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CJEU clarifies meaning ‘basic patent’ in SPC dispute

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The Court of Justice of the European Union (CJEU) has clarified when a product is ‘protected by a basic patent’ within the meaning of article 3(a) of the SPC Regulation.

In a long awaited preliminary ruling, the CJEU decided last week that:

‘Article 3(a) of Regulation No 469/2009 of the European Parliament and of the Council of 6 May 2009, concerning the supplementary protection certificate for medicinal products, must be interpreted as meaning that a product composed of several active ingredients with a combined effect is ‘protected by a basic patent in force’ within the meaning of that provision where, even if the combination of active ingredients of which that product is composed is not expressly mentioned in the claims of the basic patent, those claims relate necessarily and specifically to that combination. For that purpose, from the point of view of a person skilled in the art and on the basis of the prior art at the filing date or priority date of the basic patent:

– the combination of those active ingredients must necessarily, in the light of the description and drawings of that patent, fall under the invention covered by that patent, and

– each of those active ingredients must be specifically identifiable, in the light of all the information disclosed by that patent.’

The High Court of Justice of England & Wales, had asked for the CJEU’s preliminary ruling on 23 February 2017 in the case of Teva, Accord Healthcare, Lupin and Generics (trading as ‘Mylan’) against Gilead, in a dispute concerning the validity of an SPC granted to the latter for Truvada, a product for the treatment of HIV.

The CJEU chose not to follow significant parts of the AG’s opinion, according to Glyn Truscott, partner at Elkington + Fife, who was contacted by the Life Sciences Intellectual Property Review (LSIPR). ‘In particular, the AG’s explicit exclusion of the “core inventive advance” test has not been included in the final judgment. The AG’s requirement for the product to be ‘precisely’

identifiable has also not been followed.', LSIPR wrote.

The European Court of Justice leaves it to the UK High Court to decide whether its criteria are met. However, in art. 56 the CJEU says:

'In the present case it is apparent, first, from the information in the order for reference that the description of the basic patent at issue contains no information as to the possibility that the invention covered by that patent could relate specifically to a combined effect of TD and emtricitabine for the purposes of the treatment of HIV. Consequently, it does not seem possible that a person skilled in the art, on the basis of the prior art at the filing date or priority date of that patent, would be able to understand how emtricitabine, in combination with TD, necessarily falls under the invention covered by that patent. The onus is nevertheless on the referring court to check whether such is indeed the case. Secondly, it is also for that court to establish whether emtricitabine is specifically identifiable by that person skilled in the art in the light of all the information contained in that patent, on the basis of the prior art at the filing date or priority date of the patent in question.'

Later this year, other CJEU rulings concerning the interpretation of Article 3(a) of the SPC Regulation are expected to be handed down.

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