

Supplementary Protection Certificate (SPC) Infringement in different European Courts

In Europe, the national courts decide the infringement of SPCs. Novartis has sued Actavis for infringement of its SPCs for valsartan in the UK, French, German and Norwegian Courts.

The SPCs relate to a European patent for a group of antihypertensive compounds including valsartan.

The cases revolve around whether the Actavis' generic combination product, valsartan and hydrochlorothiazide, falls within the scope of Novartis' SPC for valsartan alone. Actavis have a separate marketing authorisation for their combination product.

United Kingdom

The UK High Court has not yet issued its decision.

Actavis argue that the Novartis' SPC for valsartan is restricted to the authorised product "Diovan" and, therefore, Actavis' separately authorised product does not infringe the SPC.

We await the decision with interest.

France

The French Court of First Instance has decided the case in France.

The French judge found that Novartis' French SPC prohibits the marketing of all pharmaceuticals containing valsartan, either alone or in combination with another active ingredient. Therefore, Actavis' product infringes Novartis' SPC in France.

The Court issued a preliminary injunction against Actavis, prohibiting them from distributing their product in France.

Actavis may appeal this decision.

Norway

The District Court of Norway has also decided the case.

The Court held that Actavis' product infringes Novartis' Norwegian SPC. The Court found that the marketing of any form of valsartan, either alone or in a combination product, infringes the SPC in Norway.

As a result of the decision, Actavis had to immediately withdraw its product from the Norwegian market.

Actavis has lodged an appeal with the Norwegian Court of Appeal.

Germany

Novartis started preliminary proceedings in the Düsseldorf District Court on 8 March 2011.

The Court held that Actavis' product infringes Novartis' German SPC. However, the Court indicated that the case raised questions on the interpretation of the SPC Regulation. The Court felt that it is an issue for the Court of Justice of the EU (CJEU), the highest Court in Europe, and ordered Novartis to file actions on the merits against Actavis by 8 April 2011. The Court has the power to refer actions on merits to the CJEU, and seem s certain to do so once Novartis files the action.

Conclusion

It is reassuring to see that the decisions in Norway, France and Germany concur, and we wait with interest to see if the UK Court does the same.

The issue remains unresolved, however. The picture could yet be changed by the Norwegian Court of Appeal or the CJEU.