EIP

Safeners can be active substances for purposes of supplementary protection certificates, says CJEU

C□11/13 Bayer CropScience AG v Deutsches Patent- und Markenamt

The Court of Justice of the European Union rules that a supplementary protection certificate (SPC) can be granted in respect of a safener.

Legal Background

Supplementary protection certificates can be granted in the European Union in respect of plant protection products pursuant to Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996, and in respect of medicinal products for human or animal use pursuant to Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009.

Under the latter Regulation, where "product" is defined as "active ingredient", it is established caselaw of the CJEU that excipients and adjuvants do not fulfil the requirement of being an active ingredient, and that an SPC cannot be obtained in respect of such substances (Massachusetts Institute of Technology C-431/04, Glaxosmithkline Biologicals and Glaxosmithkline Biologicals, Niederlassung der Smithkline Beecham Pharma, C□210/13).

Under the former Regulation, it fell to be determined in the present case whether a "safener" could be considered to be a "product", defined in the Regulation Article 1.8 to be an "active substance", which in turn is defined in Article 1.3 as:

"substances or micro-organisms including viruses, having general or specific action:

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(a) against harmful organisms; or

(b) on plants, parts of plants or plant products."

Factual Background

A safener is a compound added to a herbicide product which is "intended to prevent the harmful effects of a herbicidal active substance, in order to increase its effectiveness". There is no doubt that a herbicide itself can be the subject of an SPC, but what about the safener as such? In the present case, Bayer sought from the Deutsches Patent- und Markenamt an SPC on the basis of a patent covering isoxadifen, a safener, and a marketing authorisation in respect of a combination herbicide containing isoxadifen in combination with two herbicidal components foramsulfuron and iodosulfuron. The application having been refused, Bayer appealed, and in the course of the appeal the Bundespatentgericht referred to the CJEU the question:

"Are the terms 'product' in Article 3(1) and Article 1.8 and 'active substances' in Article 1.3 of [Regulation No 1610/96] to be interpreted as covering a safener?"

Basically considering that the question should be answered "yes" at least in the circumstances of the particular case, the CJEU in fact ruled as follows:

"The term 'product' in Article 1.8 and Article 3(1) of Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products, and the term 'active substances' in Article 1.3 of that regulation, must be interpreted as meaning that those terms may cover a substance intended to be used as a safener, where that substance has a toxic, phytotoxic or plant protection action of its own."

Analysis

The judgment teases the reader by stating that it is for the national court to ascertain whether a substance which is a safener can be classified as an 'active substance' for the purposes of granting an SPC. This observation notwithstanding, the CJEU used information from the referring decision to clearly indicate an answer, which, although stated as quoted above in the terms "may cover a substance" is in context clearly to be read definitively, so that in this case the terms "product" and "active substance" do cover a substance which acts a safener.

The reasoning is brief. First, the CJEU considered that no express provision of the

Regulation either specifically authorises or excludes the possibility of covering a safener. Secondly, while it considered that the term 'active substances' relates to substances
p3 which have a toxic, phytotoxic or plant protection action of their own, it saw no need to restrict the term 'active substances' to those whose action may be characterised as direct, and therefore considered that the term could extend to substances with indirect action. Thirdly, the CJEU saw as significant that the safener isoxadifen was examined in connection with a procedure granting of the marketing authorisation of the combination product, and that the duration of that procedure reduced the effective duration of protection provided by the patent. On the basis of these considerations, it indicated a positive answer to the question referred.

It is not expressly clear from the decision whether this effectively means that all safeners would qualify for SPC protection. However, it is clear from the reasoning that at least an indirect toxic, phytotoxic or plant protection action is required. Since a safener by definition may be regarded as having an effect at least on toxicity, it is likely that the decision will be taken to apply to safeners in general, but this cannot be concluded with certainty. The last clause of the answer to the question ("where that substance has a toxic, phytotoxic or plant protection action of its own") will give any EU court some flexibility in how it chooses to apply the decision, and leads to the prospect of divergent national rulings or further references to the CJEU on similar matters.

Superficially, this result contrasts with the situation for excipients and adjuvants. However, neither is technically completely cognate with a safener, which can perhaps legitimately be considered more "active" than the other two. Moreover, the definition of "active substance" in relation to plant protection products is not identical to the definition of "active ingredient" in relation to medicinal products, and this divergence may also justify the different outcome. This decision indicates a clear path for obtaining SPCs in respect of safeners, but is unlikely to increase the scope for SPCs for pharmaceutical constituents that have no active effect of their own.

By Darren Smyth.