Reports of Cases

Case C-557/16
Proceedings brought by Astellas Pharma GmbH

(Request for a preliminary ruling from the Korkein hallinto-oikeus)

(Reference for a preliminary ruling — Directive 2001/83/EC — Medicinal products for human use — Articles 28 and 29 — Decentralised procedure for marketing authorisation for a medicinal product — Article 10 — Generic medicinal product — Data exclusivity period for the reference medicinal product — Power of the competent authorities of the Member States concerned to determine the point in time from which the exclusivity period starts to run — Jurisdiction of the courts of the Member States concerned to review the determination of the point in time from which the exclusivity period starts to run — Effective judicial protection — Charter of Fundamental Rights of the European Union — Article 47)

Summary — Judgment of the Court (Second Chamber), 14 March 2018

1. *Approximation of laws — Medicinal products for human use — Directive 2001/83 — Authorisation to market — Generic of a reference medicinal product — Decentralised procedure — Adoption by each Member State of an authorisation decision — Possibility for a Member State to determine the point in time from which the data exclusivity period for the reference medicinal product starts to run — Precluded*

   (European Parliament and Council Directive 2001/83, as amended by Directive 2012/26, Arts 28(5) and 29(1))

2. *Approximation of laws — Medicinal products for human use — Directive 2001/83 — Authorisation to market — Generic of a reference medicinal product — Decentralised procedure — Adoption by each Member State of an authorisation decision — Action by the holder of the marketing authorisation for the reference medicinal product — Jurisdiction of the national court to review the determination of the point in time from which the data exclusivity period for the reference medicinal product starts to run — Limits*

   (Charter of Fundamental Rights of the European Union, Art. 47; European Parliament and Council Directive 2001/83, as amended by Directive 2012/26, Art. 10)

1. Article 28 and Article 29(1) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended by Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012, must be interpreted as meaning that, in a decentralised marketing-authorisation procedure for a generic medicinal product, the competent authority of a Member State concerned by that procedure cannot itself determine the point in time from which the data exclusivity period for the reference medicinal product starts to run when adopting, under Article 28(5) of that directive, its decision on the placing on the market of that generic medicinal product in that Member State.

It follows that the expiry of the data exclusivity period for the reference medicinal product is a precondition for the granting of a MA for a generic medicinal product and that, in the decentralised procedure for MAs, compliance with that condition must be verified by all the Member States participating in that procedure. It is, therefore, for those States, after the application has been submitted, and in any event before acknowledgement of the agreement, to oppose that application if that precondition is not satisfied. Consequently, the procedure which concludes with the acknowledgement of general agreement, in which all the Member States in which a MA application was submitted participate, involves verifying the expiry of the data exclusivity period for the reference medicinal product, so that the competent authorities of those Member States may not, after acknowledgement of that agreement, repeat such verification.

(see paras 29, 31, 32, operative part 1)

2. Article 10 of Directive 2001/83, as amended by Directive 2012/26, read in conjunction with Article 47 of the Charter of Fundamental Rights of the European Union, must be interpreted as meaning that a court of a Member State involved in a decentralised procedure for marketing authorisations, hearing an action brought by the holder of the marketing authorisation for the reference medicinal product against the marketing-authorisation decision for a generic medicinal product in that Member State taken by its competent authority, has jurisdiction to review the determination of the point in time from which the data exclusivity period for the reference medicinal product starts to run. By contrast, that court does not have jurisdiction to review whether the initial marketing authorisation for the reference medicinal product granted in another Member State was granted in accordance with that directive.

It follows that effective judicial protection of the rights held by the holder of a MA for the reference medicinal product as regards the data exclusivity of that medicinal product can be ensured only if that holder can rely on those rights before a court of the Member State in which the competent authority adopted a MA decision for the generic medicinal product and if it can, inter alia, plead before that court an error relating to the determination of the point in time from which the exclusivity period, affected by that decision, starts to run. However, that requirement of effective judicial protection does not mean that the holder of the MA for the reference medicinal product may call into question before that court the compatibility with Directive 2001/83 of MA decisions for that medicinal product taken in other Member States. That holder of the MA has a right to a judicial remedy which it can exercise, or which it could have exercised within the time limits set, against those decisions before the courts having jurisdiction to review the legality of the decisions adopted by the competent national authorities in each Member State.

(see paras 39-41, operative part 2)