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An SPC granted using a marketing authorisation that time has proved to be wrong: Nullification or recalculation?

Miquel Montaña (Clifford Chance) · Tuesday, September 25th, 2012

Until recently, cases involving “Supplementary Protection Certificates” (so-called “SPCs”) were relatively rare in Spain. This is due to the fact that, as a consequence of the transitional provisions of article 21 of Regulation 1768/1992 (the “SPC Regulation), SPCs became available in Spain later than in other European Union member states. However, over the last few years there has been a surge of matters dealing with SPCs. One of the topics discussed has been what should be the legal consequence of having invoked a marketing authorisation that time has proved to be wrong: the nullification of the SPC or the recalculation of its duration?

The debate around this topic has been sparked by the fact that when the SPC Regulation came into force, article 13.1 was interpreted as meaning that only authorisations granted within the European Union qualified for calculating the duration of an SPC. For the readers’ benefit, it is worth transcribing the text of article 13.1:

“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.”

During the early days, the Spanish Patents and Trademarks Office (“SPTO”) took the view that the relevant marketing authorisation in the context of article 13 was the first authorisation granted within the territory of the European Union. This was also the view of many other patent offices across Europe and the interpretation that found a better fit in the actual wording of article 13. However, all this changed on 21 April 2005, when the European Court of Justice (“ECJ”) handed down its judgment in case C-207/03 and C-252/03, *Novartis et alri v. Comptroller-General of Patents, Designs and Trade Marks for the UK*. Readers will remember that in this case the ECJ came to the conclusion that a marketing authorisation issued by the Swiss authorities and automatically recognised by the Principality of Liechtenstein under that State’s legislation qualifies as the first authorisation to place the product on the market within the meaning of article 13.

This judgment prompted the SPTO to change its administrative practice. Since then, the SPTO calculates the term of SPCs applied for after this judgment taking into account the date when the first marketing authorisation was granted in the territory of one of the States covered by the Agreement on the European Economic Area (EEA). What about SPCs granted before the ECJ clarified this point in its judgment of 21 April 2005? Unfortunately, unlike in other countries, the SPTO has not put in place an administrative procedure to recalculate the term of these SPCs. This is a matter of regret, since in some cases it was the SPTO which picked the wrong marketing authorisation among the different marketing authorisations that applicants had candidly brought to

the attention of the SPTO. A procedure to recalculate the term of these SPC before the SPTO would be highly desirable, as it would prevent unnecessary litigation.

Until, if and when the SPTO approves such a procedure, the parties will have to continue wasting their time and money discussing this point in Court. It is expected that the judicial cases under way will result in the recalculation of the term of the affected SPCs, as this was the answer provided by the ECJ in its judgment of 11 December 2003 (Case C-127/00, Hässle AB v. Ratiopharm GmbH; paragraph 88).

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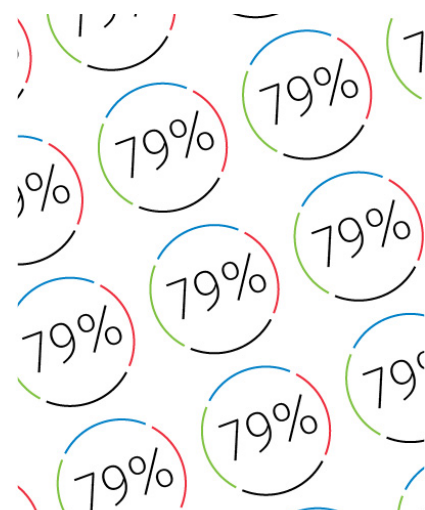
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