

Changes in supplementary protection certificates can mean a difference of millions of euros per month for the value of pharmaceutical products, say **Dr Martin Huenges** and **Dr Dirk Bühler** of **Maiwald**

## Patent term extensions

**P**atents are frequently a decisive factor in determining whether a new pharmaceutical product will be a success story. There are many reasons why this is. In contrast with other industries, a new pharmaceutical product, such as a new therapeutically active agent, may be protected only by a single patent. This is an invitation to generic manufacturers not just to challenge such a patent, but also to launch a one-to-one copy of the product, at least after a corresponding patent has expired. Further, in many countries the legal framework surrounding pharmaceutical products links prices and reimbursement by public health authorities to the existence of patents and the marketing of generic competitor products. All of this can lead to situations where revenues of proprietary drug manufacturers plummet by more than 50% after a patent expires and the first generic is launched on the market.

So, patent expiry represents a critical milestone in the life of pharmaceutical products. This is all the more so, as it frequently takes longer to obtain marketing authorization for a new product than it does to obtain a granted patent, meaning that in some cases a patentee can only launch their product years after the patent protecting it has been granted. Usually, the patent term remaining after market approval is only about 10 years.

In order to compensate patentees for the effectively reduced lifetime of their patents, supplementary protection certificates (SPCs) were introduced within the EU by Regulation 1768/92/EEC. SPCs can extend the lifetime of patents covering medicines by a maximum of five years. The recently enacted new regulation 1901/2006/EC on medicinal products for use in pediatrics allows extension of the lifetime of an SPC by an additional six months if the product is approved for children.

The economic impact of SPCs can be significant. For example, the basic patent for Prozac (fluoxetine) expired in 1995 and the European SPC expired in 2000. In the UK, about 80% of the total sales revenues were generated during the SPC term, whereas in Germany, where no SPC was available for Prozac, sales declined from 1995 onwards and by 1998 eleven generic versions of fluoxetine were being marketed there.

Although they are accessory to a patent, SPCs are, in their own way, IP rights, which must be applied for on a country by country basis and are granted to the proprietor of a basic patent. Thus, there may be a French, Dutch, German or other national SPC extending the lifetime of the corresponding national parts of a granted European-granted patent. However, as SPCs were implemented by regulation 1768/92/EEC, the provisions relating to SPCs must be construed consistently in the EU.

As a consequence of the different practice of European countries when dealing with market entry of pharmaceutical products and the fact that the wording of var-

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ious provisions of regulation 1768/92/EEC is indeed in need of further interpretation, there have been numerous decisions by courts throughout Europe, including referrals to the European Court of Justice, on SPCs.

The following overview highlights a number of decisions which have touched on two core aspects of SPCs over the last three years: firstly, what subject matter can be protected by SPCs and secondly, how is the term of an SPC calculated in specific cases?

### What can be protected by an SPC?

The filing requirements as laid down in Article 3 of the regulation stipulate that an SPC shall be granted if the product

## These and some similar decisions of the ECJ have thus finally clarified that SPCs may only be granted to extend the lifetime of patents for new pharmaceutically active agents

(a) is protected by a basic patent in force, (b) has obtained a valid marketing authorization according to directive 65/65/EEC or directive 81/851/EEC, (c) has not already been the subject of an SPC and (d) the marketing authorization referred to in (b) is the first to place the product on the market as a medicinal product. According to Article 1(b) the product is defined as “the active ingredient” or “a combination of active ingredients”.

If these requirements are taken literally, SPCs can only be granted for novel and first-to-the-market drugs, but not for novel formulations or indications. It could however be argued that this literal interpretation seems to contradict the objectives of the regulation, whose ultimate purpose was to improve public health by rewarding pharmaceutical innovations that stem from long and costly research (recitals 1 and 2 of the regulation) irrespective of whether that research is in novel compounds, methods or applications. Drawing a distinction between compounds and indications seems particularly unjust, as full clinical testing is usually necessary before a known drug may be marketed for a new disease.

### SPCs for novel formations?

The question of whether SPCs can be obtained for novel formulations was decided after the German Federal Supreme Court referred questions to the ECJ concerning the meaning of the term “combination of active ingredients”. The case related to the MIT Gliadel implant which was protected by European Patent 0 260 415. Gliadel comprises the cytotoxic drug carmustine embedded in a matrix made from the polymer polifeprosan. This specific formulation allows the use of active carmustine at increased dosage amounts over extended periods, which had not been possible in the past.

The German Federal Patent Court had originally rejected the SPC request, stating that Gliadel did not comprise a combination of active ingredients, but was rather an example of a new formulation of the already known active agent carmustine. It was held that even if polifeprosan ensured the constant delivery of therapeutic amounts of carmustine, it would not act as an active ingredient, but as an excipient.

