



Press and Information

Court of Justice of the European Union

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Order of the Court in Case C-555/13
Merck Canada Inc v Accord Healthcare Ltd, Alter SA, Labochem Ltd,
Synthon BV, Ranbaxy Portugal - Comércio e Desenvolvimento de Produtos
Farmacêuticos, Unipessoal Lda

An arbitral tribunal such as the Portuguese ‘Tribunal Arbitral necessário’ may refer questions to the Court of Justice for a preliminary ruling

The holder of a patent and a supplementary protection certificate for a medicinal product may not enjoy more than 15 years of exclusivity from the first marketing authorisation issued in any Member State

In order to avoid the period between the lodging of a patent application for a medicinal product and the marketing authorisation for that medicinal product reducing the duration of the protection conferred by the patent (20 years), EU law¹ created the supplementary protection certificate. This certificate can be granted for a maximum duration of five years. However, the total duration of protection offered by the patent and by the certificate may not exceed 15 years from the first marketing authorisation in the European Union.

On 2 October 1998, the pharmaceutical company Merck Canada acquired a patent in Portugal for the active ingredient montelukast sodium, present, in particular, in the medicinal products Singulair and Singulair junior. These medicinal products are used notably for the treatment of asthma. Merck Canada subsequently acquired a supplementary protection certificate which in its view would have effect until 17 August 2014. However, the first marketing authorisation within the EU for a medicine containing that active ingredient had been obtained in Finland on 25 August 1997.

In November 2012, Merck Canada brought an action before a Portuguese arbitral tribunal for the purpose of blocking the marketing of generic drugs containing the active ingredient at issue. Merck Canada considers that these generic drugs cannot be marketed in Portugal before 17 August 2014, the date on which, in its opinion, the certificate is due to expire. The generic drug manufacturers are of the view that the protection conferred by the patent and the certificate expired in August 2012, 15 years after the first marketing authorisation in the EU of a medicinal product containing the active ingredient.

Seeking clarification on the subject, the Tribunal Arbitral necessário decided to refer a question to the Court of Justice for a preliminary ruling.

In its order dated 13 February 2014, the Court first examined whether the Tribunal Arbitral necessário can be considered to be a court or tribunal of a Member State and is thus entitled to refer questions to the Court of Justice for preliminary ruling. To this end, the Court takes into account a number of factors, such as whether the body is established by law, whether it is permanent, whether it is independent, whether its jurisdiction is compulsory, whether its procedure is *inter partes* and whether it applies rules of law.

In that regard, the Court recalls that a conventional arbitral tribunal is not to be considered a court or tribunal of a Member State, since the contracting parties are under no obligation, in law or in fact, to refer their disputes to arbitration and the public authorities of the relevant Member State are neither involved in the decision to opt for arbitration nor required to intervene of their own accord in the proceedings before the arbitrator.

¹ 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 (OJ 2009 L 152, p. 1).

However, the Court considers that the Tribunal Arbitral necessário meets all of the requirements to be considered a court or tribunal. Its jurisdiction stems not from the will of the parties, but from Portuguese legislation. This confers compulsory jurisdiction upon the tribunal to determine, at first instance, disputes involving industrial property rights pertaining to reference medicinal products and generic drugs. In addition, if the arbitral decision is not subject to an appeal before the competent appellate court, it becomes definitive and has the same effects as a judgment handed down by an ordinary court. Furthermore, the arbitrators are subject to the same obligations of independence and impartiality as the judges of the ordinary courts. Lastly, the Tribunal Arbitral necessário observes the principle of equal treatment and the adversarial principle in the treatment of parties and decides on the basis of the Portuguese law on industrial property.

On the other hand, the Court notes that the Tribunal Arbitral necessário may vary in form, composition and rules of procedure, according to the choice of the parties, and that it is dissolved after making its decision. These factors may thus raise doubts as to its permanence. However, given that the tribunal was established on a legislative basis, that it has permanent compulsory jurisdiction and that national legislation defines and frames the applicable procedural rules, the Court considers the requirement of permanence also to be met.

With regard to the substance of the case, the Court confirms that EU law precludes the holder of a patent and a certificate from relying on the total validity period of these titles in a situation where he would enjoy a period of exclusivity of longer than 15 years from the first marketing authorisation in the EU. In fact, EU law makes reference to the first authorisation granted in any Member State, and not the first authorisation granted in the Member State of the application. Only this interpretation ensures that the extension of protection of the product covered by the certificate will expire at the same time in all Member States in which the certificate was granted.

It follows that, irrespective of the date on which the basic patent was granted in Portugal and the theoretical validity period of the certificate, the maximum period of exclusivity conferred upon Merck Canada by the patent and by the certificate cannot exceed a total duration of 15 years, calculated from 25 August 1997. The protection therefore expired in August 2012.

NOTE: A reference for a preliminary ruling allows the courts and tribunals of the Member States, in disputes which have been brought before them, to refer questions to the Court of Justice about the interpretation of European Union law or the validity of a European Union act. The Court of Justice does not decide the dispute itself. It is for the national court or tribunal to dispose of the case in accordance with the Court's decision, which is similarly binding on other national courts or tribunals before which a similar issue is raised.

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The [full text](#) of the Order is available on the CURIA website.

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