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RECENT RULINGS OF THE EUROPEAN COURT OF JUSTICE ON SPCs

In the last few months, the European Court of Justice (ECJ) has handed down several decisions relating to the grant and validity of supplementary protection certificates (SPCs; i.e. patent term extensions). Thereof, the following rulings are generally considered to have significant impact on IP strategies in the pharmaceutical industry.

1. CASE C-125/10: GRANT OF AN SPC HAVING A NEGATIVE TERM

On 8 December 2011, the ECJ provided its ruling on case C-125/10 (*Merck Sharp & Dohme Corp. vs. Deutsches Patent- und Markenamt*) relating to the possibility of obtaining a so-called "negative-term" SPC. This case concerns Merck's medicament Januvia for the treatment of diabetes that comprises as active pharmaceutical ingredient sitagliptin. Based on an EP patent Merck applied for an SPC in Germany. The request was rejected by the German Patent and Trademark Office as the period between the filing date of the patent application and the date of grant of the first marketing authorization (MA) in the European Community (EU) was less than five years, that is, the SPC had a negative term.[1]

When Regulation 1768/92/EEC entered into force, a SPC having a negative term was fruitless and thus generally not applied for. However, subsequent Regulation 1901/2006/EC concerning medicinal products for pediatric use introduced a six-month "pediatric" extension of a granted SPC. Hence, in the subject case,

[1] Article 13(1) of Regulation 1768/92/EEC stipulates that the duration of an SPC is the period of time that elapses between the filing date of the basic patent application and the grant of the first marketing authorization to place the active ingredient on the market in the European Community, subject to a reduction of 5 years and a maximum duration of 5 years.

Merck primarily sought to obtain an SPC with a negative term, so that it would retain the right to file a subsequent request for an extension under Regulation 1901/2006/EC.[2] On appeal, the German Federal Patent Court referred a question to the ECJ in order to clarify this issue.

In his opinion delivered on 9 June 2011, the competent Advocate General (AG) Yves Bot held that it should be possible to obtain an SPC when the time period between the basic patent application and the date of the first MA in the EU is less than 5 years, as it is in the present case. Neither of the two Regulations concerned provide only for SPCs having a positive term.

The AG took the view that it should also be specified at which time point the six-month pediatric extension will commence, even though such question was not explicitly referred to the ECJ. Principally, two options could be considered as to when the extension should start: (i) at the date determined on the basis of the negative term of the SPC, or (ii) the date on which the patent expires (and thus rounding up the negative term of the SPC to zero). In the first case, only an SPC with a negative term of up to six months could benefit from an extension as the resulting term would be positive. In the second case, every proprietor of a patent with an SPC could benefit from a pediatric extension, regardless of the time it took to obtain the MA.

The ECJ started its considerations with an analysis of the legal framework and held that Article 10 of Regulation 1768/92/EEC provides that, where the application for an SPC and the product to which it relates, meet the conditions laid down by that regulation, the competent authority shall grant the SPC. Neither Article 13 nor any other provision of the regulation would suggest the preclusion of the grant of an SPC having a negative term.[3]

Further, the aim of Regulation 1901/2006/EC, which amended*, inter alia*, Article 13 of Regulation 1768/92/EEC, could be seen in the grant of a reward for the

[2] Notably, corresponding proceedings resulted in the grant of a "negative term" SPC in Great Britain and the Netherlands. In Greece, however, a "zero term" SPC was granted instead as a negative term was considered not possible.
[3] Cf. C-125/10, points 28 and 30 of the reasoning.

effort involved in evaluating the pediatric effects of the medicinal product in question, by awarding a six-month extension of the SPC to the holder of the basic patent who conducted all the research proposed in the pediatric investigation plan (cf. Article 36 of the Regulation) approved for the medicinal product in question. Article 13(3) of Regulation provides for the possibility of such extension.

