and Paediatric Extensions

Where an MA is granted within 5 years of the application date of the basic patent the result would be that any resulting SPC would have a negative term, and therefore be of no interest to rights holders.

However, after the introduction of the Paediatric Regulation in 2006 it is worth applying for an SPC and paediatric extension if the theoretical negative term for the SPC is less than 6 months, as the resulting paediatric extension will have a positive term (even if very short). The 6-month paediatric extension can turn a negative SPC term into a positive net term of additional exclusivity. For the reasons explained above, medicinal products are typically at their most profitable at their end of life, as even this very short term extension can allow the rights holder to generate significant additional profits.

The effect of a negative term SPC with a paediatric extension is as follows. Assume that the basic patent was applied for on March 31, 2000 and the first MA was granted on December 31, 2004. The overall term of the SPC with paediatric extension will be 3 months. The term of the base SPC will be minus 3 months, i.e. December 31, 2004 minus March 31, 2000 (4 years 9 months) minus 5 years, but the addition of the extension converts this into a positive term of 3 months.

Paediatric extensions to negative term SPCs will therefore only be effective where the MA is granted at least 4

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years and 6 months from the application date of basic patent, so that the 6-month paediatric extension can give rise to a positive additional period of protection.

At the end of 2011 the CJEU ruled on whether the SPC Regulation allows negative term SPCs.[7] The German Patent Office had refused to grant Merck an SPC for sitagliptin because the period between the application date of the basic patent and the date of the MA was less than 5 years. The CJEU held that:

- It is permissible to grant SPCs if the period of time between the filing of the patent application and the date of the first MA in the EU is shorter than 5 years.
- Although SPCs of negative or zero term serve no prima facie purpose, they are useful if one wanted to obtain a paediatric extension, and if a paediatric extension was not granted because a negative term SPC had been refused that may jeopardise the objectives of the Paediatric Regulation.
- The paediatric extension should commence on the date for the negative term SPC calculated in accordance with SPC Regulation, Article 13. The CJEU held that negative term SPCs should not be rounded to zero, as that would be contrary to the calculation specified by Article 13; it is therefore only where (A – B) in the formula T = (A – B) – 5 years comes to exactly 5 years that the SPC term will be zero.

In *Merck* the SPC had a term of minus 3 months and 14 days. The result of the CJEU decision was that the SPC plus paediatric extension resulted in an additional exclusivity of 2 months 16 days.

V. Obtaining an SPC

The conditions for obtaining an SPC are set out in Article 3 of the SPC Regulation, as follows:

(a) The product must be protected by a basic patent[8] in force;

(b) A valid MA[9] to place the product on the market as a medicinal product[10] must have been granted;

(c) The product[11] must not already have been the subject of an SPC; and

(d) The authorisation in (b) must be the first authorisation to place the product on the market as a medical product.

Under Article 6 the SPC "shall be granted to the holder of the basic patent or his successor in title".

Article 7 requires the application for an SPC to be lodged by the later of:

(i) 6 months from the date of grant of the first MA; or

(ii) 6 months following the grant of the patent.

Article 10(2) provides that an SPC application will be rejected if the SPC application, or the product to which it relates, do not meet the requirements of the SPC Regulation. Further, Article 15(1)(a) provides that an SPC will be invalid if, among other reasons, it was granted contrary to the provisions of Article 3. The latter two provisions explain the focus of competitor attacks on SPCs and paediatric extensions.

VI. Combination Products

The SPC Regulation operates at the interface between what is meant by patent protection of "products" and by authorisation to market "medicinal products". This has thrown up particular problems in practice where SPC applications have been made for combination products, as was the case in the conjoined CJEU decisions of *Medeva* and *Georgetown*.[12]

For public health policy reasons vaccines now often contain a combination of active ingredients aimed at a number of different diseases so that multiple immunisations can be given with only one injection. This approach has led to problems in obtaining SPC protection where national courts consider there to be a mismatch between the basic patent and the SPC application and/or the MA, e.g. where the basic patent relates to only one disease but the SPC or the MA covers multiple components of a multi-disease vaccine.

In these conjoined cases the CJEU was asked head on what is meant in Article 3(a) by "the product must be protected by a basic patent in force" and what the relevant criteria are to decide that. Must Article 3(a) be interpreted as precluding the competent national patent office from granting an SPC where the active ingredients specified in the application include active ingredients not mentioned in the wording of the claims of the basic patent relied on in support of the application?

In considering this issue the CJEU placed importance on the policy rationale underlying the SPC Regulation. This sets out to establish a uniform pan-EU solution that created an SPC which could be obtained by a national or European patentee on a uniform basis in each EU Member State. The SPC Regulation's aim was to prevent the heterogeneous development of national laws leading to further disparities which could create obstacles to the free movement of medicinal products within the EU, and a restrictive approach to the underlying objectives of the SPC Regulation would therefore be undesirable.