However, the German Federal Supreme Court asked the ECJ to comment on whether a combination of active ingre-

dients necessarily meant at least two pharmacologically active compounds, or whether it could also apply where one component exerts its pharmacological potential only when combined with another substance that has no pharmacological effect as such. When referring the questions, the German Federal Supreme Court noted that authorities in the UK, France and the Netherlands had interpreted the term differently from the Federal Patent Court and had duly granted SPCs on Gliadel.

Attorney-general Léger in his opinion emphasized that the objective of the Regulation was indeed to encourage research, not only into novel drugs, but also into novel applications for known drugs by developing auxiliary sub-

stances which improve the pharmacological effect of the drug. He concluded that where there was a major innovation at stake, that is, if a known drug could attain new properties in terms of efficacy and safety when combined with specific excipients, an SPC should be allowed. In such cases, the term “combination of active ingredients”

according to Article 1b of the regulation should be construed beyond its literal meaning to encompass also combinations of a pharmacologically active ingredient and an excipient.

It therefore came as a surprise when the ECJ did not follow the Attorney-general but considered the definition of Article 1b to leave no room for the term “combination of active ingredients” to encompass also excipients which have no pharmacological effect as such, but can be used to influence the efficacy of pharmaceutically active agents. According to the ECJ, if the assessment of the role of certain excipients in formulations were left to patent offices, this would result in legal uncertainties. Consequently, if the same product, ie the same active agent, had received marketing approval in the past, a request for an SPC on a novel formulation of this active ingredient had to be denied (C-431/04).

### SPCs for new indications?

In some cases the basic patent protects a second medicinal application of a therapeutic agent, For example, the question referred to the ECJ by the UK High Court in the case of *Yissum* was whether the application of the agent plays any part in the definition of product for the purpose of the regulation. Here, the basic patent EP 0 129 003 protected the use of a known drug for treating certain skin disorders. However, an earlier marketing authorization had been granted for treating renal failure and osteoporosis with the same drug. In view of the earlier *Gliadel* decision it was logical and consistent when the ECJ shortly thereafter rejected the *Yissum* case on novel indications by simply referring to this decision (C-202/05).

These and some similar decisions of the ECJ have thus finally clarified that SPCs may only be granted to extend the lifetime of patents for new pharmaceutically active agents.

While the question of what can be protected by an SPC seems to have been answered, positions keep fluctuating as to the duration of SPCs.

### The Swiss-Liechtenstein issue

Article 13.1 of the regulation stipulates that the duration of an SPC is to be calculated as the time period between the date of the basic patent application being filed and the first

marketing authorization within the European Community, minus five years. Article 13.2 limits the maximum length of protection to five years.

To give an example: if a French applicant obtained national marketing approval on January 1 2000 for a product protected by a patent with a filing date of January 1 1990, the duration of the SPC would be five years. If, however, British marketing authorization had been granted on January 1 1997, the duration of the French SPC would be only two years.

Thus, although a national marketing authorization is a prerequisite for requesting an SPC, there are situations where the term of the SPC is calculated on the basis of a marketing authorization in another country that had been issued earlier. The rationale of calculating the SPC term on the basis of the first marketing authorization issued within the EU is to ensure that SPCs that relate to the same product and are based on the same basic patent expire on the same day throughout Europe.

The regulation provides no definition of the term "first marketing authorization within the European Community" as it is used in Article 13. However, the ECJ has previously interpreted this term as referring to a marketing authorization in accordance with directive 65/65/EEC. This directive was implemented in 1965 to harmonize the legal framework for obtaining marketing authorizations for medicinal products throughout the EU.

One question that had recently to be decided by the ECJ was whether a Swiss marketing authorization determines the SPC term. At first glance, this idea would seem strange, given that Switzerland is not a member of the EU or the European Free Trade Association (EFTA), for which the SPC regulation also applies. However, Liechtenstein is part of EFTA and at the same time there exists a contract between Liechtenstein and Switzerland stipulating that any marketing authorization issued in Switzerland is also valid in Liechtenstein. Since the national marketing authorizations of an EFTA member are considered to be on a par with authorizations according to directive 65/65/EEC, the ECJ decided in cases C-207/03 and C-252/03, which were handled jointly, that national marketing authorizations from Switzerland are also to be regarded as a marketing authorization in accordance with directive 65/65/EU. About 40 products were affected by this decision, with an estimated loss to the innovator industry of about €1 billion (\$1.6 billion).

As a consequence, when calculating the term for an SPC, Swiss marketing authorizations must also be taken into consideration. It is noted, however, that as of June 1 2005 there is an automatic delay of 12 months between the authorization being granted in Switzerland and the authorization of the product in Liechtenstein.

### The Finasteride decision

A more recent decision from Germany deals with the issue of whether the date on which a request for an SPC is filed can have an impact on term calculation.

