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PATENT TERM EXTENSION FOR MEDICAL DEVICES: NEW OPPORTUNITIES, OPEN QUESTIONS

The first German patent term extension granted for a medical device, a combination product, may open the door for extended patent protection for combination products. It thus offers new opportunities in product development. At the same time, a number of questions remain open, in particular in the light of conflicting case law.

NEW OPPORTUNITIES

On August 19, 2010, the German Patent Office published the grant of a Supplementary Protection Certificate ("SPC") for a medical device, glass microspheres with the radiopharmaceutical Yttrium-90. The issuance came as no surprise, as it followed in the wake of a decision of the 14th Senate of the German Federal Patent Court ("*Bundespatentgericht*" or "BPatG") dated January 26, 2010 (Case 14 W (pat) 12/07). This decision had overturned an earlier rejection of the Patent Office and granted an SPC for "Yttrium-90 glass microspheres."

The door may thus be open for applications for patent term extensions in Germany for medical devices, at least for combination products, and the same is true in The Netherlands. Based on the precedents, similar decisions in other jurisdictions of the European Economic Area are conceivable. Accordingly, manufacturers may seek to improve on the life cycle management of a patented product by extending the patent protection, and thus improve on the rate of return on investment. In addition, new product development opportunities present themselves. At the same time, a decision of the 15th Senate of the *Bundespatentgericht* calls into question the eligibility of medical devices, alone or in combination with pharmaceuticals. Careful attention also needs to be paid to the regulatory category of a product and to the claims of the patent in question.

Accordingly, with regard to the development of new products, the clinical mode of action has to be carefully scrutinized. And during prosecution, even if the focus is on the use by a "material only" medical

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device, not by a combination product, the latter use should be anticipated as optional and thus provided for in the claims.

THE GERMAN CASE

The German Federal Patent Court had to decide on an application for an SPC for the product "Yttrium-90 glass microspheres," authorized as "Therasphere® Yttrium-90 Glass Microspheres." The applicant was the patent proprietor of EP 0 201 601, including its German part (DE 35 86 129), the basic patent in the terminology of the European legislation on SPCs (Regulation 469/2009/EC, the "SPC Regulation"). The basic patent was still in force at the time the SPC application was filed. The Office had rejected the application on the grounds that under the SPC Regulation, only products that had obtained a marketing authorization according to the Community Code for Medicinal Products for Human Use (directive 2001/83/EC, the "Community Code"), *i.e.*, as a pharmaceutical, were eligible for an SPC.

The court disagreed. It pointed out that under the European legislation on medical devices, combination products, i.e. products that also contain an active pharmaceutical ingredient ("API"), require an assessment of the API according to the Community Code in the context of the conformity assessment of the medical device. For this purpose, the Notified Body selected by the manufacturer to assess and certify the device has to submit the dossier for the API to the European Medicines Agency or a national authority within the EU competent to approve pharmaceuticals. Only upon review and confirmation of the API dossier is the Notified Body entitled to issue a certification for the medical device.

Accordingly, the court held that while no marketing authorization for a pharmaceutical is issued, such a combination product still undergoes the review and approval under the Community Code. Therefore, by analogy, the SPC Regulation applied to such medical device in case of certification.

The court found that the other preconditions for an SPC were fulfilled. The product was covered by a valid patent in force at the time of the application for patent term extension. The application sought the first SPC for the product. And the certification of the medical devices was the first marketing authorization (in the terms of the SPC Regulation) for the product (*i.e.*, the combination of Yttrium-90 and glass microspheres). The patent term extension was calculated according to the rules of the SPC Regulation, leading to an SPC valid for five years after expiry of the original term of the basic patent.

OPEN QUESTIONS

The court, in discussing whether the device constituted a "product" in the sense of the SPC Regulation, held that the glass microspheres containing the radiopharmaceutical Yttrium-90 not only incorporated the API, but also constituted a medicinal product. The court referred to the definition of a "radiopharmaceutical" in the Community Code, which requires an API in a formulation ready for use. At the same time, the court held that the definition of "active implantable medical device" according to directive 90/385/EEC was met as well. The product had a therapeutic purpose, was applied parenterally, and remained at its site of application within the body.

However, from a European regulatory perspective, a product can only be either a medicinal product or a medical device. The distinction is made according to the predominant mode of action. If it is predominantly pharmacological, immunological, or metabolical, it is a medicinal product; otherwise, it is a medical device. The court did not discuss the mode of action but accepted the product as a certified medical device. The question remains whether the case law applies only to combination products with a composition comparable to a pharmaceutical formulation, as the microspheres in this case, or also to other compositions, *e.g.*, drug-eluting stents or other implants combined with API. Given the fact that the latter products have to undergo, within the conformity assessment, a review and approval of the API dossier according the Community Code, the case law should be applied to such products as well.

