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Validity of Gilead's Swiss TRUVADA® SPC confirmed but Switzerland will move away from the "infringement test" for future SPCs for combination products

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The Swiss Federal Supreme Court issued a landmark decision concerning the requirements for Supplementary Protection Certificates (SPCs) for combination products. Until recently, Switzerland stood solid as a rock and defended the so-called infringement test for SPCs for combination products. The Federal Supreme Court has now ruled that while the infringement test shall still apply to existing SPCs, new SPCs for combination products shall be examined in light of the Medeva ruling and other decisions of the CJEU concerning combination products. Whether the Swiss SPC in dispute meets the requirements of the EU case law is not relevant and, therefore, has not been decided by the Swiss Federal Supreme Court (the German version of the decision of the Swiss Supreme Court will soon be published here).

(By Simon Holzer, Kilian Schärli and Marco Borer. Note that Meyerlustenberger Lachenal AG has been involved in this matter on behalf of Gilead)

The Swiss dispute in a nutshell

The Swiss litigation is about the validity of Gilead Sciences Inc.'s Swiss SPC C00915894/01 for the combination of tenofovir disoproxil fumarate plus emtricitabine. The SPC was granted by the Swiss Institute of Intellectual Property on 29 August 2008 based on the marketing authorization for TRUVADA®, a medication used to treat (and in some jurisdictions also to prevent) HIV/AIDS. It is a fixed-dose combination of the two antiretroviral medications tenofovir disoproxil fumarate and emtricitabine.

On 3 January 2017 Mepha Pharma AG, a Swiss subsidiary of Teva, filed a revocation action against Gilead's Swiss SPC. Mepha essentially argued that the *ratio legis* of the Swiss law on SPCs requires that the "infringement test", which had been confirmed in a decision of the Swiss Federal Supreme Court in 1998 (BGE 124 III 375), be set aside, and that this change of practice shall be applicable with immediate effect even for existing SPCs. Mepha was of the opinion that Swiss courts should apply EU case law and if it did, Gilead's SPC would be invalid in light of the practice of the CJEU for combination products because the two active ingredients were not specified in the claims of the basic patent and did not correspond to the basic patent's core inventive

advance.

Gilead argued several lines of arguments. First, it was of the opinion that Switzerland should stick to the infringement test. Second, it argued that even if the EU practice for SPCs for combination products were to be introduced in Switzerland, this practice would only apply to new SPCs whose applications were filed after the change of practice. A change of practice could not have a retroactive effect according to Gilead. Third, Gilead took the position that even if the criteria established by the CJEU would apply to existing Swiss SPCs, those requirements – if correctly interpreted and applied – would be fulfilled by the SPC for TRUVADA®.

In October 2017 the Swiss Federal Patent Court ruled that it was not appropriate to move away from the infringement test that had been applied in Switzerland since the Supreme Court's decision BGE 124 III 375 (Fosinopril) in 1998. The Federal Patent Court examined several decisions of the CJEU dealing with SPCs for combination products (i.e. C-322/10 – Medeva, C-518/10 – Yeda, C-630/10 – University of Queensland, C-6/11 – Daiichi Sankyo, C-493/12 – Eli Lilly, and C-443/12 – Actavis/Sanofi) and came to the conclusion that the requirements of Article 3(a) of the EU SPC-Regulation No 469/2009, i.e. whether the product of an SPC is protected by the basic patent, are unclear and, therefore, there was no reason to move away from the infringement test.

According to previous Swiss case law, it was not necessary that the product of the SPC be named and described in the basic patent. Rather, it was sufficient if the product was covered by the scope of the basic patent. The Federal Patent Court therefore dismissed the revocation action brought by Mepha against Gilead's Swiss SPC.

The decision of the Federal Supreme Court

Mepha filed an appeal against the verdict of the Federal Patent Court with the Swiss Federal Supreme Court. On 11 June 2018 the Federal Supreme Court dismissed Mepha's appeal, but the dismissal is based on other grounds.

The Federal Supreme Court concluded that SPCs for combination products granted under the infringement test (as confirmed by the Federal Supreme Court in 1998) were still to be assessed in light of the requirements of the infringement test. In an *obiter dictum,* however, the Federal Supreme Court ruled that new SPCs for combination products must comply with the requirements of the Medeva et al. case law of the CJEU in the future.