In general, Article 7 of the regulation sets a six-month time limit after the date of the national marketing authorization for filing the SPC request. In the *Finasteride* case, an SPC was requested on the basis of a German marketing authorization for *Finasteride* dated September 29 1994. The basic patent had been filed on February 27 1985 and a marketing authorization had been issued in the UK on May 27 1992. With the UK

authorization being the first in the EU, the SPC term was calculated to be about two years and three months. As the SPC request had been filed on January 13 1995, well within the six-month time limit of Article 7, the SPC was granted with a term to expire on May 27 2007.

However, on January 1 1995 Austria became a member of the EU. A transitional provision to Article 3b of the regulation stipulates that Austrian national marketing authorizations are considered to be on a par with an authorization in accordance with directive 65/65/EEC. This transitional provision was introduced to allow applicants to request an SPC, even after Austria joined the EU, on the basis of a national marketing authorization that was granted in Austria before

## There is uncertainty even as to how the six-month deadline of Article 7 for filing an SPC request needs to be calculated

January 1 1995.

Marketing authorization had been granted for *Finasteride* in Austria on April 28 1992. The party attacking the SPC argued that at the time of filing the German SPC request (January 13 1995), Austria had been a member of the EU. Therefore, the Austrian marketing authorization of April 28 1992 should be considered to be the first authorization within the meaning of Article 13 and be used for calculating the SPC term. In this case, the term would be one month shorter.

The Federal Patent Court followed this argument, stating that the ECJ had decided in the past that the term "marketing authorization" should be construed consistently in the regulation. If a national Austrian authorization was regarded as being in line with directive 65/65/EEC for the purposes of Article 3b of the regulation, there would be no reason not to consider such an authorization for the purposes of Article 13 once Austria had entered the EU. According to this decision, the relevant date for determining the first authorization according to Article 13 of the regulation is the filing date of the SPC request (BPatG 3 Ni 2/06).

The Federal Patent Court did not refer the decision to the ECJ, even though the same court (though another senate) had come to the opposite conclusion in a similar case. However, if the *Finasteride* decision is confirmed at higher courts, this could have interesting consequences. If the applicant filed the request before January 1 1995 the SPC term would have had to be calculated on the basis of the British marketing authorization. This means that, contrary to the rationale behind Article 13 of the regulation, SPCs for the same product and on the basis of the same patent can have different terms throughout Europe.

Hence, future applicants should carefully plan their SPC filing strategy when further countries become members of the EU and corresponding transitional provisions apply. It is easy to imagine scenarios where the accession of a new member, in which a national marketing authorization already exists for the respective product, does not reduce the SPC term by one month only (as in the *Finasteride* case), but actually erases the complete SPC term throughout Europe. In such situations, it would be wise not to use the whole six-month deadline of Article 7 for filing an SPC request. Hence the need for a well thought-out filing strategy is evident. At

the same time, the generic industry should carefully check whether the accession of the Eastern European countries, Malta and Cyprus to the EU have opened up new attacks for existing SPCs.

### The Porfimer referral

As one may expect in view of the above cases, there is uncertainty even as to how the six-month deadline of Article 7 for filing an SPC request needs to be calculated. This issue has recently been referred to the ECJ by the German Federal Supreme Court (BGH X ZB 30/05, *Porfimer*).

## It seems likely that the recent Finasteride decision of the German Federal Patent Court will not be the last one dealing with these issues

In that case, the marketing authorization was issued on July 9 1997 and was served to the applicant on July 15 1997. The SPC request was filed on January 13 1998. The lower courts refused the request as being too late and concluded that the six-month term had to be calculated from the date of the authorization. However, according to section 25 of the German Medicinal Preparations Act (*Arzneimittelgesetz*), a German marketing authorization becomes effective only upon notification to the applicant. In this case, the applicant would have filed the SPC request in good time.

The German Federal Supreme Court therefore asked the ECJ to answer the following questions: (i) whether the six-

months term of Article 7 is to be interpreted according to Community law or the national law of the respective member state and (ii) from what date the six months deadline has to be calculated if Community law applies (X ZB 30/05 of June 27 2007).

### An evolving situation

The last few years have brought clarity as to what subject matter can be protected by SPCs. From a series of congruent decisions, it can be shown that SPCs may be granted only for novel and first-to-the-market drugs or drug combinations. However, no SPCs may be obtained for inventive follow-up developments on drugs such as novel formulations and further medical applications. This should be taken into account when creating a life cycle management for a patented pharmaceutical product.

As regards the term of an SPC, the situation is still evolving. It has been decided that Swiss marketing authorizations must be considered when calculating an SPC term, and new questions arise from transitional provisions dealing with the accession of new member states to the EU. It seems likely that the recent *Finasteride* decision of the German Federal Patent Court will not be the last one dealing with these issues and that we will likely see more referrals to the ECJ dealing with cases that hinge on the accession of Malta, Cyprus and the Eastern European countries such as Poland, Hungary, and the Czech Republic, as well as of countries yet to enter the EU.

Hence, innovative as well as generic companies should carry out a thorough analysis of the transitional provisions in regulation 1768/92/EEC when developing their strategies for pursuing or challenging SPCs.



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