Special Report

A Step Back from the Cliff? CJEU Rules on SPCs

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The Court of Justice of the European Union has on November 24 delivered its highly anticipated judgments on the grant of EU-wide Supplementary Protection Certificates (SPCs) for medicinal products.[1] These judgments are of great importance for life science companies, who are facing much-publicised patent expiries for high-value drugs, and for competitors and manufacturers of generic medicines who are keen to enter the market. The decisions bring some welcome harmonisation to EU law on SPC applications, and have a potentially strategically significant effect on the position across the EU.

Case Summary

- An SPC can only be granted for active ingredients that are specified in the claims of the basic patent.
- An SPC may be granted even if the medicinal product in question (e.g. a multi-disease vaccine) contains not only an active ingredient or a combination of two active ingredients that are specified in the claims of the basic patent, but also other active ingredients.
- The CJEU has confirmed (at paragraph 41 of *Medeva*) the court's earlier ruling in *Biogen* that only one SPC may be granted per basic patent.

SPC Legal Context

As part of pan-EU harmonised legislation,[2] SPCs can be granted to patentees to extend the life of patent protection for specific medicinal products. The rationale for this is to compensate patentees where the length of their effective patent monopoly has been eroded by what is often a lengthy marketing authorisation ("MA") process for the medicinal product, which in turn makes the remaining period of effective patent protection insufficient to cover the investment put into the research.

Under Article 3 of the SPC Regulation, certain requirements must be met to get an SPC, including:

(a) The product must be protected by a basic patent[3] in force;

(b) A valid authorisation to place the product on the market as a medicinal product[4] must have been granted;

(c) The product[5] must have not already been the subject of an SPC; and

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

The SPC Regulation is the result of the interaction between the laws and practices of the patent system and of the medical regulation system, the former being a question of national law for member states — no pan-EU system yet being in force — and the latter being the result of a 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".

This has raised particular problems in practice where SPC applications have been made for combination products, as in the present cases before the CJEU.

Factual Background

In both *Medeva* and *Georgetown University* the SPCs in issue related to multi-disease vaccines.

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 in turn 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 MA, e.g. where the basic patent relates to only one disease but the SPC or MA covers multiple components of a multi-disease vaccine.

Medeva were patentees of a European patent for a method for preparing a whooping cough vaccine by mixing antigens (see "Medeva's SPC Applications — Court of Appeal Refers Questions to CJEU" [24 WIPR 31, 8/1/10]). Medeva did not market this as a single vaccine but rather as a multi-disease combination vaccine with other antigens so as to be effective against a number of childhood diseases. Medeva applied for five SPCs relating to five multi-disease vaccines comprising the antigens along with a number of other active ingredients.

The UK Patent Office rejected all the SPC applications on the basis that Articles 3(a) and 3(b) were not satisfied. It concluded for four of the SPC applications that the "products" for which the SPCs were requested were not protected by the basic patent in force, as they were required to be for the purposes of Article 3(a). On the remaining application it concluded that the MA for the product was not a "valid authorisation" for the purposes of Article 3(b).

The Patents Court upheld this view on appeal, and Medeva appealed to the Court of Appeal on the basis that the meaning of "a product protected by a basic patent" in Article 3 had been wrongly construed and that this should include any product which could be subject to successful proceedings for infringement of the patent (the so-called "infringement test").

The Court of Appeal referred six questions to the CJEU. These raise the issue 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. Subsequently in *Georgetown* the Patents Court referred a single question to the CJEU on the same issue regarding Article 3(b) in identical terms, and the cases were therefore dealt with together by the CJEU.

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Interpretation of SPC Regulation

The CJEU dealt together with the first five questions referred by Court of Appeal. These ask, in essence, whether Article 3(a) must 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 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.

Specifically, the CJEU reasoned that:

- Article 5 of the SPC Regulation 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. It therefore follows that Article 3(a) precludes an SPC being granted for active ingredients 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) of the SPC Regulation therefore had to be interpreted as precluding national patent offices from granting an SPC covering active ingredients which are not specified in the claims of the basic patent relied on in support of the SPC application.
- For public policy reasons — such as the need to encourage pharmaceutical research and to provide a proper return on the R&D investment, and the current government-led trend to multivalent vaccines to improve public health — a restrictive approach to the underlying goals of the SPC Regulation would be undesirable. Given the public policy antecedents of the regulation's legislative history such criteria are legitimately to be considered when interpreting it.
- 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. Further, 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, national patent offices can properly grant an SPC for a combination of two active ingredients that correspond to those specified in the claims of the basic patent relied on, where the medicinal product for which an MA is submitted in support of the SPC application contains not only that combination of the two active ingredients but also other active ingredients.

Strong Limitations Imposed on SPC Regime

Having given this welcome clarification on the interpretation of the SPC Regulation, the CJEU then however, imposed some significant restrictions on the SPC regime that strictly limit SPCs to what the underlying patents cover — and no more.

These limitations are directed at what is to be regarded as the relevant MA for the purposes of the SPC application, and to the number of SPCs that can be granted per basic patent.

- 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) of the SPC Regulation.
- Where a patent protects a product, under Article 3(c) of the SPC Regulation only one SPC may be granted for that basic patent.

Implications

This latter point in particular cuts directly across current patent office and industry practice across Europe, where multiple SPCs are being granted out of the same basic patent despite the prohibition against doing so from the earlier 1997 Court of Justice *Biogen*[6] decision.

The effect of reiterating that such multiple SPCs are impermissible is that the existing multiple SPCs can now be invalidated by competitors, life science companies with such SPCs stand to lose valuable monopolies (with potentially significant stock market and market share implications), and competitors will be aggressively seeking to enter the market.

The consequence of the "there can be only one SPC per basic patent" rule will potentially be an increase in litigation in national courts seeking to cancel existing multiple SPCs. This could lead to continued uncertainty and divergent opinions from national courts across Europe as they set about working out the boundaries and implications of this rule — which will inevitably be a very fact-specific exercise.

In the longer term these cases will have a significant effect on how life science companies craft their patent life cycle strategies. Life sciences companies should now be giving much attention at the granular level to how patents are written to maximise the types of SPCs that may subsequently follow, to the choice that has to be made between keeping or abandoning active ingredients or combinations for SPCs, and to how marketing authorisations can be best deployed to boost the position.

Notes

[1] Cases C-322/10 *Medeva BV v. Comptroller-General of Patents, Designs and Trade Marks* and C-422/10 *Georgetown University, University of Rochester, Loyola University of Chicago v. Comptroller-General of Patents, Designs and Trade Marks*. Broadly, SPCs are the EU equivalent to patent term extensions under the US Hatch-Waxman Act.

[2] EU Regulation 469/2009.

[3] 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 a certificate.

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

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

[6] See paragraph 28 of the ECJ (as it then was) decision in C-181/95 *Biogen Inc v. SmithKline Beecham Biologicals SA* [1997] ECR I-357.