## DECISION OF THE COURT OF JUSTICE (EIGHTH SECTION)

Case C-555/13 – February 13, 2014

**The Court of Justice issued a ruling on the interpretation of Article 13 of Regulation (EC) no. 469/2009 concerning the duration and maximum exclusivity period of Supplementary Protection Certificate for medicines.**

This request has been filed to the Court of Justice in the scope of a dispute opposing Merck Canada Inc. (henceforth "Merck Canada") to the companies Accord Healthcare Ltd, Alter SA, Labochem Ltd, Synthon BV and Ranbaxy Portugal – Comércio e Desenvolvimento de Produtos Farmacêuticos, Unipessoal Lda. concerning the exclusivity maximum period granted by the basic patent and by the supplementary protection certificate (henceforth "certificate") owned by Merck Canada.

### I – THE QUESTION REFERRED TO THE COURT OF JUSTICE

The question referred to the Court was: "*May Article 13 of Regulation No 469/2009 (1) be interpreted as permitting, by means of a supplementary protection certificate for medicinal products, the period for exclusive exploitation of the patented invention to be more than fifteen years from the date of the first authorization 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)?*"

**II – LEGAL FRAME**

The recital 9 of the Regulation no. 469/2009 has the following wording:

"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 in the Community [henceforth "MA"]."

Article 2 of referred regulation foresees:

"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 (2) or Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (3) may, under the terms and conditions provided for in this Regulation, be the subject of a certificate."

Article 3 of the same 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 authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate;
(c) the product has not already been the subject of a certificate;
(d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.

In what concerns the validity period of the certificate article 13, no. 1 to 3 of the Regulation no. 469/2009 lays down:

"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 authorisation to place the product on the market in the Community, 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."

**DISPUTE IN THE MAIN ACTION**

On October 11, 1991, Merck Canada filed a patent application in Portugal for the active ingredient Montelukast Sodium, present namely in the medicinal products *Singulair* and *Singulair junior.* On October 2, 1998, following this patent application, the said company was granted the patent No. 99 213 in Portugal.

The first MA for a medicinal product containing this active ingredient in the European Union was obtained in Finland, on August 25, 1997.

On February 3, 1999, Merck Canada applied for a supplementary protection certificate for the medicinal product related to patent No. 99 213. Following this application, on January 10, 2000 the said company was granted the certificate No. 35 for the active ingredient montelukast sodium.

According to the proceedings available at the Court of Justice, on November 6, 2012 Merck Canada initiated proceedings before the Arbitral Tribunal to have the Defendants, in the main file, ordered to refrain from producing, importing and/or commercializing, in the Portuguese market, generic medicines containing the said active ingredient.

In support of its action Merck Canada claims within the meanings of article 13 of Regulation no. 469/2009 the full validity of certificate no. 35 that lasts until August 17, 2014. It bases its reasoning on the fact that, in accordance with this article 13, the certificate produces effects until the end of the legal validity period of the basic patent, that is to say, on October 2, 2013, fifteen years after the granting date of referred patent in Portugal. According to Merck Canada the certificate produces effects as from October 3, 2013, during a period of ten months and fifteen days, that is to say, until August 17, 2014 even if in application of this period that is added to the one of the patent which it owns the same company may benefit from an exclusivity period concerning the referred active ingredient during a period superior to fifteen years.

The defendants in the main action plead that Regulation No. 469/2009 have the goal of guaranteeing to the holder of a patent and of a certificate a maximum exclusivity period of fifteen years as from the first MA issued in the EU of the medicine at issue.

**THE DECISION FROM THE COURT OF JUSTICE (EIGHTH SECTION)**

According to a decision issued on February 13, 2014, the European Court decided that: "*The article 13 of the 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 of this regulation, must be interpreted as meaning that it opposes that the holder of a patent and of a supplementary protection certificate may invoke the whole duration of the said certificate, applying this article 13 in a situation where, due to the said duration, the said holder would benefit from a period of exclusive exploitation of an active ingredient of more than fifteen years from the date of the first marketing authorization within the Community, of the medicinal product consisting of the said active ingredient or containing it.*"

Lisbon, February 13, 2014