Every cloud has a silver lining: Portugal's loss may be the UK's gain

The innovator pharmaceutical industry was disappointed by a recent CJEU ruling relating to supplementary protection certificates in Portugal. However, there could be a positive flip side, writes *Mike Snodin*.

A ruling by the Court of Justice of the EU in a case involving pharmaceutical company *Merck Canada* in Portugal has already resulted in the curtailing of the term of certain supplementary protection certificates (SPCs) in that country. This is of course disappointing for the companies concerned and for the innovator pharmaceutical industry as a whole. More broadly, however, there may be two positive aspects to the ruling, which has implications for how the duration of the protection provided by SPCs should be calculated. In the opinion of this author, the ruling ought to lead to increased harmonization of the SPC term across the EU and European Economic Area. It could also, in some circumstances, ultimately provide an additional day of SPC term – and therefore one additional day of market exclusivity – in territories such as the UK.

The CJEU's ruling in case C-555/13 (*Merck Canada*)[1] was provided in the context of a situation that is peculiar to Portugal. This article reports the ruling and looks at the potential consequences.

SPCs

SPCs are Europe's answer to Hatch-Waxman patent term extensions (PTEs) in the US. SPCs have their own unique character, and differ in several important respects from PTEs. Nevertheless, they serve a similar, ultimate purpose to PTEs, in that they provide additional protection (ie beyond normal patent expiry) for active ingredient(s) present in marketed medicinal products.

Thus, an SPC protects the authorized uses of a "product" (defined as an active ingredient or combination of active ingredients) that has been protected by a patent (the "basic patent"). Although the SPC is a stand-alone right, it is connected to the basic patent in many ways, not least in that the scope of SPC protection cannot be any broader than that provided by the basic patent.

SPC duration

The SPC legislation contains various provisions that govern the duration of SPC protection. For a normal (ie not extended) SPC, these provisions can effectively be summarized by way of the following equations:

(A) Normal term = X - 5 years

[X = (date of first marketing authorization (MA) in European Community) - (date of filing of basic patent)]

(B) Normal term cannot exceed 5 years

(C) Normal term endures for a maximum of 15 years from date of the first MA in the Community

In equations (A) and (C), "Community" refers to the member states of the EU and the European Economic Area.

For SPCs to medicinal products, equations (A) and (B) reflect the provisions of Article 13(1) and Article 13(2), respectively, of Regulation 469/2009[2]. It is to those provisions that national patent offices and courts have typically turned when determining the duration of SPC protection.

Equation (C) derives from the provisions of Recital (9) of Regulation 469/2009. That recital appears to have been intended by the legislators to reflect the same concept as that which is expressed (in different terms) in Equation (A). Indeed, equations (A) and (C) can produce the same SPC expiry date if the patent upon which the SPC is based has a (now standard) term of 20 years from filing.

However, equations (A) and (C) produce different results if the term of the basic patent is anything other than 20 years from filing. Such different results are the basis of the dispute in *Merck Canada*.

The dispute

The *Merck Canada* case reached the CJEU as a result of a dispute between *Merck Canada* and various generics companies; the dispute related to the expiry date of an SPC to montelukast, the active ingredient in the medicinal product Singulair.

Merck Canada's Portuguese patent protecting montelukast (patent no 99.213) was filed before Portugal changed the term of its national patents to be 20 years from filing. Thus, patent no 99.213 was awarded a term of 15 years from grant, and so expired almost 22 years after its filing date.

Merck Canada subsequently filed an SPC application in Portugal, based upon patent no 99.213. As a result of the Portuguese patent office's use of Equation (A) (only) when calculating the duration of protection for *Merck Canada*'s SPC application, that SPC was granted with a term such that the protection did not expire until almost 17 years after the date of the first authorization in the Community for montelukast. In other words, the SPC term awarded was in conflict with (ie it was significantly longer than) the term that would have been obtained if Equation (C) had been used instead of Equation (A).

The CJEU's ruling

In essence, the CJEU decided that SPC term cannot exceed that calculated using Equation (C). In other words, even if Equation (A) would suggest a longer SPC term, the combined period of (patent and SPC) exclusivity cannot exceed 15 years from the date of the first MA in the Community.

Consequences for calculation of SPC expiry dates

The CJEU's decision means that, for an SPC that has not been extended, the last day in force of the SPC can never be any later than 15 years from the date of the first MA in the Community for the "product" in question.

It is possible for the last day in force of an SPC to be earlier than 15 years from the date of the first MA. This happens when the date of the first MA in the Community is more than 10 years after the date of patent filing, which is when Equation (B) applies. In that instance, the last day in force of the SPC is instead five years from the last day in force of the basic patent.

Put another way, the CJEU's ruling ought to mean that an SPC for a "product" will endure until the earlier of:

(I) 15 years from the first MA for the "product" in the Community; and

(II) 5 years from expiry of the basic patent for the SPC.

