CJEU judgment in Case C-650/17 Royalty Pharma

Europe’s highest court restricts the types of patents that can be used as the basis for SPCs

Earlier today, the CJEU delivered its judgment in Case C-650/17 Royalty Pharma. In a decision with potentially far-reaching effects, the Court held that products falling under a functional definition in a patent claim but developed only after the filing date of a patent, after an independent inventive step, are not “protected” by that patent within the meaning of Article 3(a) of the SPC Regulation.

Although the CJEU had gone some way to clarifying the meaning of “protected” in Article 3(a) SPC law in its previous judgments, questions remain about the types of patents that can be used as the basis for SPCs.

In Royalty Pharma, the CJEU had been called upon by the German Federal Patent Court to provide guidance as to whether an active ingredient which is neither expressly mentioned in the claims nor provided as a concrete embodiment in the patent, but which is covered by a functional definition in the claims of that patent, is “protected” within the meaning of Article 3(a) of the SPC Regulation, even if that product was developed only after the filing date of the patent. The facts of the case related to Royalty Pharma’s SPC application for sitagliptin based on its patent claiming uses of dipeptidylpeptidase IV (DP IV) inhibitors for lowering blood glucose levels.

Sitagliptin is a DP IV inhibitor and falls under the functional definition of the claims, but is not individualised in the basic patent as it was not developed until after the patent’s filing date.

The CJEU held as follows:

1. Article 3(a) of Regulation (EC) 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 is protected by a basic patent in force, within the meaning of that provision, if it corresponds to a general functional definition used by one of the claims of the basic patent and necessarily comes within the scope of the invention covered by that patent, but is not otherwise indicated in individualised form as a specific embodiment of the method of that patent, provided that it is specifically identifiable, in the light of all the information disclosed by that patent, by a person skilled in the art, based on that person’s general knowledge in the relevant field at the filing date or priority date of the basic patent and on the prior art at that date.
2. Article 3(a) of Regulation No 469/2009 must be interpreted as meaning that a product is not protected by a basic patent in force, within the meaning of that provision, if, although it is covered by the functional definition given in the claims of that patent, it was developed after the filing date of the application for the basic patent, following an independent inventive step.

Point 1 appears to follow the test established in the CJEU’s earlier judgment in C-121/17 Teva (see here). Point 2, however, seems to go further by precluding grant of SPCs for products covered by a functional definition but developed after the filing date of the patent on the basis of an independent inventive step. In practice, this may restrict the choice of patentees deciding which patents to rely on to obtain SPCs for new products. This new element of the Article 3(a) test is also likely to raise fresh headaches for patent offices and national courts, which may now need to examine not only whether a product is the subject of a later inventive step but also whether that inventive step was “independent”.

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