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CJEU-REFERRAL: SPCs FOR DRUG-DEVICE COMBINATIONS?

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The German Federal Patent Court ("FPC"), in its decision of 18 July 2017, referred to the Court of Justice of the European Union ("CJEU") the question whether and under which prerequisites the granting of a Supplementary Protection Certificate ("SPC") for an active ingredient, which is an integral part of a "drug-device combination" ("combination product"), is permitted. The FPC holds that the granting of an SPC is not generally excluded at least for such products for which the quality, safety and efficacy of the drug component was assessed in the CE-marking process at the same level of rigor as medicinal products. So far, the FPC has only shared a similar view in its earlier Yttrium decision relating to a nanomedical radiotherapeutic product, an active implantable medical device.

BACKGROUND: MARKET ACCESS REGULATIONS FOR COMBINATION PRODUCTS

Nowadays, many innovative medical devices are combination products, such as antimicrobial impregnated catheters or drug-eluting stents. Such combination products thus contain a medical device as well as a drug (medicinal product) component, whereas the drug component often forms an integral part of the medical device.

From a regulatory perspective, a combination product is either a medicinal product or a medical device. The authorization procedure (for medicinal products) or the conformity assessment procedure (for the CE-marking of medical devices), which need to be followed prior to placing a given product on the market, is therefore governed either by the EC Directives 2001/83/EC ("Medicinal Product Directive" / "MPD") or 93/42/EEC ("Medical Devices Directive" / "MDD") and respectively 90/385/EEC ("Active Implantable Medical Devices Directive" / "AIMD"). Usually, the given procedures are mutually exclusive under these directives. However, as an exception, for certain products, such as combination products, inter alia the MDD makes cross-references to specific authorization provisions in the MPD regime (cf. Art. 1(4) and Annex I, Sec. 7.4 of the MDD in conjunction with Annex I of the MPD), which are therefore also applicable in the procedure for conformity assessment of the given medical devices (cf. European Commission, Medical Devices: Guidance document, MEDDEV 2. 1/3 rev 3).

WHAT IS AN SPC AND WHEN IS IT GRANTED?

The purpose of an SPC is to extend the statutory term of protection of a basic patent (for a drug or a veterinary drug) by a period of not more than five years (or five and a half years for pediatric drugs) after the patent term has expired in order to compensate the de facto shortening of the statutory patent term, which the patentee suffers due to the long duration of regulatory marketing authorization proceedings for the (veterinary) drug. The legal

basis for the SPC is Regulation (EC) No. 469/2009 concerning the supplementary protection certificate for medicinal products ("SPC Regulation") in conjunction with Sec. 16a para. 1 of the German Patent Act.
The scope of the SPC Regulation, according to Art. 2 of the SPC Regulation, is opened up to any product protected by a patent in the territory of an EU member state and subject, prior to being placed on the market as a (veterinary) medicinal product, to an administrative authorization procedure as laid down in the MPD or the Directive 2001/82/EC ("Veterinary Medicinal Products Directive" / "VMPD"). According to Art. 3 of the SPC Regulation, a certificate shall be granted if, at the date of that application:

a) the product is protected by a basic patent in force;
b) a valid authorization to place the product on the market as a medicinal product has been granted in accordance with the MPD or VMPD, as appropriate;
c) the product has not already been the subject of a certificate; and
d) the authorization referred to in point b) is the first authorization to place the product on the market as a medicinal product.

The SPC, under the aforementioned requirements, is not granted for a drug in itself, but only for the active ingredient (or combination of active ingredients) of a drug, which is covered by the authorization of the given drug (Art. 4 of the SPC Regulation). Otherwise, the SPC grants the same rights like the basic patent and is subject to the same limitations and duties (Art. 5 of the SPC Regulation).

GENERAL PRINCIPLE: NO GRANTING OF AN SPC FOR MEDICAL DEVICES

The grant of an SPC for a medical device, according to the case law of the FPC, regularly falls outside of the scope of the SPC Regulation, since such a product having no drug effects (i. e. the principal intended action is not achieved by pharmacological, immunological or metabolic means) is per definition no suitable "product" in the light of Art. 2 of the SPC Regulation which, according to Art. 1 lit. b) of the SPC Regulation only includes the active ingredient or combination of active ingredients of a medicinal product (BPatG GRUR Int. 2016, 339 - Aminosilanbeschichtete Eisenoxid-Nanopartikel).

EXCEPTION FOR COMBINATION PRODUCTS?

In its present order for reference to the CJEU, the FPC takes the view that in case of combination products within the meaning of Art. 1 (4) of the MDD, an exemption from this general principle may be justified (BPatG GRUR Int. 2017, 861 - Paclitaxel freisetzender Stent): The basic patent in these proceedings is related to the use of Taxol (INN: Paclitaxel) for the preparation of a drug to maintain an expanded vessel luminal area. The FPC holds that the granting of an SPC for Paclitaxel (a cytostatic active ingredient already known from cancer therapies), which, as an ancillary drug component, is an integral part of a stent (medical device) eluting this active ingredient (for the prevention of restenosis), cannot generally be excluded under following considerations:

Which question was referred to the CJEU for clarification?