Conclusions from the ruling

When SPC duration is as defined in (I) above, then the CJEU's ruling clearly prevents an SPC from enduring beyond 15 years from the date of the first MA in the Community.

However, when (I) applies, the ruling would also appear to prevent an SPC from expiring before a full 15 years have elapsed from the date of the first MA in the Community. In other words, when the term cap of Equation (B) does not apply, the CJEU's ruling would appear to require the SPC to endure for precisely 15 years from the date of the first MA in the Community.

This latter conclusion is likely to prove controversial. However, in the view of this author, it is a conclusion that is inescapable when the SPC legislation is properly interpreted. For the reasons outlined below, it is also a conclusion that, for some SPCs in a small number of EU territories, could provide one additional day of protection.

Interpretation of the SPC legislation

The relevant provision to interpret here is Recital (9), which is the basis for Equation (C) above and which the CJEU has indicated is the dominant provision when calculating SPC duration.

Recital (9) reads as follows.

The duration of the protection granted by the certificate should be such as to provide adequate effective protection. For this purpose, the holder of both a patent and a certificate should be able to enjoy an overall maximum of 15 years of exclusivity from the time the medicinal product in question first obtains authorisation to be placed on the market in the Community.

Thus, Recital (9) indicates that "adequate effective protection" is provided by way of a certificate expiring 15 years from the date of the first MA in the Community.

There is nothing in Recital (9), or indeed in any other provision of the SPC legislation, to indicate that any other period of effective protection would be adequate in circumstances where the term cap of Equation (B) does not apply.

In other words, when less than 10 years have elapsed between the date of patent filing and the date of the first MA in the Community, the provisions of Recital (9) will only be satisfied when the term awarded to the SPC is such that endures until precisely (ie no later than but also no earlier than) 15 years have elapsed from the date of the first MA in the Community.

Possibilities for increased harmonization

If the above conclusions are accepted, this could lead to increased harmonization of SPC expiry dates across the EU and EEA.

This is because the various different patent offices currently use a variety of different calculation methods for determining the last day of SPC protection, and these methods do not always arrive at the same result. Thus, the widespread adoption of a simple method that only ever has a single answer (ie 15 years from the date of the first MA in the Community) ought to ensure harmonization, at least in situations where the term cap of Equation (B) does not apply.

Such harmonization would be consistent with the stated intentions of the legislators. This is because, as outlined at point 27 of the explanatory memorandum to the original proposal for an SPC system (COM(90) 101 final - SYN 255, Brussels, 11 April 1990[3]):

*The introduction of **a different period of protection for medicinal products in each of the Member States of the Community would create obstacles to their free movement within the internal market and distort the conditions of competition**.*

*The introduction of **a standard, adequate period of protection** for the results of pharmaceutical research, on the other hand, will be sure to encourage innovation and technical progress at Community level and to promote intra-Community trade in medicinal products* (emphasis added).

Additional term?

The CJEU has made it clear that SPC protection endures for a maximum of 15 years from the date of the first MA in the Community. However, when determining the last day in force of an SPC for which the term cap of Equation (B) does not apply, it has to be decided upon which day the period of 15 years begins.

The options in this respect are:

(1) the date of the MA; and

(2) the subsequent day.

Option (1) provides a last day in force that is the day before the 15th anniversary of the date of the MA. Option (2), however, provides the more intuitive result that the 15th anniversary of the date of the MA becomes the last day in force of the SPC.

This author is of the view that Option (2) is the only choice that is supported by the relevant legislation. This is because the EU legislation governing expiry of time periods (Regulation 1182/71, "Euratom"[4]) indicates, in Article 3(1), that Option (2) should be used for periods expressed in years that are *"to be calculated from the moment at which an event occurs or an action takes place"*.

In the view of this author, the grant of the MA clearly qualifies as a "triggering" event under Article 3(1) of Euratom. If correct, this would have the consequence that SPCs across the EU whose term is not capped by Equation (B) would uniformly have a last day in force that is the 15th anniversary of the date of the MA.

For some EU territories, including the UK, this would provide an additional day of SPC term. This is because patents in a minority of territories (including the UK) currently expire a day earlier than equivalent patents in the majority of EU territories (including Germany, Italy and Spain).

This author has previously argued this point before the UK Intellectual Property Office (in the Genzyme case leading to the change of UK IPO practice reported in December 2013 by this author in *Scrip Regulatory Affairs*[5]). Although the hearing officer on that occasion rejected arguments based upon Euratom, this was largely on the basis of the assumption that Recital (9) did not overrule the provisions of Article 13(1) – an assumption that the CJEU's ruling has now shown to be false. Thus, there would now appear to be good grounds to revisit this argument in the UK, as well as in other territories awarding insufficient periods of SPC protection.

In conclusion, therefore, while the ruling certainly has negative consequences for some companies in Portugal, the cloud may well have a silver lining for the innovator industry as a whole in the shape of increased harmonization of SPC term across the EU and EEA and an additional day of SPC term in countries such as the UK.

References

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