From a patent prosecution perspective, it is of note that the basic patent explicitly referenced Yttrium-90 as API to be incorporated in the claimed microspheres. This leads to the

question whether only combination products that incorporate an API explicitly mentioned in a claim of the basic patent are eligible for patent term extensions. Drawing on the case law on SPCs for fixed-combination medicinal products, it should be sufficient if there is an "identifier" in the basic patent to the medical device's use in a composition with an API. Thus, patent applications referring to medical devices should seek to contain claims under which the invention in question may be used alone or in combination with an API.

With regard to the preconditions under the SPC Regulation, it is of interest that the court referred to the "marketing authorization" (*i.e.*, conformity assessment) for the combination product, not for the API (which had undergone the review and approval under the Community Code, and thus made the product eligible for an SPC). The API itself, Yttrium-90, is a well-known API that had been approved as a radiopharmaceutical earlier. In this context, it is important to note that in other cases, the Court of Justice of the European Union (the "CJEU") held that a known and approved API that comes in the form of a new controlled release formulation would not be eligible for patent term extension (such as Gliadel®, a medicinal product to be implanted into the cranium for the treatment of recurrent brain tumors, where carmustine, a highly cytotoxic active ingredient, is released slowly and gradually by the polifeprosan, which acts as a bioerodible matrix; Case C-431/04).

Given that the patent term extension under the SPC Regulation is granted in view of the lengthy pre-clinical and clinical development for pharmaceuticals, the question is whether the case law also applies to combination products, which draw on bibliographical data for the API dossier, or whether the review under the Community Code has to be carried out with specific data obtained in clinical trials with the combination product. However, a revision to the European medical devices legislation that entered into force in 2009 tightened the requirements for clinical trials of medical devices. Therefore, combination product medical devices in all likelihood will have to undergo clinical trials. The question will thus probably remain academic in most cases; such specific clinical data will have to be generated for the medical device conformity assessment.

Of a more fundamental nature is the question whether medical devices without an additional API are eligible for patent term extension in the EU. Conventional wisdom holds this not to be the case. Considering that the patent term extension is intended to compensate for long development timelines required for regulatory product approvals, it would be a logical conclusion to extend the analogy under the SPC to medical devices as such, at least to those that under the revised medical devices legislation have to undergo comprehensive clinical trials, thus significantly lengthening the development timeline. Whether courts would accept such analogy, or rather deem this a policy decision, remains an open question.

The 15th Senate of the *Bundespatentgericht* has answered this question in the negative (case 15 W (pat) 28/08) but has allowed an appeal to the German Federal Court of Justice in Civil Matters ("*Bundesgerichtshof*" or "BGH"). In that case, the basic patent covered a method for preparing hylan and novel hylan product. The applicant had applied for an SPC for the combination of "Hylan A and Hylan B" and had referred to the certificate of a notified body on the conformity assessment according to the medical devices directive 93/42/EC. That case, therefore, did not involve a medical device plus pharmaceutical active ingredient product, but a product that had been authorized only via the regulatory pathway for medical devices. The 15th Senate confirmed the rejection of the application by the German Patent Office on the grounds that medical devices cannot be the object of an SPC. It denied that the preconditions for an analogy were met, given that the SPC Regulation had been revised multiple times, and only recently had been codified again after subsequent amendments in 2009. In all those years, medical devices had already been known, but the legislator had not taken the decision to include them in the scope of the SPC Regulation.

This is not the most compelling argument, as the 15th Senate failed to demonstrate that the issue of extending the SPC Regulation to medical devices had ever been brought to the attention of the legislator. In that regard, it has to be kept in mind that the threshold for obtaining a marketing authorization has been lower for medical devices,

compared to medicinal products. Thus, development timelines have been faster, and there has not been much need for patent term extension. This has now changed, since medical devices, depending on their classification, also have to undergo strict clinical trials, with all the ensuing impact on development timelines.

The second argument of the 15th Senate is that the SPC Regulation requires an "authorization" in accordance with the Community Code, and that even in the case of combination products, the review carried out by an authority for the pharmaceutical part of the medical device does not formally qualify as an authorization. This is not compelling, either, as the reference to the authorization under the Community Code in substance reflects the comprehensive pre-clinical and clinical development efforts required for such authorization. And the same efforts have to be carried out for the pharmaceutical part of a medical device.

OUTLOOK

Patent term extensions for combination product medical devices currently are based on a limited number of cases in Europe, and the case law of the *Bundespatentgericht* is conflicting. Further cases may shed light on the open questions discussed above, in particular any decision of the *Bundesgerichtshof* on appeal against the rejection by the 15th Senate of the *Bundespatentgericht*. It is of note that on a European level, only the CJEU will be in the position to render decisions that are binding for all Member States. However, applicants cannot appeal to the CJEU but have to rely on their national courts to submit a request for a preliminary judgment to the CJEU.

With regard to the question of patent term extensions for medical devices as such, industry should seek to convince the European legislators to extend the SPC Regulation to medical devices, in view of lengthening development timelines, or to create similar provisions specifically for medical devices.

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