Thus, if an SPC application had to be refused because the calculation provided for in Article 13(1) of Regulation 1768/92/EEC resulted in a negative or zero duration, the proprietor of the basic patent could not obtain an extension of term, even if the pediatric investigation plan was complied with. Such a refusal would be liable to adversely impact on the useful effect of Regulation 1901/2006/EC and might jeopardize the objectives of that regulation.[4]

The ECJ thus held that it follows from both Regulations when read in conjunction that the SPC and the pediatric extension together confer on the holder of the basic patent an exclusive right of a maximum duration of 15 years and 6 months from the date of the grant of the MA for the medicinal product in question in the EU. Accordingly, a pediatric extension is of use if the negative duration of an SPC is not more than six months. Therefore, an SPC can be granted where less than five years have elapsed between the date of the application for a basic patent and the date of the first MA.

Hence, in accordance with the opinion of the AD, the ECJ concluded that the grant of an SPC cannot be refused by reason only of the fact that the duration determined in accordance with the calculation rules laid down in Article 13(1) of Regulation 1768/92/EEC is not positive.[5]

As to the question concerning the time at which the pediatric extension of six months must begin to run, the ECJ held that, in the case where the period that has elapsed between the date on which the application for a basic patent was lodged and the date of the first MA in the EU is less than five years, the starting point for that

[4] Cf. C-125/10, point 37 of the reasoning.
[5] Cf. C-125/10, points 38-40 of the reasoning.

extension cannot be established as the expiry date of the basic patent, so that the duration of that certificate is be considered to be equal to zero. Such an approach would be contrary to Article 13(1) of Regulation 1768/92/EEC, in so far as that provision provides that the duration of an SPC corresponds to the period which elapsed between the date on which the application for the basic patent was lodged and the date of the first MA in the EU, reduced by a period of five years.

Therefore, where the duration of an SPC is negative, it cannot be rounded to zero. The period of the pediatric extension provided for by Regulation 1901/2006/EC starts to run from the date determined by deducting from the patent expiry date the difference between five years and the duration of the period which elapsed between lodging the patent application and obtaining the first MA.[6]

Accordingly, the ECJ ruled:

Article 13 of Regulation 1768/92/EEC, read in conjunction with Article 36 of Regulation 1901/2006/EC, must be interpreted as meaning that medicinal products can be the object of the grant of an SPC where the period that has elapsed between the date of lodging the basic patent application and the first MA in the EU is less than five years. In such a case, the period of the pediatric extension provided for by the latter regulation starts to run from the date determined by deducting from the patent expiry date the difference between five years and the duration of the period which elapsed between the lodging of the patent application and the grant of the first MA.[7]

[6] Cf. C-125/10, points 41 and 42 of the reasoning. In the present case: the SPC has a protection period of minus three months and 14 days: Adding the paediatric extension of 6 months would result in an additional protection period of 2 months and 16 days after expiry of the basic patent
[7] Cf. C-125/10, headnote.

2. CASES C-195/09 AND C-427/09: VALIDITY OF AN SPC FOR A PRODUCT LAUNCHED ON THE MARKET BEFORE OBTAINING A MA

On 28 July 2011, the ECJ provided its rulings on parallel cases C-195/09, (*Synthon BV vs. Merz Pharma GmbH & Co KG*) and C-427/09 (*Generics (UK) Ltd. vs. Synaptech Inc.*) concerning the validity of a SPC for products that were first placed on the EU market before a MA was obtained.

Case C-195/09 relates to the validity of an SPC for the active ingredient memantine. Although Merz already commercialized memantine since 1976 for the treatment of Parkinson's disease, it was able to obtain a second medical use EP patent for the treatment of Alzheimer's disease, which expired in 2009. In May 2002, Merz was granted by the EMA, a series of MAs for memantine in the treatment of Alzheimer's disease. At this time, the previous German and Luxembourg MAs granted for the treatment of Parkinson's disease under national law and without going through the administrative procedure laid down in Council Directive 65/65/EEC (i.e. the provision of safety and efficacy assessments) were withdrawn. In November 2002, Merz applied for an SPC in Great Britain citing the 2002 MA as the first authorization to place the product on the market. In revocation proceedings initiated by Synthon before the UK High Court of Justice, a referral to the ECJ was placed whether such national MAs must be taken into account in determining the validity and term of an SPC.

