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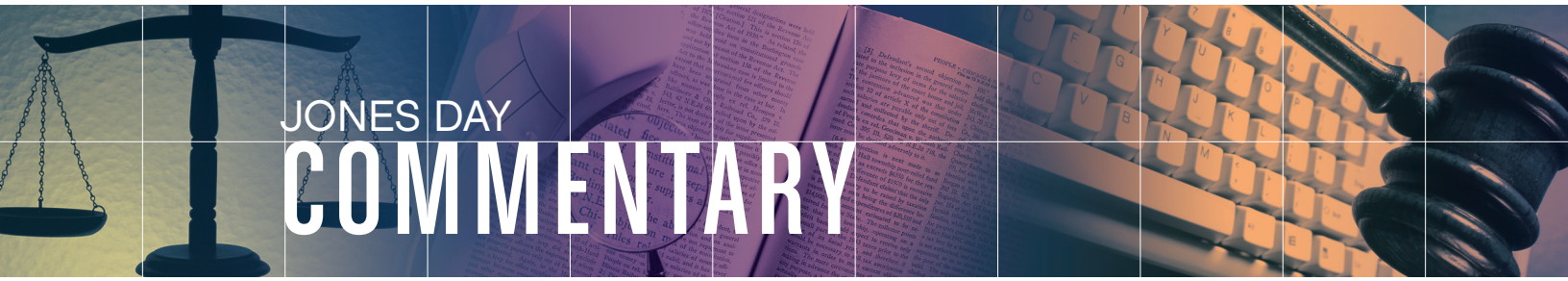

EUROPE'S HIGHEST COURT DECIDES ON PATENT TERM EXTENSIONS FOR FIXED-COMBINATION MEDICINAL PRODUCTS

Several national patent term extension proceedings regarding fixed-combination medicinal products have been stayed in Europe since UK courts have referred two cases to the highest European court—the Court of Justice of the European Union. The Court of Justice has now decided these cases ("*Medeva*," C-322/10, and "*Georgetown et al.*," C-422/10), and therewith provided answers to key questions regarding the conditions for obtaining patent term extension covering fixed-combination products. While the decisions provide long-awaited guidance for applicants, uncertainties still remain on how to interpret the rulings. At the same time, the impact of the decisions may also reach beyond fixed-combination products to SPCs for single active ingredients.

In Europe, patent term extension can be obtained by means of a supplementary protection certificate ("SPC") for a maximum of five years in order to compensate patent proprietors for the time consumed by development and the market authorization procedure required for medicinal and plant protection products.

SPCs for medicinal products are granted on the basis of the European Community Regulation 469/2009 concerning the supplementary protection certificate for medicinal products ("SPC Regulation").

Article 3 of the SPC Regulation stipulates four basic requirements for obtaining a certificate. The first two requirements are of particular relevance for SPC applications and the validity of already granted SPCs covering fixed-combination medicinal products. The first requirement is set out in Art. 3 (a), which provides that the product, *i.e.*, the active pharmaceutical ingredient ("API") or combination of APIs, be protected by a basic patent in force. Art. 3 (b) defines the second requirement and specifies that a valid authorization to place the product on the market as a medicinal product ("marketing authorization") must have been granted.

In a situation where the product recited in the SPC application is mentioned in the claims of the basic patent and is also the active ingredient of the medicinal product for which a marketing authorization has been issued, the national authorities regularly grant SPCs as Art. 3 (a) and 3 (b) are considered to be met. However, the situation is less clear where a basic patent claims the API A, but the SPC application is for a combination of two APIs, namely A and B. In this situation, the question arises whether Art. 3 (a) is met, *i.e.*, whether the active ingredient of the SPC application is protected by the basic patent. Similarly, there is also a question of whether the requirement of Art. 3 (b), *i.e.*, the existence of a valid marketing authorization for the product of the SPC application, is met, when the SPC application refers to API A only, but the respective marketing authorization is for a medicinal product containing API A in combination with a further API B.

Regarding the requirement of Art. 3 (a), *i.e.*, regarding the question whether the combination of two APIs (A and B) is protected by the basic patent, when the claims are directed to API A only, two different concepts have been applied by European authorities. Some jurisdictions followed the so-called "infringement test," whereas other jurisdictions applied a test that can be described as the "identification test."

The rationale behind the "infringement test" appears familiar as it comes down to whether a fixed-combination medicinal product containing the APIs A and B, which is the subject of an SPC application, would infringe a patent claiming the API A. Applying the basic principles of assessing infringement, one would come to the conclusion that the product of the SPC infringes the patent as the combination of A and B fulfills all features of a claim directed to A, with the additional presence of B being irrelevant. Thus, in such a situation, the product of the SPC is regarded as being protected by the basic patent pursuant to Art. 3 (a) of the SPC Regulation.

In contrast, in jurisdictions applying the "identification test," it is required that the product, which is the subject of an SPC, must be identifiable with the invention of the designated basic patent. Thus, in a strict application of the "identification test," the product of the SPC must be specified in the wording of the claims of the basic patent.

