Court of Justice EU, 12 February 2014, Merck Canada

PATENT LAW – LITIGATION

Tribunal Arbitral necessário must be considered to be a court or tribunal for the purposes of article 267 TFEU

- **Taking all of those considerations into account, it must be held that, in circumstances such as those of the main proceedings, the Tribunal Arbitral necessário fulfils all of the conditions laid down by the case-law of the Court, as set out in paragraphs 16 to 19 of the present order, and must be considered to be a court or tribunal for the purposes of Article 267 TFEU.**

Validity of SPC is no longer than 15 years from the first MA in the European Union

- **In the light of the foregoing considerations, the answer to the question referred is that Article 13 of Regulation No 469/2009, when read in conjunction with recital 9 thereto, must be interpreted as meaning that it precludes the holder of both a patent and a certificate from relying on the entire period of validity of the certificate, calculated in accordance with Article 13, in a situation where, pursuant to such a period, it would enjoy a period of exclusivity as regards an active ingredient, of more than 15 years from the first MA, in the European Union, of a medicinal product consisting of that active ingredient, or containing it.**

Source: curia.europa.eu

Court of Justice EU, 31 March 2010
(C.G. Fernlund, C. Toader and E. Jarašiūnas)
ORDER OF THE COURT (Eighth Chamber)
13 February 2014 (*)
(Request for a preliminary ruling — 'Court or tribunal' for the purposes of Article 267 TFEU — Tribunal Arbitral necessário — Admissibility — Regulation (EC) No 469/2009 — Article 13 — Supplementary protection certificate for medicinal products — Period of validity of a certificate — Maximum period of exclusivity)
In Case C‑555/13,
REQUEST for a preliminary ruling under Article 267 TFEU from the Tribunal Arbitral necessário (Portugal), made by decision of 17 October 2013, received at the Court on 28 October 2013, in the proceedings
Merck Canada Inc.
v
Accord Healthcare Ltd,
Alter SA,
Labochem Ltd,
Synthon BV,
Ranbaxy Portugal — Comércio e Desenvolvimento de Produtos Farmacêuticos, Unipessoal Lda,
THE COURT (Eighth Chamber),
composed of C.G. Fernlund, President of the Chamber, C. Toader (Rapporteur) and E. Jarašiūnas, Judges,
Advocate General: N. Jääskinen,
Registrar: A. Calot Escobar,
having decided, after hearing the Advocate General, to give a decision by reasoned order, pursuant to Article 99 of the Rules of Procedure of the Court of Justice,
makes the following
Order
1 This reference for a preliminary ruling concerns the interpretation of Article 13 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 (OJ 2009 L 152, p. 1).
2 The request has been made in proceedings between Merck Canada Inc. ('Merck Canada') and Accord Healthcare Ltd, Alter SA, Labochem Ltd, Synthon BV and Ranbaxy Portugal — Comércio e Desenvolvimento de Produtos Farmacêuticos, Unipessoal Lda, concerning the maximum period of exclusivity granted by both the basic patent and the supplementary protection certificate ('the certificate') held by Merck Canada.
Legal context
3 Recital 9 to Regulation No 469/2009 is worded as follows:
'The duration of the protection granted by the certificate should be such as to provide adequate effective protection. For this purpose, the holder of both a patent and a certificate should be able to enjoy an overall maximum of 15 years of exclusivity from the time the medicinal product in question first obtains authorisation to be placed on the market ["MA"] in the [European Union].'
4 Article 2 of the regulation provides:
'Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure as laid down in 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 [OJ 2001 L 311, p. 67] ... may, under the terms and conditions provided for in this Regulation, be the subject of a certificate.'
5 Article 3 of the regulation states:
'A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:
(a) the product is protected by a basic patent in force;

(b) a valid [MA] as a medicinal product has been granted in accordance with Directive 2001/83/EC …;
(c) the product has not already been the subject of a certificate;
(d) the authorisation referred to in point (b) is the first [MA] as a medicinal product.'
6 With regard to the period of validity of the certificate, Article 13(1) to (3) of Regulation No 469/2009 provides:
'1. The certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first [MA] in the [European Union], reduced by a period of five years.
2. Notwithstanding paragraph 1, the duration of the certificate may not exceed five years from the date on which it takes effect.
3. The periods laid down in paragraphs 1 and 2 shall be extended by six months in the case where Article 36 of Regulation (EC) No 1901/2006 applies. In that case, the duration of the period laid down in paragraph 1 of this Article may be extended only once.'