Related issues arose in case C-427/09. The active ingredient galantamine received its first MA under national law in Austria in 1963 (and shortly afterwards another one in Germany) for the treatment of polio. Synaptech obtained a European patent claiming the use of galantamine for the treatment of Alzheimer's disease, which expired in 2007. In March 2000, MAs were granted under EU legislation in Sweden and in Great Britain. In December 2000, Synaptech applied for an SPC listing these MAs as first authorization to place the product on the EU market. Generics brought an action for its revocation in Great Britain. Similar questions relating to the concept of "first authorization to place a product on the market" were referred to the ECJ.

In his opinion dated 31 March 2011, the competent AG Paolo Mengozzi reformulated those referred questions to in essence ask whether by virtue of Article 2 of Regulation 1768/92/EEC[8] products for which a MA under Directive 65/65 was granted after those products had first been placed on the market fall within the scope of the regulation. For the AG, it was within the objective of the Regulation to limit the extent to which the duration of the patent right is eroded as a result of the need to go through the regulatory authorization procedure which, by delaying the placing of the product on the market, defers the point at which the patent can begin to be commercially exploited. The AG did not consider it compatible with the objectives of the Regulation to extend the protection provided under the SPC to products which were already present on the EU market on a different basis before the MA was obtained in accordance with Directive 65/65/EEC.

In the present rulings, the ECJ adopted the opinion of the AG and held:

Article 2 of Regulation 1768/92/EEC must be interpreted as meaning that products, such as those at issue in the respective proceedings giving rise to these judgments, which had been placed on the market in the Community as a medicinal product for human use before obtaining a MA in accordance with Directive 65/65/EEC, and, in particular, without undergoing safety and efficacy testing, were not within the scope of Regulation 1768/92/EEC and thus could not be the subject of SPCs.[9]

The ECJ further pointed out that this Regulation seeks, through the creation of an SPC for a medicinal product, to compensate for the fact that the period of effective protection under the basic patent covering such medicinal product is insufficient to cover the investment put into the research, given the period that elapses between the filing of an application for a patent for a new medicinal product and obtaining authorization to place that product on the market.

[8] This provision stipulates that "any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure as laid down in [...] Directive 65/65 [...] may, under the terms and conditions provided for in this regulation, be the subject of a certificate."
[9] Cf. C-195/09, points 40-44 of the reasoning and headnote 1; C-427/09, point 33 of the reasoning and headnote.

It would be contrary to that objective of offsetting the time taken to obtain a MA – which requires long and demanding testing of the safety and efficacy of the medicinal product concerned – if an SPC, which amounts to an extension of exclusivity, could be granted for a product which has already been sold on the EU market before being subject to an administrative authorization procedure as laid down in Directive 65/65/EEC, including safety and efficacy testing.

Hence, in the subject cases, the respective products were not within the scope of Regulation 1768/92/EEC, as the relevant first MAs claimed were not the authorization under the EU legislative but earlier national Mas. Accordingly, these products shall not be subject of an SPC.

In case C-195/09 the ECJ was also asked whether an SPC granted for a product outside the scope of Regulation 1768/92/EEC, as that scope is defined by Article 2 thereof, is invalid.

The ECJ noted that the grounds on which an SPC is invalid are set out in Article 15 of the Regulation. Infringement of Article 2 is not included among those grounds. By contrast, under Article 15(1)(a) of the Regulation, the SPC is to be invalidated if it was granted contrary to the provisions of Article 3. The concept of 'product' in Article 3 refers necessarily to a product within the scope of that regulation, as defined in Article 2 thereof. Consequently, issuing an SPC for a product outside the scope of that regulation disregards the meaning of 'product'.[10]

Hence, the ECJ held:

An SPC granted for a product outside the scope of Regulation 1768/92 is invalid.[11]

[10] Cf. C-195/09, points 53-56 of the reasoning.
[11] Cf. C-195/09, points 57 of the reasoning and headnote 2.