The FPC holds that the aforementioned requirements for granting an SPC are mostly fulfilled and that it is only questionable whether a valid (administrative) authorization procedure for placing the product Paclitaxel as a medicinal product on the market has been granted in accordance with the MPD, which is required for the applicability of the SPC Regulation according to Art. 2 of the SPC Regulation as well as for granting an SPC according to Art. 3 lit. b) of the SPC Regulation.
The active ingredient Paclitaxel has for itself not undergone a formal authorization procedure as a medicinal product, but the combination product was CE-marked according to Art. 1(4) of the MDD. According to Art. 1(4) of the MDD, a combination product (as a complete product) must be assessed and authorized as a medical device (and not as a medicinal product) where it incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of Art. 1 of the MPD and which (according to the specifications and scientific data

provided by the manufacturer) is liable to act upon the body with action ancillary to that of the medical device. In this case, the principal intended action of the combination product is not achieved like a medicinal product, but primarily by physical means (medical device). In that respect, however, the quality, safety and efficacy of the drug component of such a combination product must be assessed and evaluated in a consultation process by the drug authority of an EU member state at the same level of rigor as a medicinal product (cf. Art. 1(4) and Annex I, Sec. 7.4 of the MDD in conjunction with Annex I of the MPD). In the context of such consultation process, Paclitaxel was positively assessed by the competent drug authority.
Now, the CJEU must clarify whether a product, which was positively assessed in a consultation process at the same level of rigor as a medicinal product, does or does not fulfill the procedural and substantive requirements of Art. 2 of the SPC Regulation (and respectively Art. 3 lit. b) of the SPC Regulation), according to the wording of which a valid authorization as a medicinal product must have been granted for the active ingredient under the MPD.

How does the FPC interpret Art. 2 and Art. 3 lit. b) of the SPC Regulation?

The FPC takes the view that it is not apparent from the wording of Art. 2 of the SPC Regulation (and Art. 3 lit. b) of the SPC Regulation respectively) that the authorization of a product according to the MDD cannot fulfill the requirements of the SPC Regulation. The applicability of the scope of the SPC Regulation as well as the granting of an SPC were not generally excluded, if a product in principle being worthy of protection according to the objectives of the SPC Regulation under European laws, mandatorily had to be authorized under a different directive than the MPD. Rather, it was essential whether the given authorization fulfills the procedural and substantive requirements of the MPD for placing a medicinal product on the market. This was the case here, particularly since, according to Art. 1(4) in conjunction with Annex I, Sec. 7.4 of the MDD, in the context of the consultation process, the safety and quality of Paclitaxel as well as its efficacy over its potential risks were (analogously to Annex I of the MPD) reviewed and positively assessed at the same level of rigor as medicinal products by the competent drug authority of an EU member state taking into account the specific intended purpose of the stent. Here, particularly the clinical assessment in the consultation process, whether the intended purpose (clinical benefit) of the drug component as claimed by the manufacturer to be achieved in conjunction with the use of the given medical device is fulfilled, was substantively equivalent to the assessment of the clinical efficacy of a medicinal product in a formal authorization proceeding under the requirements of the MPD. Insofar, the FPC emphasizes that particularly proving the safety and therapeutic benefit of an active ingredient component of a combination product in consultation proceedings requires the manufacturers to provide, in part, very extensive clinical data.
Furthermore, the conformity proceeding to be conducted for combination products was equivalent to an administrative authorization as laid down in Art. 2 of the SPC Regulation. The inspection authority (Notified Body) was not an authority within the meaning of public law, but the evaluation standards were not subject to freedom of contract. The inspection body had to take into account the results of the expert opinion of the competent authority for medicinal products determined in the consultation process and a possible negative expert opinion would lead to refusal of the CE certificate.
The referral to the CJEU follows the view taken by the FPC in its earlier Yttrium decision (BPatG PharmR 2010, 237) relating to a nanomedical radiotherapeutic product. This proceeding concerned tiny glass microspheres containing as an integral part the radioactive isotope Yttrium-90 (as an active ingredient) which, when used separately, may be considered a "radioactive medicinal product" within the meaning of Art. 1 No. 6 of the MPD and whose purpose was to accumulate within the tumor tissue following parenteral administration and to destroy the tumor cells by radiation from the inside. According to Art. 1 (4) of the AIMD, which essentially corresponds to Art. 1 (4) of the MDD, the product had to be assessed and authorized mandatorily as an active implantable

medical device (CE-marking). This CE-marking as well was, according to the FPC, an authorization within the meaning of Art. 2 of the SPC Regulation (and Art. 3 lit. b) of the SPC Regulation) as the quality, the safety and the benefit of the isotope were examined in accordance with medicinal products standards as part of the certification procedure (cf. Art. 1 (4) in conjunction with Annex I, Sec. 10. of the AIMD).

CONCLUSION

CE-marking for combination products is generally more complex than for medical devices having no drug component. In case the CJEU follows the view of the FPC, the granting of an SPC would be possible at least for drug-device combinations within the strict limits of Art. 1 (4) of the MDD. This would be in line with the objectives of the SPC Regulation since only the granting of an SPC for the drug component of a combination product would enable the proprietor of the basic patent to receive a compensation for the long duration of CE-marking proceedings due to the clinical data necessary for the evaluation of the active ingredient. Furthermore, for the novel use of the active ingredient according to the teachings of the basic patent, the possibility of a formal authorization as a medicinal product under the MPD is generally excluded due to its specific use as an integral part of a combination product. The granting of an SPC continues to be excluded for medical devices not containing any integral medicinal product components.

In case you have any questions, please do not hesitate to contact us.

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