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The marketing authorization holder of a reference product has the right to appeal against the approval of the generic in court

Judgment of the Court of Justice of the European Union of 23 October 2014, Case C-104/13, Olainfarm

Background

This case began when Olainfarm filed a case in the Latvian courts against the granting of a marketing authorization of a generic of its product Neiromidin in favour of Grindeks.

The Latvian judges, when analyzing the appeal, understood that it was convenient to raise two issues to the European Court of Justice.

The first issue dealt with whether a medicinal product approved through the bibliographic procedure may be considered as a reference product for the purposes of the approval of a generic. The second issue dealt with the possibility that a holder of a marketing authorization of a reference product files a court action against the approval of a generic version of its product, if it considers that the authorities have acted incorrectly.

Generics of products with a well-established medical use

Although the wording of Directive 2001/83 could allow other interpretations, the ECJ understands that medicines approved through this procedure may qualify as reference products.

In its reasoning, the Court relies, in particular, on the idea that these products have proven their efficacy and safety in a full manner on the basis of a dossier containing all the information and documentation needed for providing such evidence. Therefore, it is possible to approve a generic of such products if the applicant complies with all the conditions established in the directive and provided that the applicable data protection period is respected.

Court appeals

In connection with the second issue, the ECJ confirms that the administrative procedure under which a marketing authorization for a generic is granted or denied is a bilateral procedure in which the holder of the reference product is not called to intervene.

However, the ECJ refers to the Charter of Fundamental Rights of the European Union, according to which any person has the right to file a Court action if the rights that it holds under European Union Law have been violated. Under this principle, the ECJ states in a very clear manner that the holder of the reference medicinal product has the right to appear in Court and request that the conditions contemplated for the approval of generics be respected, at least with regard to those aspects that affect the holder of the marketing authorization.

On this basis, the holder of the reference medicinal product must be allowed to file a Court appeal if it wishes to revise whether its product could be considered a reference product or not, and also it it wishes to have the Courts review whether the requirements regarding similarity have been met, in particular as regards to composition and pharmaceutical form. Likewise, the holder may request the Court to review whether the applicable data protection periods have been respected.