The AG's Clarification of the Specific Mechanism - C-681/16

OPINION OF ADVOCATE GENERAL TANCHEV
(Delivered on 7 February 2018)

BACKGROUND

One of the key principles upon which the European Union ("EU") is founded is the free movement of goods. This has resulted in the development of a pan-European doctrine of exhaustion of rights, which restricts patentees from bringing proceedings for infringement in a member state where the patentee has already marketed or consented to the marketing of its goods in another member state.

A difficulty with this doctrine was identified when the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Slovenia and Slovakia ("new member states") sought to join the EU. Prior to their accession to the EU in 2004, the level of protection afforded to holders of some patents and SPCs for pharmaceutical products was lower than that enjoyed by them in existing member states.

Pharmaceutical companies were facing the prospect of parallel importation of their products from new member states to existing member states in circumstances where equivalent patent or SPC protection had been unavailable in the new member states. To remedy this problem, the specific mechanism was introduced as a specific derogation to the doctrine of exhaustion of rights, whereby the holder of a patent or SPC for a pharmaceutical product can prevent the parallel importation of that product from any of the new member states, provided that: (i) no equivalent protection was available in the new member state; and (ii) the product is still protected in the member state(s) into which the product is being imported.

C-681/16 (*Pfizer Ireland Pharmaceuticals v Orifarm*) concerned parallel imports of *etanercept* from new member states into Germany. The Claimant sought an injunction prohibiting such parallel imports during the term of the German SPC, as this SPC was based on a German patent filed at a time when patent protection was not available in the relevant new member states. Despite SPCs theoretically being available in the new member states at the date of filing the German SPC, in reality, such SPCs could not be sought as there was no underlying patent in those countries. The referring court asked the CJEU for guidance on the scope of the specific mechanism as follows:

Questions referred to the CJEU…

Q1. Can the holder of a German SPC rely on the specific mechanism to prevent the importation of products into Germany from the new member states if the German SPC was applied for when SPC protection already existed in the relevant new member states but could not be applied for by, or issued to, the holder of the German SPC because the basic patent required for the issuing of the SPC did not exist in the new member state?

Yes. Even though the laws of the relevant new member state provided for an SPC, such an SPC could not be obtained without a basic patent and it was not possible at the relevant time to obtain a patent in any of these States. Lack of a basic patent for this reason should be accepted as a valid reason for holding that the SPC "could not be obtained". As no equivalent protection was available the specific mechanism could, therefore, be relied upon.

Q2. Does it make any difference to the answer to Q1 if it was merely at the time of the filing of the application for the basic patent (issued in Germany) that such protection could not be obtained in the new member state but, by the time of publication of the application it could be so obtained?

No. The relevant date should be that of filing the application for the patent in the existing member state and not a period extended until the publication of that application. Otherwise, this would impose too high a burden on the patentee to monitor the laws of the relevant new member state until that publication date.

Q3. Can the holder of a German SPC rely on the specific mechanism to prevent the importation of products into Germany from the new member states after the expiry of the SPC but before the expiry of a six-month paediatric extension (on the basis of Regulation No1901/2006, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004)?

Yes. The paediatric extension falls within the scope of the specific mechanism because it is not a separate right to the patent and SPC, but rather an extension of the SPC term.

Q4. Does it make any difference to the answer to Q3 that, in the case of Croatia, the specific mechanism did not come into force until after the legislation listed in Q3 above (as a result of the accession of Croatia to the EU in 2013)?

No. If one new member state was treated differently to the others, parallel imports could come in through that State; as a result there would be a hole in EU patent protection which could ultimately negate the protection created by the specific mechanism.