Better Protection for Innovative Pharmaceuticals in Europe?

An advisor to the Court of Justice of the European Union (CJ) has suggested that certain pharmaceutical products in Europe should benefit from longer protection where the innovator carries out studies to determine whether the products are safe for children. The CJ is likely to follow this approach when it rules on the case, likely at the end of 2011.

In an Opinion published on 9 June 2011 in Case C-125/10 *Merck & Co Inc* v. *Deutsches Patent- und Markenamt*, Advocate-General Yves Bot has recommended that the CJ require member states to grant so-called "negative term" Supplementary Protection Certificates (SPCs). These would allow innovator companies to benefit from up to six months' longer protection for their pharmaceutical products where the companies complete a "Paediatric Investigation Plan."

Supplementary Protection Certificates

Patents in Europe last up to 20 years from the date of filing. However, for pharmaceutical products much of that term of protection can be lost due to the time it takes to obtain a marketing authorization (MA) to place a new product on the market. Under Regulation 469/2009 (which codified Regulation 1768/92) pharmaceutical innovators can apply to be compensated for that loss of time by the grant of an SPC, extending the term of protection for the product protected by the patent. If the MA is not granted until more than five years after the patent is filed, the innovator can obtain an SPC with a term equal to the additional delay beyond five years, up to a maximum SPC term of five years. SPCs are granted by the patent offices in each member state of the EU. They are similar to the patent term extensions available under the Hatch-Waxman Act in the United States.

Research on the Suitability of Medicines for Children

The EU also wants to encourage pharmaceutical companies to determine whether their products are safe for children. Article 36 of Regulation 1901/2006 provides for a six-month extension to the SPC term for companies which complete trials in accordance with an agreed Paediatric Investigation Plan. However, no such extension is available where there is no SPC or no patent which qualifies for the grant of an SPC. These Paediatric Extensions are again granted by the individual patent offices and similar extensions are available in the United States.

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The *Merck* case concerns the drug Januvia (sitagliptin), used to help control blood glucose levels for patients with type 2 diabetes. The difference between the date of Merck's patent filing and grant of the first MA was only four years, eight months, and 16 days. An SPC would normally be of no value. However, as the necessary studies in children had been completed, Merck would be entitled to a Paediatric Extension of six months if it could obtain an SPC. Merck therefore wanted to obtain a "negative" (or zero) term SPC, to which the six-month Paediatric Extension could be added.

Merck's applications were handled quite differently by the patent offices in various member states:

- In the UK, Netherlands, and Bulgaria, the patent offices granted Merck an SPC with term of minus three months and 14 days, meaning the Paediatric Extension could be applied to take the term into positive territory.
- In Greece, the negative term was rounded up to zero, meaning the addition of the Paediatric Extension gave a full six-month term extension.
- In Germany (among others), the patent office refused to grant an SPC at all, holding that an SPC could not be granted where the time difference between date of patent filing and grant of the first MA was less than five years. With no granted SPC, the Paediatric Extension was impossible.

Merck appealed the German refusal to the German Federal Patent Court. In the light of the divergent approaches across Europe, that Court referred the question to the CJ for clarification. A-G Bot approved the approach taken in the UK, the Netherlands, and Bulgaria and the decision of the CJ is now awaited.

A-G Bot's approach is a common sense solution. It avoids the arbitrary distortion where a product for which the first MA is granted the day before the five-year anniversary of the patent filing would be incapable of gaining any term extension at all, whereas if the first MA is granted two days later, a full six-month Paediatric Extension would be available. It also ensures that the extension continues to reflect the actual delay in the grant of the MA.

The CJ is not required to follow A-G Bot's Opinion. However, in the majority of cases it does follow the A-G's Opinion, and A-G Bot's Opinion here is carefully reasoned and persuasive. Assuming it is followed, the approval of "negative term" SPCs removes a potentially significant distortion in the system and allows pharmaceutical innovators who invest in paediatric studies some additional time in which they can be rewarded for their investment.

If you have any questions about any of the topics discussed in this Advisory, please contact your Arnold & Porter attorney or any of the following attorneys:

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