Kluwer Patent Blog

An SPC Present from the Christmas Court

Thorsten Bausch (Hoffmann Eitle) · Friday, December 20th, 2024

It's this time of the year again – merry Christmas, happy holidays and/or best wishes for whatever you are celebrating next week. This year's Christmas present comes from the CJEU and is specifically directed to the SPC Community. It's the decision in the joint cases C-119/22 and C-149/22.

The decision has every potential to bring joy to the SPC community. On the one hand, the CJEU put an end to the debate about the interpretation of Art 3c of Regulation (EC) No 469/2009 ("the SPC Regulation") in the case of combination products. Art 3c stipulates that an SPC 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 the product has not already been the subject of an SPC. The question was how this Article is to be applied if the SPC applied for pertains to a combination of active ingredients A and B, in a situation where an SPC has already been granted for A. The CJEU held that such an earlier SPC does not preclude the grant of a later SPC to A + B.

In the court's own words:

> 1. Article 3(c) 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 not precluding the grant of a supplementary protection certificate (SPC) for a product consisting of two active ingredients even if one of those two active ingredients has already been, alone, the subject of an earlier SPC and it is the only one to have been disclosed by the basic patent, whereas the other active ingredient was known at the filing date or priority date of that patent.

On the other hand, the CJEU also had to deal with referrals of questions on the meaning of Art 3a of the SPC Regulation. And here the Court managed to secure the business of countless attorneys and patent attorneys for the years to come. Let us first remind ourselves what Art 3a says. It is deceptively simple:

> 3. [An SPC] 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

How do you find out whether something is protected by a patent? Nothing easier than that: you look at the claims. This is because Art 84 EPC (which the CJEU even cited in its decision) stipulates:

> The claims shall define the matter for which protection is sought.

And Art 69 EPC adds to this:

> (1) The extent of the protection conferred by a European patent or a European patent application shall be determined by the claims. Nevertheless, the description and drawings shall be used to interpret the claims.

So, if a combination comprising A and B is literally recited in the claims, it should be protected by the patent, should it not?

It is not. At least not according to the CJEU and if we are talking about an SPC and Art 3a. Then everything is different. In the court's own words (emphasis added):

> 2. Article 3(a) of Regulation No 469/2009
>
> must be interpreted as meaning that it does **not suffice** that a product is expressly mentioned in the claims of the basic patent in order for that product to be regarded as being protected by that patent, within the meaning of that provision. **It is also necessary**, in order to satisfy the condition laid down in that provision, **that that product necessarily fall**, from the point of view of a person skilled in the art, and in the light of the description and drawings of that patent, **under the invention covered by that patent** at the filing date or priority date.
>
> 3. Article 3(a) of Regulation No 469/2009
>
> must be interpreted as meaning that a product consisting of two active ingredients (A+B) is protected by a basic patent, within the meaning of that provision, where A and B are expressly mentioned in the claims of that patent and the specification of that patent teaches that A may be used as a medicinal product for human use alone or in combination with B, which is an active ingredient in the public domain at the filing date or priority date of that patent, **provided that the combination of those two active ingredients necessarily falls under the invention covered by the same patent**.

So I guess that my profession will have some fun in finding out whether something that is literally mentioned in a claim actually and "necessarily falls under the invention" covered by the patent. Apparently, the claims no longer define the invention for which protection is sought; an additional

step of interpretation is required.

In the second case at stake it seems that the CJEU might recognize that a combination of A + B falls under the invention, if the basic patent discloses that the combination of the two active ingredients has a combined effect **going beyond the mere addition** of the effects of those two active ingredients and which contributes to the solution of the technical problem (paragraph 70). Mere aggregations, i.e. simply putting two known and approved active ingredients into one pill, with no further effect than the sum of the effects of each of those active ingredients taken separately, might not be sufficient (paragraph 72).

On this joyous note, we can state that we now have a further Christmas gift bringer in Europe, this time from Luxembourg.

from Jirka.h23, CC BY-SA 4.0 <https://creativecommons.org/licenses/by-sa/4.0>, via Wikimedia Commons with some addition by the author

---

To make sure you do not miss out on regular updates from the Kluwer Patent Blog, please subscribe here.

This entry was posted on Friday, December 20th, 2024 at 9:13 am and is filed under Patents
You can follow any responses to this entry through the Comments (RSS) feed. You can leave a response, or trackback from your own site.