More questions on the first marketing authorisation for SPC's

The Court of Justice of the European Union (CJEU), the highest court in Europe, has been asked to provide further guidance on what constitutes the first marketing authorisation (MA) in European Community (EC).

In Europe, SPCs are national rights and so separate applications must be made in each European country. However, the duration of each SPC is calculated on an EC basis.

The duration of an SPC is calculated by subtracting 5 years from the period between the filing date of the patent and the date of first authorisation in the EC, but is a maximum of 5 years.

The EC covers any State which is a Contracting Party to the EU or the EEA agreement including Norway, Iceland and Liechtenstein, even through Liechtenstein does not grant SPCs. Switzerland is not part of the EU or EEA agreement. However Liechtenstein, through its bilateral agreement with Switzerland, automatically recognises Swiss MAs.

The CJEU (the highest Court in Europe) has previously held that the fact Swiss MAs are valid in Liechtenstein means that the Swiss MA can constitute the first MA in the EC.

In response to that decision, Switzerland and Liechtenstein have made moves to reduce the need to delay applications for MAs in Switzerland by amending the bilateral agreement as of 1 June 2005. Liechtenstein now maintains a list of medicinal products whose Swiss authorizations are not automatically recognised. Normally, this recognition will be 12 months after the Swiss authorization, but this is variable. This means that, usually Swiss MAs will only become valid in Liechtenstein 12 months after issuance.

This case arose before the introduction of the list by Liechtenstein. However, this issue is relevant to cases post-introduction of the list.

Background to the referral

Astrazeneca obtained a Swiss MA for gefitinib in March 2004. This was automatically recognised by Liechtenstein. The MA was, however, conditional on the provision of further clinical dat

Therefore, the Swiss MA was not granted in accordance with the Europe-wide regulatory rules referred to in the law concerning SPCs. Those rules required certain safety and efficacy testing to be carried out before marketing the product in the Community.

Indeed, when Astrazeneca applied for a centralised European MA based on the original data, the European authorities rejected their application.

The Swiss authorities suspended the Swiss MA in October 2005, until the additional data was submitted.

Astrazeneca prepared the additional data and obtained a MA via the centralised European procedure that did comply with the Europe-wide regulatory rules in 2009. Their Swiss MA was subsequently reinstated using this data in 2010.

Therefore, the product could be legally marketed in Liechtenstein (and Switzerland) from 2004 to 2005, but nowhere else in the EEA. The product could not be legally marketed anywhere in the EEA from 2005 to 2009.

Astrazeneca claimed that the MA obtained via the centralised European procedure should be the first MA in the EC from which to calculate the SPC term because it was the first to comply with the Europe-wide regulatory rules.

The CJEU has previously decided that an SPC for a product will be valid only if the first MA in the EC is under the Europe-wide regulatory rules. If the product was on the market in the EC before the Europe-wide regulatory rules came into force, the product is outside the SPC Regulation and you cannot have an SPC for such a product (which we reported here).

However, Astrazeneca argued that the previous CJEU decisions on this point are inconsistent and do not also sit well with the previous CJEU decision that because Swiss MAs are valid in Liechtenstein, the Swiss MA can constitute the first MA in the EC.

The UK Patents Court agreed that there were inconsistencies and decided to refer questions to the CJEU.

The questions referred

The Court asks whether a Swiss MA, not granted in accordance with the European-wide regulatory rules, but automatically recognised in Liechtenstein is

the first MA in the EC or whether that product is outside the SPC Regulation, so cannot be the subject of an SPC.

The Court supplemented this question with asking whether it makes a difference if the Swiss MA was suspended after grant and only reinstated after submission of additional data satisfying the European-wide regulatory rules.

Conclusion

The outcome of this decision will have a significant impact the strategy pharmaceutical companies use to obtain MAs in Europe.

Pharmaceutical companies will need to ensure their products remain on the Liechtenstein list of medicinal products whose Swiss authorizations are not automatically recognised until they have received a European MA that complies with the SPC Regulation. If possible, the Swiss MA should be delayed until after the European MA has been obtained.

We await the CJEU decision with interest.