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BRIEFING

EU enlargement: pharmaceutical issues

Executive summary

This briefing covers three issues of significance for the pharmaceutical industry that arise from the enlargement of the EU in May 2004:

- marketing authorisations for medicinal products;
- Supplementary Protection Certificates (SPCs); and
- parallel importation of medicinal products from new member states.

Introduction

On 1 May 2004, Cyprus, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia and Slovenia will join the European Union (EU). A number of IP and competition law issues arise from this enlargement of the EU: this briefing looks at three issues affecting the pharmaceutical industry.

Marketing authorisations

Under EU law, a medicinal product for human use must have a marketing authorisation before it can be placed on the market of a member state. There are two procedures for obtaining authorisations: the 'centralised procedure', compulsory for biotechnology products and optional for other innovative new medicines, where an application is made to the European Agency for the Evaluation of Medicinal Products (EMA); and the 'mutual recognition' procedure, based on mutual recognition by the EU member states' pharmaceutical regulatory bodies of each other's national marketing authorisations.

Under the Accession Treaty new member states must comply with EU law by 1 May 2004, in the absence of a specific derogation. Cyprus, Lithuania, Malta, Poland and Slovenia have negotiated transitional periods during which marketing authorisations (for medicinal products) granted under national legislation not compliant with EU law will continue to be valid in that country, but not in the rest of the EU. (Poland has also negotiated a transitional period for marketing authorisations for medical devices.) Existing national marketing authorisations in the Czech Republic, Estonia, Hungary, Latvia and Slovakia must be upgraded to comply with EU law by 1 May 2004, or withdrawn.

From 1 May 2004, a marketing authorisation granted under the centralised procedure will be valid in all member states of the enlarged EU. An authorisation applied for under the mutual recognition procedure may designate one or more of the new member states.

Action

- List national marketing authorisations in new member states that have no current equivalent in the EU. Check whether additional regulatory data is required to meet EU standards. If so, then update dossiers by 1 May 2004 or, in the case of Cyprus, Lithuania, Malta, Poland and Slovakia, by the end of the transitional period.

Supplementary Protection Certificates (SPCs)

The SPC system aims to compensate patentees for time lost in the commercialisation of medicinal products due to delays in obtaining marketing authorisations. An SPC extends the protection of the basic patent beyond the term of the patent, but only in respect of the active ingredient of a medicinal product that is the subject of a marketing authorisation. An SPC must be applied for separately in each country where protection is required.

The Accession Treaty amends the EU SPC regulation, introducing transitional arrangements in the new member states. It addresses the extent to which marketing authorisations granted in new member states before 1 May 2004 can be used as the basis for an SPC application in that country. The provisions vary considerably, resulting from political negotiation and historical differences in national patent, SPC and pharmaceutical legislation. They can, in very general terms, be divided into two categories – those that allow SPC applications:

- within six months of the date of the first marketing authorisation of the medicinal product in the relevant new member state; and
- in a six-month period after 1 May 2004 for medicinal products authorised in the new member state within a certain period before 1 May 2004.

The Accession Treaty is silent on the effect of existing medicinal products for which the first marketing authorisation (in the enlarged EU) was obtained in a new member state before accession. It is not clear what, for the purposes of calculating the duration of an SPC, will be the first marketing authorisation in the European Economic Area (EEA). If it is the first marketing authorisation in the new member states (which was obtained before the first marketing authorisation in the current 15 member states), then this would effectively reduce the term of an SPC.

Action

- Check the detailed provisos in the amended SPC regulation for each new member state, and file SPC applications where possible.
- For some new member states, you need only apply for an SPC in the six-month period after accession (ie by 1 November 2004). For others (Cyprus, the Czech Republic, Estonia and Slovenia), you may need to apply far sooner.

Parallel imports

In general, from 1 May 2004 the principle of 'exhaustion of rights' will apply to the new member states (as it does to existing member states and the other three members of the EEA: Iceland, Liechtenstein and Norway). So, once a product has been put on the market in the area comprising the enlarged EU and EEA by an IP right holder, or with his consent, the IP right holder will not be able to prevent the product being resold anywhere within the 28 countries of the enlarged EU and EEA.

However, the Accession Treaty contains a 'specific mechanism' relating to parallel imports of patented pharmaceutical products. This special measure allows for the fact that patent protection for pharmaceutical products was introduced only relatively recently (in the 1990s) in all the new member states except Cyprus and Malta:

'With regard to [new member states other than Cyprus or Malta], the holder, or his beneficiary, of a patent or supplementary protection certificate for a pharmaceutical product filed in a Member State at a time when such protection could not be obtained in one of the abovementioned new Member States for that product, may rely on the rights granted by that patent or [SPC] in order to prevent the import and marketing of that product in the Member State or States where the product in question enjoys patent protection or [SPC] protection, even if the product was put on the market in that new Member State for the first time by him or with his consent.'

This is best illustrated by example:

A patent application for a pharmaceutical product was filed in the UK in 1992. The patent was granted in 1998 and the first marketing authorisation for the product was obtained in the EEA in 2000.

In Estonia, there was no patent protection for pharmaceutical products in 1992, so the special mechanism is triggered. The UK patent expires in 2012 and the UK SPC expires in 2015. Applying the special mechanism, the patented product may not be exported from Estonia to the UK until expiry of the SPC in 2015, approximately 11 years after Estonia joins the EU on 1 May 2004.

The period of transitional protection against parallel imports of medicinal products from the new member states must be examined on a product-by-product basis for each new member state.

The specific mechanism in the Accession Treaty requires anyone intending to import a product covered by the mechanism to notify the patent owner, who has one month in which to object to the import on the basis of the mechanism.

Action

- Be prepared for increased competition from parallel imports. Consider whether marketing your goods or services in the new member states is commercially appropriate if they are to be priced beneath the level of the existing member states.
- Check whether the specific mechanism allows you to prevent parallel imports from the new member states (other than Malta and Cyprus).
- If you receive notice of intended parallel importation, respond to that notice within one month.

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