THE FACTS UNDERLYING THE CASES C-322/10 AND C-422/10

Whether the "infringement test" or the "identification test" is to be applied for evaluating if the product of an SPC application is protected by the basic patent pursuant to Art. 3 (a) of the Regulation has now been decided by the Court of Justice in the *Medeva* case (C-322/10). In the same case, as well as in a second referral, *i.e.*, the Georgetown et al. case (C-422/10), the Court of Justice also decided on the construction of Art. 3 (b), *i.e.*, whether the requirements of Art. 3 (b) are met when an SPC application refers to API A only, but the respective marketing authorization is for a medicinal product containing API A in combination with a further API B.

In the *Medeva* case, the claims of the basic patent only recite the antigens pertactin and filamentous hemagglutinin ("FHA"), which can be used for vaccination against whooping cough. Referring to the basic patent, *Medeva* BV filed five different SPC applications. Only one of these five SPC applications recites the product to be the combination of pertactin and FHA only. The other four SPC applications specify the product as being pertactin and FHA in combination with varying specific additional antigens (*see* Table below).

API	Basic Patent	SPC applications nos. 1-4		SPC application no. 5	
	Claims recite	SPC sought for	MA granted for	SPC sought for	MA granted for
pertactin	+	+	+	+	+
FHA	+	+	+	+	+
additional antigens	–	+	+	–	+

All marketing authorizations referred to in the five SPC applications are for multi-disease vaccines, three of which are for multi-disease vaccines against whooping cough, polio, tetanus, meningitis, and diphtheria, and two of which are for multi-disease vaccines against four of the above cited diseases except meningitis. Thus, all marketing authorizations are for multi-disease vaccines with pertactin and FHA in combination with additional antigens as active ingredients.

The UK Patent Office refused to grant the SPCs and argued that in four of the cases, more active ingredients were specified in the SPC applications than were identified in the wording of the claims of the basic patent (*see* SPC nos. 1-4 in the above Table). In other words, the UK Patent Office applied the "identification test" and was of the opinion that the product was not protected by the basic patent in the sense of Art. 3 (a). The fifth SPC application (*see* SPC no. 5 in the above Table), however, was found not to comply with Art. 3 (b) because the SPC application referred to pertactin and FHA only, whereas the marketing authorization was for a vaccine containing additional antigens as active ingredients.

THE RULING OF THE CJEU

Art. 3 (a) of the SPC Regulation. The UK Court of Appeal, which eventually heard the *Medeva* case, could not decide whether the "infringement test" or the "identification test" is to be applied under Art. 3 (a) of the Regulation. As this question concerns the interpretation of European law, the Court of Appeal referred the following question to the Court of Justice of the European Union: What is meant in Article 3 (a) of the SPC Regulation by "the product is protected by a basic patent in force," and what are the criteria for deciding this?

With a quite brief reasoning, the Court of Justice decided against the "infringement test": Determination of infringement would need to be done on a national level, and this part of European patent law is still not harmonized. According to the Court of Justice, this would endanger a uniform solution for the grant of SPCs throughout Europe and thus harm the free movement of goods within the European Union. Instead, the Court of Justice saw the patent itself as the correct reference for a decision on grant of SPCs.

Without any more detailed reasoning, the Court of Justice then held that "Art. 3 (a) must be interpreted to preclude the competent industrial property office of a member state from granting an SPC relating to active ingredients which are not specified in the wording of the claims of the basic patent relied on in support of the application for such a certificate." In short, an SPC shall not be granted when the SPC relates to active ingredients that are not "specified in the wording of the claims" of the basic patent.

Art. 3 (b) of the SPC Regulation. Regarding Article 3 (b) of the SPC Regulation, the UK Court of Appeal in the *Medeva* case had posed the question to the Court of Justice whether the requirement of Article 3 (b) is fulfilled in an SPC application specifying that the product is a combination of two active ingredients, corresponding to that recited in the wording of the claims of the basic patent, but the medicinal product for which the marketing authorization is submitted in support of the SPC contains not only that claimed combination of the two active ingredients but also other active ingredients.

In the *Medeva* case, the SPC applications referred to marketing authorizations granted by the French, German, and United Kingdom authorities for medicinal products, which contain the antigens pertactin and FHA in combination with other active ingredients as a multi-disease vaccine.

As previously found for Art. 3 (a), a quite brief reasoning led the Court of Justice to the finding that Art. 3 (b) does not preclude the competent industrial property office of a member state from granting SPCs for a combination of two active ingredients, corresponding to that specified in the wording of the claims of the basic patent relied upon, where the authorized medicinal product not only contains that combination but also other active ingredients. Thus, the Court considers the requirement of Art. 3 (b) to be fulfilled in an SPC application for a combination of active ingredients, although the marketing authorization refers to a medicinal product that contains active ingredients in addition to the claimed combination.

