



April 2014

PATENT OFFICE TO REASSESS SPCs' MAXIMUM EXCLUSIVITY PERIOD

Directive No. 2/2014, of April 10, of the Patent Office: as a result of the CJEU judgment delivered on February 13, 2014 in Case C-555/13, the maximum exclusivity period conferred by supplementary protection certificates will be reassessed.

Over the last few years there have been some doubts concerning the interpretation of Recital 9 and of 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 certificates for medicinal products.

In this context, a request for a preliminary ruling was submitted to the Court of Justice of the European Union (CJEU), as follows:

“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 [MA] for the medicinal product in question within the [Community] (not including the extension provided for in the said Article 13(3))?”

As previously reported, through the judgment delivered on February 13, 2014 in Case C-555/13, the CJEU ruled that:

“Article 13 of Regulation (EC) No 469/2009 [...], 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.”

In compliance with the above judgment, the Executive Board of the PTO established that:

a) The duration of all supplementary protection certificates shall be reassessed and, if necessary, rectified (with the corresponding publication in the Industrial Property Bulletin), so as to guarantee that the maximum exclusivity period defined by the CJEU is not exceeded;

b) Without prejudice to the preceding point, the holders of supplementary protection certificates shall be entitled to request the extension of the duration foreseen in article 115-A of the Industrial Property Code (IPC) and in Regulation (EC) No. 1901/2006 of the European Parliament and of the Council, of December 12, 2006, in case of medicinal products for paediatric use, being therefore possible to enjoy a six-month extension of the exclusivity period of 15 years, from the first Marketing Authorization in the European Union.

BMA – April 2014