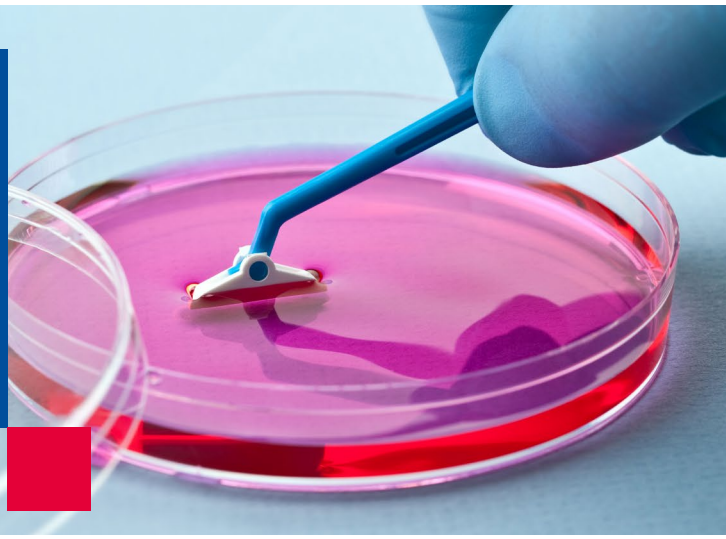
Comment on Truvada German Supreme Court



Introduction

The recent decision "Truvada" of the Federal German Supreme Court, dated 22 September 2020 (docket no. X ZR 172/18) is a landmark decision in the field of supplementary protection certificates („SPCs").

According to the decision, the legitimate legal interest ("Rechtsschutzbedürfnis") for filing a nullity action after the expiry of the term of an SPC is only to be denied if the assertion of infringement claims by the patent proprietor is "evidently" no longer a possibility.

Moreover, the Federal German Supreme Court held that the combination of two active ingredients is usually not protected by a basic patent within the meaning of Art. 3 lit. a of the Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products („Regulation"), if the basic patent describes one of the two active ingredients only as an "optional further component".

Subject of the decision

The defendant is the proprietor of European patent 915 894, which was filed on 25 July 1997 and concerns intermediates for nucleotide analogues.

Claim 25 of the patent protects the compound tenofovir disoproxil. Claim 27, which refers back to claims 1-25, protects a pharmaceutical composition containing tenofovir disoproxil and optionally further therapeutic components which are not specified in the claims or in the description of the patent.

On 21 February 2005, the defendant obtained a marketing authorization for the medicinal product „Truvada", which contains tenofovir disoproxil and emtricitabine as active ingredients.

The defendant applied for an SPC on the basis of the above cited patent as basic patent and the marketing authorization for the medicinal product „Truvada".

The defendant was subsequently granted SPC 12 2005 000 041 for the combination of tenofovir disoproxil and emtricitabine. The term of the SPC expired on 24 February 2020.

In 2016, four nullity actions against the SPC were filed at the Federal Patent Court by four different plaintiffs.

The four plaintiffs market generic medicinal products with the combination of the active ingredients tenofovir disoproxil and emtricitabine. Two of the plaintiffs were sued by the defendant for injunctive relief for infringement of the SPC.

In response to the nullity actions, the Federal Patent Court declared the SPC null and void on 22 September 2020, i.e. after its expiry, pursuant to Art. 15 para (1) lit. a in conjunction with Art. 3 lit. a of the Regulation.

The defendant appealed against the decision of the Federal Patent Court.

Two questions were of particular interest in this case: First, on what conditions an SPC be declared null and void after its expiry? Second, was the product concerned protected by the basic patent in the sense of Art. 3 lit. a of the Regulation?

The decision

The Federal German Supreme Court followed its established case law of interpreting the legitimate legal interest ("Rechtsschutzbedürfnis") for filing a nullity action after the expiry of a patent/SPC generously. This legitimate legal interest is affirmed if it cannot be ruled out that the plaintiff of the nullity action will be held liable for infringement of the SPC due to acts of a company associated with it.

Moreover, the Federal German Supreme Court confirmed that the SPC is invalid under Art. 15 I lit. a and Art. 3 lit. a of the Regulation, because the combination of the active ingredients tenofovir disoproxil and emtricitabine is not „protected" by the basic patent in the sense of the Regulation.

The Federal German Supreme Court held that in order to fulfil this requirement, an active ingredient does not necessarily have to be named in the basic patent. Rather, it is sufficient if the active ingredient falls within a structural or functional definition contained in the claims of the basic patent. The Federal German Supreme Court cites the Court of Justice for the European Union, which had explained that the combination of active ingredients must „necessarily" be covered by the basic patent and that each of the active ingredients must be „specifically identifiable" in the light of all the information disclosed in the basic patent (Teva UK et al. C-121/17).

The Federal German Supreme Court concluded that the combination of the active ingredients tenofovir disoproxil and emtricitabine was not „necessarily" covered by the invention protected by the basic patent in the light of the description and drawings of the basic patent. The further therapeutic components recited in claim 27 were only „optional". According to the established case law of the Federal German Supreme Court, optional features were not to be taken into account when determining the subject-matter protected by a patent.

Moreover, emtricitabine was not „specifically identifiable". According to the Federal German Supreme Court, the requirement in claim 27 to combine one of the active ingredients protected in claims 1-25 with an „arbitrary" further active ingredient does not result in a structural or functional definition of this further active ingredient. Rather, its selection is simply left to the discretion of the skilled person.

Summary

The legitimate legal interest ("Rechtsschutzbedürfnis") for filing a nullity action after the expiry of the term of an SPC is only to be denied if a claim by the patent proprietor is evidently no longer a possibility.

The combination of two active ingredients is usually not protected by a basic patent within the meaning of Art. 3 lit. a of the Regulation, if the basic patent describes one of the two active ingredients only as an optional further component. The decision is in line with the case law of the European Court of Justice on Art. 3 lit. a of the Regulation.

Thus, the use of optional features in patent claims should be considered carefully. In the end, they have not effect on the scope of the patent nor on its validity.

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