The dispute in the main proceedings and the question referred for a preliminary ruling

7 According to the order for reference, on 11 October 1991, Merck Canada lodged an application in Portugal for a patent for the active ingredient montelukast sodium, present in particular in the medicinal products Singulair and Singulair junior. Following that application, Patent No 99 213 was granted to that company, on 2 October 1998, in Portugal.
8 Within the European Union, the first MA for a medicinal product containing that active ingredient was obtained in Finland on 25 August 1997.
9 On 3 February 1999, Merck Canada applied for a certificate with the Instituto Nacional da Propriedade Industrial (National Institute of Intellectual Property) for a medicinal product relating to Patent No 99 213. Following that application, Certificate No 35 was granted to that company on 10 January 2000 for the active ingredient montelukast sodium.
10 According to the documents before the Court, on 6 November 2012, Merck Canada brought an action before the Tribunal Arbitral necessário seeking to compel, inter alia, the defendants in the main proceedings to abstain from producing, importing and/or launching on the Portuguese market generic drugs containing the abovementioned active ingredient.
11 In support of its action, Merck Canada relies, pursuant to Article 13 of Regulation No 469/2009, on the full period of validity of Certificate No 35, which is to run until 17 August 2014. It bases its reasoning on the fact that, under Article 13, the certificate is to take effect at the end of the lawful term of the basic patent, which was to expire on 2 October 2013, being 15 years after the date on which that patent was granted in Portugal. According to Merck Canada, the certificate was to take effect on 3 October 2013, for a period of 10 months and 15 days, until 17 August 2014, even if, under such a period which falls to be added to that of the patent it holds, that company may enjoy a period of exclusivity over the abovementioned active ingredient for a period which is greater than 15 years. As a result, the generic drugs produced by the defendants in the main proceedings should not be placed on the Portuguese market before the expiry date of that certificate.
12 By contrast, the defendants in the main proceedings claim that the aim of Regulation No 469/2009 is to guarantee the holder of both a patent and a certificate a maximum period of 15 years of exclusivity from the first MA, in the European Union, for the medicinal product in question.
13 Considering that the nature of the case required that it be processed within the shortest period possible, the Tribunal Arbitral necessário requests the application of the provision of Article 105 of the Rules of Procedure of the Court on the expedited procedure.
14 In those circumstances, the Tribunal Arbitral necessário decided to stay the proceedings and to refer the following question to the Court:
'Is Article 13 of Regulation No 469/2009 to be interpreted as permitting, by means of a [certificate] for medicinal products, the period for exclusive exploitation of the patented invention to be more than 15 years from the date of the first authorisation to place the medicinal product in question on the market within the Community (not including the extension provided for in Article 13(3) of that regulation)?'

The question referred for a preliminary ruling

Admissibility

15 First, it is must be examined whether the Tribunal Arbitral necessário should be considered to be a court or tribunal for the purposes of Article 267 TFEU.
16 In that regard, it should be noted that, according to settled case-law of the Court, in order to determine whether a body making a reference is a 'court or tribunal' within the meaning of Article 267 TFEU, which is a question governed by EU law alone, the Court takes account of a number of factors, such as whether the body is established by law, whether it is permanent, whether its jurisdiction is compulsory, whether its procedure is *inter partes*, whether it applies rules of law and whether it is independent (see C‑394/11 *Belov* [2013] ECR, paragraph 38 and the case-law cited).
17 It should also be stated that a conventional arbitration tribunal is not a 'court or tribunal of a Member State' within the meaning of Article 267 TFEU where the parties are under no obligation, in law or in fact, to refer their disputes to arbitration and the public authorities of the Member State concerned are not involved in the decision to opt for arbitration nor required to intervene of their own accord in the proceedings before the arbitrator (Case C‑125/04 *Denuit and Cordenier* [2005] ECR I‑923, paragraph 13 and the case-law cited).
18 However, the Court has held admissible preliminary questions referred to it by an arbitral tribunal, where that tribunal had been established by law, whose decisions were binding on the parties and whose

jurisdiction did not depend on their agreement (see, to that effect, Case 109/88 *Danfoss* [1989] ECR 3199, paragraphs 7 to 9).

19 In the main proceedings, it is clear from the order for reference that the jurisdiction of the Tribunal Arbitral necessário does not stem from the will of the parties, but from Law No 62/2011 of 12 December 2011. That law confers upon that tribunal compulsory jurisdiction to determine, at first instance, disputes involving industrial property rights pertaining to reference medicinal products and generic drugs. In addition, if the arbitral decision handed down by such a body 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.

20 The Member State at issue has therefore chosen, in the context of its procedure autonomy and with a view to implementing Regulation No 469/2009, to confer the jurisdiction for this type of dispute upon another body rather than an ordinary court (see, to that effect, Case 246/80 *Broekmeulen v Huisarts Registratie Commissie* [1981] ECR 2311, paragraph 16).

21 It is, moreover, apparent from the order for reference that the conditions laid down in the case-law of the Court referred to in paragraph 16 of the present order, relating to whether the body is established by law, whether its procedure is *inter partes*, whether it applies rules of law and whether it is independent, are met.

22 It is clear from the order for reference that Article 209(2) of the Constitution of the Portuguese Republic lists the arbitral tribunals among those entities capable of exercising an adjudicative function and that the Tribunal Arbitral necessário was established by Law No 62/2011 of 12 December 2011.