In the *Georgetown et al.* case, which in fact concerns SPC applications of three different applicants, *i.e.*, Georgetown University, University of Rochester, and Loyola University of Chicago, all SPC applications also rely on marketing authorizations for medicinal products containing additional active ingredients. Thus, the UK High Court asked in essence the same question regarding Article 3 (b) as did the Court of Appeal in the *Medeva* case. Consequently, the Court of Justice gave essentially the same answer, *i.e.*, that Art. 3 (b) is met for an SPC application for a combination of ingredients, even where the medicinal product for which the marketing authorization is issued contains additional active ingredients.

RESULTING CONSEQUENCES FOR PATENT AND SPC APPLICATIONS

In summary, according to the above referenced decisions of the Court of Justice:

- Art. 3 (a) is met when the SPC relates to the active ingredient(s) that are specified in the wording of the claims of the basic patent; and
- Art. 3 (b) is fulfilled even when the marketing authorization refers to a medicinal product, which contains active ingredients in addition to the active ingredient(s) specified in the wording of the claims.

Thus, regarding Art. 3 (b), the ruling of the Court of Justice is a relief and facilitates the filing of SPC applications in situations where approved medicinal products contain further active ingredients in addition to the patented active ingredient or ingredients, as is often the case in the vaccine field. As a consequence, there is no need to synchronize the product of the SPC application with the active ingredients in the medicinal product of the marketing authorization and *vice versa*, as long as the approved medicament simply contains additional, *i.e.*, more, active ingredients. In the triangle consisting of the claims of the basic patent, the product of the SPC application, and the medicinal product of the marketing authorization, the decision slackens one side of this triangle—the connection between the product of the SPC application and the medicinal product of the marketing authorization. Hence, the ruling uncouples the extension of protection for a product (SPC application) from the form in which the product is finally brought on the market (marketing authorization).

On the other side of this triangle, the Court of Justice established a very tight connection between the claims of the basic patent and the product of the SPC application by requiring that the active ingredients referred to in the SPC application shall be specified in the wording of the claims of the basic patent. In this regard, the ruling appears not to be limited to fixed-combination products but seems equally applicable to SPC applications directed to a single product. Although the ruling clearly dismisses the "infringement test" and favors the "identification test," it remains uncertain how strict the product description should be tied to the wording of the claims. What is exactly meant that the active ingredients need to be "specified in the wording of the claims"? Does "specify" require a specific recital of a substance in the claim? Or—and then to what extent—can a general construction of the patent claim be taken into account? For example, will a specific compound falling under a generic formula of the claims of the basic patent, without being explicitly mentioned in the claims, still be "specified in the wording of the claims"? Can a general definition within the patent claim according to the knowledge of a skilled person be taken into account, and how would evidence on this be properly established? And moreover, will a particular compound be considered as specified in the wording of a method of production claim that does not explicitly recite the end product?

Further light will be shed on the new rulings regarding Art. 3 (a) and 3 (b) when the respective national authorities apply the decisions of the Court of Justice to pending proceedings. It should be noted that the Court of Justice did not use the terms "infringement test" or "identification test," so that recourse to such terms carries the risk of distorting the content of the ruling. The Court of Justice emphasized the importance of the patent claim, while at the same time rejecting that infringement determination according to national laws should be the basis for a decision on an SPC. This suggests an "identification test," but does not rule which "variety" of a potential multitude of imaginable identification tests should be applied. The practical question will thus be how strict the term "specified in the wording of the claims" should be interpreted.

Regarding SPC applications for fixed-combination products, it can be expected that a generic pointer in the claims of the basic patent to a combination with "at least one other therapeutic ingredient" may not be sufficient to meet the requirements of Art. 3 (a). Otherwise, a patent with claims reciting a particular combination of active ingredients will most likely be acknowledged as a basic patent that "protects" the product of the SPC. For patents with claims directed to a single product in the form of a generic formula, a dependent claim specifying the formula to the particular product of the SPC application should also be suitable to make the patent a basic patent according to Art. 3 (a) of the Regulation. In the absence of such dependent claim that specifies the active

ingredient, it is unclear what route the authorities in their interpretation of the recent rulings will take. It remains to be seen whether a broad claim may be sufficient, and to what extent specific support from the description may be required. The safest way to proceed to avoid initial refusal of an SPC application thus seems to be to include in the claims of the basic patent an embodiment that explicitly recites the product of the SPC application.

In spite of the above mentioned uncertainties regarding the interpretation of the new rulings, the restriction under Art. 3 (a) to the wording of the claims of the basic patent may result in challenges to the validity of at least those SPCs that were granted for fixed-combination products, even though the claims of the basic patent recite only a single compound. Also, SPCs for a single active ingredient may see challenges if the API is not explicitly mentioned in the claims of the basic patent. This will likely result in further qualification by the highest European court in the years to come.

Beside the statements regarding Art. 3 (a) and 3 (b) of the SPC Regulation, it is of note that the Court reminds the national courts and offices that all other preconditions according to Art. 3 have to be met as well; no SPC may have been issued before for the product, and the marketing authorization has to be the first for the product as medicinal product.

Although the decision of the Court of Justice as well as this *Commentary* focus on SPCs for medicinal products, it should be kept in mind that the consequences resulting from the decisions of the Court of Justice will apply equally to SPCs for plant protection products.

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