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Update

Newsflash June 2018

Fresh from the Swiss courts – Important new judgments on supplementary protection certificates

The action continues at the Swiss SPC front. This month brought two judgments dealing with important legal questions in connection with SPCs that are of core importance to pharmaceutical companies with business in Switzerland.

The catalogue of nullity grounds of Article 140k of the Swiss Patent Act is exhaustive.

In a judgment dated 12 June 2018 the Federal Patent Court (FPC) decided that article 140k of the Swiss Patent Act (PA) lists in an exhaustive manner all nullity grounds which can be invoked against SPCs. The six months application deadline of article 140f PA is not listed in this catalogue and therefore an allegedly wrong reinstatement of such deadline cannot be invoked as nullity ground in civil proceedings.

According to the Swiss Patent Court, the same applies for the catalogue of nullity grounds of article 15 i.c.w. article 3 Regulation (EC) No 469/2009.

The catalogue of article 140k PA basically corresponds to article 15 in connection with article 3 of the SPC Regulation (Regulation (EC) No 469/2009). The Swiss rules on SPCs were enacted in 1995 with the aim to largely harmonise Swiss law with EC law. Accordingly, article 140l para. 2 PA orders the Federal Council to take the EC regulations into account when enacting ordinances on the grant procedure, the registration in the patent registry and publications of the Federal Institute of Intellectual Property. However, according to the FPC, article 140l para. 2 PA does not address the civil courts and does therefore not oblige these to follow EC case law. Nonetheless, the FPC took EC case law into account when deciding this case. Defendant (who had invoked nullity of the SPC as a result of an allegedly wrong reinstatement) had argued with reference to several judgments of the CJEU, the German Federal Patent Court and the High Court of England and Wales that EC law does not restrict the catalogue of nullity grounds. The FPC however followed Plaintiff's view that none of these judgments enlarged the catalogue of nullity grounds of article 15 in connection with article 3 SPC Regulation, but that additional provisions, such as article 19 or article 2 had only been used to interpret the criteria of article 3.

Please note that this judgment is not yet final as it could still be appealed to the Federal Supreme Court.

New test for combination products: the infringement test will be replaced by the disclosure theory for new SPCs.

On 11 June 2018 the Federal Supreme Court issued a landmark decision in the *Truvada*® case where it decided to move away from the infringement test for future SPCs for combination products.

In Switzerland the infringement test had been applied since 1998 when the Federal Supreme Court (FSC) decided in the *Fosinopril* case (SCJ 124 III 375) that this test was applicable. As a consequence, it was not necessary that the product of an SPC be named and described in the basic patent as long as it was covered by the scope of such patent. At the time of the *Fosinopril* judgment, the infringement test was also the pertinent test in the EU and the FSC had explicitly stated that EU practice needs to be taken into account in view of the large harmonization of the Swiss SPC rules with the EC regulation.

The infringement test had been applied ever since, although newer judgments somewhat reflected the considerations of the CJEU that had meanwhile moved to the disclosure theory (for instance, the Federal Administrative Court had considered the "patented idea of invention" and the "core of the invention" in its *Panitumumab* decision of 18 August 2011).

In the *Truvada*® case the question was brought before the FPC which ruled in October 2017 that the infringement test was still applicable in Switzerland and that there was no necessity to move away from such test, particularly in view of the uncertainties regarding the application of the newer criteria developed by the CJEU.

Not right so, found the FSC upon appeal. The aim to harmonize the level of protection granted by Swiss SPCs with the level of protection applicable in the EU, also brought a certain necessity to follow EU practice in this respect, at least to the extent it reflects the solution enacted by the Swiss legislator and as long as there are no better reasons for a deviant Swiss practice.

The FSC concluded that the CJEU's disclosure theory, which had been introduced with the *Medeva* judgment and has been further developed since, should now also be applied in Switzerland, however only for new SPCs.

SPCs that have been granted prior to the judgment of 11 June 2018 remain subject to the infringement test.

Pursuant to the FSC, SPCs granted by a formally final administrative act cannot be reconsidered or reversed on the basis of changed case law. The acquired legal positions continue to enjoy protection. The infringement test therefore remains applicable to SPCs granted prior to 11 June 2018.

Which test applies to pending SPC applications?

Note that the FSC did not state which test will be applicable for pending SPC applications. To our knowledge, the Federal Institute of Intellectual Property (FIIP) has not yet decided how to proceed with respect to such applications. In our view, against the background of the FSC's considerations, pending applications should be assessed under the newly applicable disclosure theory. There is not yet a formally final administrative act that would need to be respected. What is more, no legal position has been acquired so far which could be weighed up against the public interests in health care and in a harmonization of the scope of protection of SPCs in our neighbouring countries.

Should the FIIP follow this view, it will likely give applicants a possibility to amend their applications to the extent necessary in view of the changed practice.

How will new combination products be assessed in Switzerland?

The FSC judgment of 11 June 2018 made it clear that an SPC for new combination products can only be granted if all active ingredients are encompassed by the wording of the claims, either explicitly or, if construed in the light

of the description, implicitly, but necessarily and specifically. It therewith took up the *Medeva* and *Eli Lilly* criteria.

Interestingly, the application of these criteria had already been the subject of a consultation process started by the FIIP some years ago as part of an initiative of the FIIP to change its SPC granting practice to bring it in line with EU case law. After the FPC had confirmed the applicability of the infringement test in the *Truvada*® litigation and it became clear that the FSC would have to assess this question on appeal, the FIIP had stayed its initiative. However, now that the FIIP's autonomous approach became the blessing of the FSC, the FIIP can rely on its previous work with respect to the application of the *Medeva/Eli Lilly* criteria.

And the *Actavis* approach of the CJEU? On this point the consultation of the FIIP had shown major disagreement. The FIIP will likely have to revise its initial suggestions and will possibly open a new consultation over the next months.

Update on the introduction of paediatric extensions/paediatric SPCs – Call for questions

We have previously reported that in the course of the revision of the Therapeutic Products Act (TPA), the availability of medicinal products for paediatric use has been enhanced by providing incentives to the industry in the form of special paediatric SPCs or prolongations of existing SPCs (paediatric extensions). It is currently planned to enact the new provisions as of 1 January 2019.

The FIIP will hold an information event on 16 October 2018 where questions in relation to the new paediatric extensions/SPCs will be answered. The FIIP encourages interested parties to file specific questions beforehand in order to ensure that it can address them appropriately. Please do get in touch with us if you have questions that we should report to the FIIP.

Please do not hesitate to contact us in case of any questions.

Your contacts

Thierry Calame
thierry.calame@lenzstaehelin.com
Tel: +41 58 450 80 00

Lara Dorigo
lara.dorigo@lenzstaehelin.com
Tel: +41 58 450 80 00

Our offices

Geneva
Lenz & Staehelin
Route de Chêne 30
CH-1211 Genève 6
Tel: +41 58 450 70 00
Fax: +41 58 450 70 01

Zurich
Lenz & Staehelin
Brandschenkestrasse 24
CH-8027 Zürich
Tel: +41 58 450 80 00
Fax: +41 58 450 80 01

Lausanne
Lenz & Staehelin
Avenue de Rhodanie 58
CH-1007 Lausanne
Tel: +41 58 450 70 00
Fax: +41 58 450 70 01

www.lenzstaehelin.com