23 Furthermore, according to the order for reference, the arbitrators are subject to the same obligations of independence and impartiality as judges belonging to the ordinary courts and the Tribunal Arbitral necessário observes the principle of equal treatment and the adversarial principle in the treatment of parties and gives its rulings on the basis of the Portuguese law on industrial property.

24 The Tribunal Arbitral necessário may vary in form, composition and rules of procedure, according to the choice of the parties. Moreover, it is dissolved after making its decision. It is true that, those factors may raise certain doubts as to its permanence. However, given that that tribunal was established on a legislative basis, that it has permanent compulsory jurisdiction and, in addition, that national legislation defines and frames the applicable procedural rules, it should be found that, in the present case, the requirement of permanence is also met.

25 Taking all of those considerations into account, it must be held that, in circumstances such as those of the main proceedings, the Tribunal Arbitral necessário fulfils all of the conditions laid down by the case-law of the Court, as set out in paragraphs 16 to 19 of the present order, and must be considered to be a court or tribunal for the purposes of Article 267 TFEU.

Substance

26 Pursuant to Article 99 of its Rules of Procedure, where the reply to a question referred to the Court for a preliminary ruling may be clearly deduced from existing case-law or admits of no reasonable doubt, the Court may at any time, on a proposal from the Judge-Rapporteur and after hearing the Advocate General, decide to rule by reasoned order.

27 The Court considers that to be the case in the present proceedings and holds that, taking into account the making of the present order, it is not necessary to rule on the application for an expedited procedure made by the referring court (see, to that effect, order in C‑503/07 P *Saint-Gobain Glass Deutschland v Commission* [2008] ECR I‑2217, paragraph 45). The answer to the question referred by the Tribunal Arbitral necessário leaves no room for reasonable doubt and may, in addition, be clearly deduced from existing case-law, inter alia from the order in Case C‑617/12 *Astrazeneca* [2013] ECR.

28 By its question, the Tribunal Arbitral necessário essentially asks whether Article 13 of Regulation No 469/2009, when read in conjunction with recital 9 thereto, must be interpreted as meaning that it precludes the holder of both a patent and a certificate from relying on the entire period of validity of the certificate, calculated in accordance with Article 13, in a situation where, pursuant to such a period, it would enjoy a period of exclusivity as regards an active ingredient, of more than 15 years from the first MA, in the European Union, of a medicinal product consisting of that active ingredient, or containing it.

29 An affirmative answer to that question follows from a literal interpretation of Article 13 of Regulation No 469/2009, read in conjunction with recital 9 thereto.

30 That interpretation was also confirmed most recently in the order in *Astrazeneca*, paragraph 42 of which provides that the holder of both a patent and a supplementary protection certificate should not be able to enjoy more than 15 years of exclusivity from the time the first MA, in the European Union, of the medicinal product concerned.

31 Furthermore, it should be recalled that the wording '*first authorisation to place the product on the market in the [European Union]*', for the purposes of Article 13(1) of Regulation No 469/2009, make reference to the first MA granted in any Member State and not to the first authorisation granted in the Member State of the application. Only that interpretation ensures that the extension of protection of the product covered by the certificate will expire at the same time in all of the Member States in which the certificate was granted (see, to that effect, Case C‑127/00 *Hässle* [2003] ECR I‑14781, paragraphs 74, 77 and 78).

32 In the main proceedings, it is not in dispute that the first MA, in the European Union, of medicinal products containing the active ingredient protected by the basic

patent of which Merck Canada is the holder was granted on 25 August 1997 in Finland.

33 As a result, irrespective of the date on which the basic patent was granted in Portugal and the theoretical validity period of the certificate resulting from the application of Article 13 of Regulation No 469/2009, the maximum period of exclusivity conferred by both Patent No 99 213 and Certificate No 35 cannot exceed a total duration of 15 years, calculated from 25 August 1997.

34 In the light of the foregoing considerations, the answer to the question referred is that Article 13 of Regulation No 469/2009, when read in conjunction with recital 9 thereto, must be interpreted as meaning that it precludes the holder of both a patent and a certificate from relying on the entire period of validity of the certificate, calculated in accordance with Article 13, in a situation where, pursuant to such a period, it would enjoy a period of exclusivity as regards an active ingredient, of more than 15 years from the first MA, in the European Union, of a medicinal product consisting of that active ingredient, or containing it.

Costs

35 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court.

On those grounds, the Court (Eighth Chamber) hereby rules:

Article 13 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, read in conjunction with recital 9 to the same regulation, must be interpreted as meaning that it precludes the holder of both a patent and a supplementary protection certificate from relying on the entire period of validity of such a certificate, calculated in accordance with Article 13, in a situation where, pursuant to such a period, it would enjoy a period of exclusivity as regards an active ingredient, of more than 15 years from the first authorisation to be placed on the market, in the European Union, of a medicinal product consisting of that active ingredient, or containing it.

[Signatures]

*Language of the case: Portuguese.