Whether Gilead's SPC for TRUVADA® meets these requirements was left open by the Federal Supreme Court, as this question is irrelevant since this SPC will continue to be judged according to the infringement test.

Change of practice

The Federal Supreme Court held that a diverging practice between the CJEU and the Swiss courts in the field of SPCs could be a serious reason for a change in practice of the Swiss law. The Federal Supreme Court was of the opinion that Swiss lawmakers

wanted to harmonize the Swiss law on SPCs with the laws in the EU. In this context, the Federal Supreme Court emphasized that the interpretation of the requirement "protected by a patent" according to Article 140b para. 1 lit. a of the Swiss Patent Act in the Fosinopril decision in 1998 (BGE 124 III 375) differed from the interpretation of "protected by a basic patent in force" according to Article 3(a) of the EU SPC-Regulation No 469/2009 by the CJEU according to the previous Swiss case law.

Due to the fact that the Swiss legislature wanted to bring the protection of SPCs into harmony with that of the neighboring jurisdictions the Federal Supreme Court advocates an adaptation to the concept of the CJEU case law as expressed in the decisions of Medeva et al. However, the CJEU case law shall only apply to new SPCs according to the Federal Supreme Court.

Existing SPCs are still subject to the infringement test

The Federal Supreme Court examined whether a change of practice could and should have an effect on SPCs that had already been granted, and, thus, whether Gilead's SPC is valid even in the (not conclusively assessed and therefore hypothetical) case that the requirements for granting an SPC in light of the case law of the CJEU might not be fulfilled.

The Federal Supreme Court emphasized that Gilead's SPC had been legally granted in light of the infringement test in force at the time of the application and grant of Gilead's SPC. The nullity grounds of the Swiss Patent Act refer to the question of whether the conditions for granting the SPC were fulfilled at the time of filing the SPC application. In the opinion of the Federal Supreme Court, this was clearly the case, since the infringement test was undisputedly the relevant test at the time Gilead's SPC application was submitted to the Swiss Institute of Intellectual Property.

The Federal Supreme Court then examined whether, as an exception, a validly granted SPC can be revoked only because of a later change of practice, or more generally speaking, whether a legally binding administrative decision like the grant of an SPC could be reconsidered or revised as a result of a legal change of practice. As a general rule, the grant of an SPC cannot be revoked due to a later change of practice if the interest of the holder of the SPC in protecting his exclusive rights precedes the interest in the uniform implementation of the new law. Although this rule does not apply in absolute terms, the Federal Supreme Court could not see any particularly significant interest that would clearly demand a revocation of Gilead's lawfully granted SPC simply because a change of practice has taken place many years after the grant. In the opinion of the Federal Supreme Court, Gilead's interest in protecting its exclusive rights is clearly higher than the interest that in Switzerland all SPCs for combination products must be subject to exactly the same rules in the future.

Comments

The recent ruling of the Federal Supreme Court strikes an interesting balance between the confidence of the owners of existing SPCs in the current practice and the industry's interest in creating an EU-compatible system for Swiss SPCs. The judgment tries to protect the interests of patent owners and marketing authorization holders of

originator pharmaceutical products who have made time-consuming and costly efforts in the authorization and marketing of their products on the one hand and the interest of the industry in bringing Swiss case law in line with the European Union practice.

One question seems to remain open even after the decision of the Federal Supreme Court: According to the language of the decision of the Federal Supreme Court, the infringement test seems to apply to already granted SPCs. However, what happens with pending applications for SPCs for combination products? Those applications have been filed in light of the previous practice (i.e. by relying on the infringement test) as well. The Swiss Federal Patent Act explicitly provides that an SPC shall be granted if the requirements for the grant of the SPC are met at the filing date of the application. The applications for SPCs for combination products that are still pending before the Swiss Institute of Intellectual Property were filed in light of the then valid infringement test. It remains to be seen whether the fact that those applications have not yet resulted in a formal grant will make a major difference in whether they are examined in light of the infringement test or the EU case law.

For example, on 11 January 2007 the Grand Chamber of the European Court of Human Rights decided that a trademark application had to be protected as private property in the sense of Article 1 of the Protocol to the Convention for the Protection of Human Rights and Fundamental Freedoms (Anheuser-Busch, Inc. v. Portugal, Case No. 73049). Although Switzerland has not ratified this protocol the considerations of the Grand Chamber of the European Court of Human Rights nevertheless seem to be relevant when examining the legal nature of an SPC application.

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