Specifically, the CJEU reasoned that:

- Article 5 provides that an SPC confers the same rights as conferred by the basic patent, and is subject to the same limitations and the same obligations. Article 3(a) therefore precludes an SPC being granted for active ingredients which are not specified in the claims of the basic patent.
- If a patent claims that a product is composed of two active ingredients but makes no claim to one of those active ingredients individually, an SPC cannot be granted on the basis of such a patent for the one active ingredient considered in isolation.
- Article 3(a) therefore prevents SPCs being granted that cover active ingredients which are not specified in the claims of the basic patent relied on in support of the SPC application.

- The requirement that the "product" must be covered, as a medicinal product, by an MA does not rule out that the MA may cover other active ingredients contained in such a product. Moreover, under Article 4 an SPC is intended to protect the "product" covered by the MA, not the medicinal product as such.

- Provided therefore that the other Article 3 requirements are also satisfied, an SPC can properly be granted for a combination of two active ingredients that correspond to those specified in the claims of the patent relied on, where the medicinal product for which an MA supporting the SPC application is submitted, contains not only that combination of the two active ingredients but also other active ingredients.

- However, only the MA for the first medicinal product placed on the EU market that comprises the combination of the two active ingredients identified in the patent claims among its active ingredients may be regarded as the first MA for that "product" as a medicinal product within the meaning of Article 3(d).

The CJEU has subsequently issued further judgments in other SPC cases concerning combination products.[13] In *Daiichi*, the terms of the CJEU's judgment made it clear that the decision in *Medeva* was not limited to multivalent vaccines but applied to all types of combination products. In *Yeda*, the CJEU ruled that an SPC cannot be granted for Product X if the patent claims the combination of X + Y, yet the MA applies to Product X alone.

VII. SPCs and Product-by-Process Claims

The CJEU decision in *Queensland* concerned a parent patent covering certain active ingredients by product-by-process claims, and divisional patents claiming additional active ingredients. The relevant MAs relied on for the SPCs related to a combination of active ingredients from both the parent and the divisional patents.

The case turned on whether with a basic patent containing a product-by-process claim it is necessary for the medicinal product to be obtained via that process.

The CJEU held that it does not matter whether the medicinal product is obtained directly from that process or not, but held that Article 3(a) prevents "an SPC being granted for a product other than that identified in the wording of the claims of that patent as the product deriving from the process in question".

The position therefore is that an SPC cannot be granted for an active ingredient derived via product-by-process means if the resulting product is not specified or identified in the wording of the basic patent's claims. An SPC cannot be granted for a product other than that identified in the wording of the claims of that patent as the product deriving from the process in question — whether it is possible to obtain the product directly as a result of that process is irrelevant.

VIII. Only One SPC Per Basic Patent?

In *Biogen v. SKB* the Court of Justice ruled that there can be only one SPC per basic patent.[14] In *Medeva*, *Georgetown*, and *Queensland* the CJEU reiterated this prohibition.[15] It held that where a product is protected by a number of basic patents, each of those patents may be designated for the purposes of an SPC, but only one SPC may be granted for that basic patent.

Current patent office and industry practice in Europe is for multiple SPCs to be granted out of the same basic patent despite the prohibition against doing so from the earlier 1997 *Biogen* decision. This should remain possible provided the patent claims multiple active ingredients independently, i.e. not as part of a combination.

This potential conundrum has, helpfully, been considered by the English Patents Court responsible for the *Queensland* reference in the context of deciding how to apply the CJEU's ruling in that case.[16] The judge stated in terms that he was aware that some commentators have interpreted the Court of Justice's statement literally as meaning that there can only be one SPC per basic patent, whereas others have interpreted it as meaning that there can only be one SPC per product per patent. Relying on the approach of the UK patent office — namely that the CJEU was not intending to change the law as previously stated in *Biogen*, which has been generally understood across Europe to mean that there can be one SPC per product per patent — the court allowed two SPCs based on the same basic patent but for different active ingredients.

IX. Article 3(d) and "First Authorisation to Place Product on Market"

On July 19, 2012 the CJEU handed down its judgment in *Neurim Pharmaceuticals*, a case on the meaning of Article 3(d).[17] Under Article 3(d) it is a condition for obtaining an SPC that the MA upon which the SPC is based must be "the first authorisation to place the product on the market".

Neurim had developed a formulation of melatonin for the treatment of sleep disorders, and had been granted a patent for that new use. However, melatonin had previously been authorised for controlling seasonal breeding in sheep.

In accordance with established jurisprudence on Article 3(d) the "product" was therefore the active ingredient as such, i.e. the melatonin. The CJEU held that the MA for the use of melatonin for sheep breeding was not relevant in identifying the "first authorisation" in Article 3(d) because it did not relate to the particular formulation and use which was claimed by the basic patent.

The CJEU also held that the SPC term under Article 13 was determined by reference only to MAs falling within the scope of the protection of the basic patent.

