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Will the judgment of the CJEU in Seattle Genetics Inc allow you to recalculate the term of your SPC retrospectively?

Miquel Montaña (Clifford Chance) · Thursday, December 24th, 2015

One of the legacies that the year we are about to leave behind will leave us is the Judgment of 6 October 2015 handed down by the Court of Justice of the European Union (“CJEU”) in Case C-471/14 Seattle Genetics Inc. v. Österreichisches Patentamt (“Austrian Patent Office”). The case had its origins in a request for a preliminary ruling made by the latter in connection with the interpretation of Article 13(1) of Regulation (EC) 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (“SPC Regulation”). The request was made in the context of proceedings between Seattle Genetics Inc. and the Austrian Patent Office regarding the duration of an SPC. The main point under discussion was whether the relevant date for the purposes of calculating the term of the SPC under Art. 13 (1) of the SPC Regulation is the date of the first marketing authorization or the date when the applicant was notified of the first marketing authorization.

In its Judgment, the CJEU offered the following responses:

“1) Article 13(1) 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 must be interpreted as meaning that the ‘date of the first authorisation to place the product on the market in the [European Union]’ is determined by EU law.

2) Article 13(1) of Regulation No 469/2009 is to be interpreted as meaning that the ‘date of the first authorisation to place the product on the market in the [European Union]’ within the meaning of that provision is the date on which notification of the decision granting marketing authorisation was given to the addressee of the decision“.

It is clear from the Judgment that, within the context of Article 13(1), the relevant date for calculating the term of the SPC is the date when the applicant was notified of the decision granting the marketing authorisation. What the Judgment did not clarify is whether this interpretation will apply to future SPCs or also to SPCs already granted, which would allow owners of SPCs to recalculate their term.

As a general rule, judgments handed down by the CJEU in response to requests for preliminary rulings normally apply retrospectively. However, it appears that not all the stakeholders concerned are on the same page. This is the case of the Spanish Patents and Trademarks Office (“SPTO”) at any rate, which on 22 October 2015 published a Notice to Applicants stating the following:

“The judgment of the European Court of Justice (Eighth Chamber) dated 6 October 2015, in case C-471/14, declares:

“1) Article 13(1) 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 must be interpreted as meaning that the ‘date of the first authorisation to place the product on the market in the [European Union]’ is determined by EU law.

2) Article 13(1) of Regulation No 469/2009 is to be interpreted as meaning that the ‘date of the first authorisation to place the product on the market in the [European Union]’ within the meaning of that provision is the date on which notification of the decision granting marketing authorisation was given to the addressee of the decision“.

As a result, we hereby announce that, as of the date indicated and for Supplementary Protection Certificate procedures currently in progress, the Spanish Patent and Trademark Office will take into consideration as “date of the first authorisation to place the product on the market” the date on which notification of the decision granting marketing authorisation was given to the addressee of the decision, with the requirement that documentation be submitted to provide authoritative proof of said date of notification.”

By contrast, the SPTO has informally announced that it will not allow the recalculation of the term of SPCs already granted. Notwithstanding the respectful opinion of the SPTO, as always, the Courts will have the last say...

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