X. The Third Party SPC Issue

Is it possible for one entity to apply for an SPC in respect of that entity's patent based on any MA obtained by another party for that party's own product?

The practical problem is that in large multinational organisations patent ownership and MA ownership may

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well be split, even though the respective owners may be connected. The SPC Regulation is silent on this, but the way in which the CJEU has addressed this factual scenario in cases before it suggests that in principle it is possible to grant an SPC even where the patent is held by one person and the MA is held by another.

Yet what of a scenario where it is a competitor that applies for the SPC — can this be prevented? Is there a material difference between a case where the parties are connected and a case where there is no connection at all between the parties?

This issue was recently ruled on by the English Patents Court.[18] There, the court concluded that the holder of a basic patent can indeed make an application for an SPC in reliance on an MA granted to a third party having no connection of any sort with the patent holder. The court held that this was sufficiently clear that no reference was required to the CJEU for clarification.

The result on this issue was therefore that Pharma A could apply for an SPC in relation to Pharma A's own patent based on an MA obtained by Pharma B for Pharma B's own product. This raises a set of high stakes and compelling strategic opportunities — thus, given the one SPC per product per patent rule, a party can prevent competitors getting SPCs for their products if it is able to secure this kind of SPC itself.

XI. Conclusion

That these cases have only been decided within the past nine months demonstrates the pace at which Europe's SPC jurisprudence is moving. It is also indicative of the commercial focus life sciences companies are placing on their end-of-life strategies, and the values that can be extracted from these patent term extensions.

What all these cases show is that the CJEU fully recognises that one of the fundamental objectives of the SPC system is encouraging pharmaceutical R&D by guaranteeing appropriate protection for the results of that R&D. These cases also demonstrate that the teleological approach now being adopted by the CJEU post-*Medeva* allows the CJEU not to get overly caught up in legal analysis of what is by any reckoning a confusingly written piece of legislation, but instead focus on its purpose.

Lastly, and of particular interest to patent lawyers, these cases suggest that the true boundaries to SPC protection are increasingly the same as the boundaries to patent protection. Whether the two can be fully elided — so that anything properly patentable can be the subject of an SPC — will have to be fully worked through by the CJEU in the coming months and years.

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Notes

[1] Broadly, SPCs are the EU equivalent to patent term extensions under the US Hatch-Waxman Act.

[2] EU Regulation 469/2009.

[3] Interested readers are referred to the previous articles in this series (see "Developing and Managing a European Patent Litigation Strategy" [26 WIPR 45, 5/1/12]; "Key Features of the Primary European Patent Litigation Countries" [26 WIPR 38, 6/1/12]; "Current Patent Litigation Trends: UK and Germany" [26 WIPR 40, 7/1/12]).

[4] Article 13 of the SPC Regulation.

[5] Regulation EC 1901/2006.

[6] Article 36(1) of the Paediatric Regulation.

[7] *Merck Sharp & Dohme Corp v. Deutsches Patent und Markenamt* (Case C-125/10), CJEU, December 8, 2011 (sitagliptin). For further background, see the Advocate General's Opinion on the case discussed in "Advocate General Gives Opinion on 'Negative Term' SPCs" [25 WIPR 41, 8/1/11].

[8] Under Article 1(c) "basic patent" means a patent which protects a product as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of an SPC.

[9] A valid MA must have has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC.

[10] Under Article 1(a) "medicinal product" means any substance or combination of substances presented for treating or preventing disease in human beings.

[11] Under Article 1(b) "product" means the active ingredient or combination of active ingredients in a medicinal product.

[12] *Medeva BV v. Comptroller-General of Patents, Designs and Trade Marks* (Case C-322/10) and *Georgetown University & Ors v. Comptroller-General of Patents, Designs and Trade Marks* (Case C-422/10), CJEU, both dated November 24, 2011 (see "A Step Back from the Cliff? CJEU Rules on SPCs" [26 WIPR 44, 1/1/12]).

[13] See *Yeda* (Case C-518/10), *Queensland University* (Case C-630/10), and *Daiichi Sankyo* (Case C-6/11), CJEU, all dated November 25, 2011.

[14] Case C-181/95, January 23, 1997, at para 28.

[15] See for example *Medeva*, para 41.

[16] *Queensland University v. Comptroller-General of Patents, Designs and Trade Marks* [2012] EWHC 223, February 14, 2012.

[17] *Neurim Pharmaceuticalsv. Comptroller-General of Patents, Designs and Trade Marks* (Case C-130/11), CJEU, July 19, 2012. For further background, see the Advocate General's Opinion on the case discussed in "New Uses for Old Products — SPC Applicants Get Boost From Advocate General Opinion" [26 WIPR 45, 7/1/12].

[18] *Eli Lilly v. Human Genome Sciences* [2012] EWHC 2290, August 3, 2012.

Strategic and Planning Considerations for Patent Litigation in Europe

Part V of this six-part series continues next month in World Intellectual Property Report on national patent litigation and the interface with the European Patent Office.