Kluwer Patent Blog

Things to remember about Swiss patent litigation in 2017

Simon Holzer (MLL Meyerlustenberger Lachenal Froriep Ltd.) · Sunday, January 7th, 2018

I hope that all the readers of the Kluwer Patent Blog enjoyed a good start into a joyful, healthy and successful 2018. At the beginning of the new year it seems to be the right point in time to look back at the past year and recall the most remarkable developments and cases in Swiss patent litigation.

New President of the Swiss Federal Patent Court

Probably the most sustaining innovation will be the new presidency of the Swiss Federal Patent Court. On 14 June 2017, the Swiss parliament voted Dr. Mark Schweizer, LL.M., into office as President of the Swiss Federal Patent Court. He began his duties on 1 January 2018 and replaced Dr. Dieter Brändle, who retired as the first President of the Swiss Federal Patent Court. Mr. Brändle contributed very much to the success story of the new court. We would like to thank him for his tremendous job and wish Mr. Schweizer all the best in his new position.

Decision of the Swiss Federal Supreme Court in the Pemetrexed saga concerning the doctrine of equivalence

One of the Swiss cases that will outlive the past year and stick in our memories for a longer period of time is the Pemetrexed decision of the Federal Supreme Court of 20 October 2017 in the matter of Eli Lilly vs. Actavis regarding the infringement by equivalent means of Eli Lilly's patent EP 1 313 508 (not only because the Supreme Court remanded the case back to the Federal Patent Court and we can therefore expect a new decision in this matter in 2018).

Unlike in other jurisdictions, the Federal Supreme Court's decision focused on the question of the infringement of Eli Lilly's patent by equivalent means and did not deal with the issue of direct and indirect infringement.

The Swiss Supreme Court sided with the German Court of Justice (BGH) (see the German court's decision X ZR 29/15 here) and the UK Supreme Court (see the UK court's decision [2017] UKSC 48 here) and came to the conclusion that the fact that the wording of the claims of Eli Lilly's patent had been narrowed down during prosecution from the broad term "antifolate" to "pemetrexed" and finally to "pemetrexed disodium" does not exclude that these claims are infringed by equivalent means by Actavis' pharmaceutical product Amtiris®, which comprises pemetrexed diacid.

As most of the readers are well aware, the independent claims of Eli Lilly's patent as granted include inter alia pemetrexed disodium in combination with vitamin B12 or a pharmaceutical

derivative thereof for inhibiting tumor growth.

The Swiss Supreme Court overturned the previous declaratory judgment of non-infringement of the Swiss Federal Patent Court and found Actavis' generic pemetrexed diacid product, Amtiris®, to infringe Eli Lilly's patent EP 1 313 508.

While the Federal Patent Court denied infringement of Eli Lilly's patent by Actavis' generic version comprised of pemetrexed diacid because of the limitation introduced by the patentee during examination proceedings, the Supreme Court disagreed and granted Eli Lilly's appeal against the decision of the Federal Patent Court. The Supreme Court applied the Swiss standard test for patent infringement by equivalent means (*three-step-test)* based on its settled case law (BGE 142 III 772 E. 6.2 with references)*: Firstly*, the modified feature must objectively achieve the same function for the implementation of the technical teaching as the feature claimed in the patent ("same effect"); *secondly*, the modified feature and its objective function must be made obvious to the skilled person by the patented teaching ("accessibility"), and as *third* criterion, parity is required in the sense that the skilled person considers the modified embodiment as a solution of equal value ("equality").

The Swiss Federal Supreme Court did not follow the Federal Patent Court's opinion with respect to the third question, in other words: whether the skilled person, after having read the patent, would consider the modified embodiment (i.e. a pharmaceutical product comprising pemetrexed diacid) as a solution of equal value as the claimed solution (pemetrexed disodium). By contrast to the opinion of the Patent Court, which essentially denied equality in its finding because the appellant willingly limited its patent claims to the disodium form of pemetrexed, the Supreme Court concluded that the skilled would have no reason to assume that the patent proprietor had claimed protection only for the literal embodiment. Even a limited patent claim might enjoy protection against equivalent infringement.

This interpretation of the Swiss Federal Supreme Court follows the judgments of the UK Supreme Court and the German Court of Justice in their parallel procedures. The German court came to the conclusion that the pemetrexed matter does not have to be decided the same way as the "Okklusionsvorrichtung" case (X ZR 16/09, 10 May 2011).

In its previous decision, the Swiss Federal Patent Court criticized the ruling of the German Court of Justice with regard to the *third question* of the equivalent infringement test. According to the Swiss Federal Patent Court, the mere fact that the Eli Lilly's pemetrexed patent does not contain an (implicit) waiver of the patentee in the sense of the "Okklusionsvorrichtung" decision does not mean that the third question of the equivalent infringement test should be affirmed:

"Der BGH fokussiert sich bei der Beurteilung der dritten Äquivalenzfrage allerdings sehr auf diese Frage des Verzichts. Dem kann nicht gefolgt werden. Die Tatsache, dass kein Verzicht gemäss "Okklusionsvorrichtung" vorliegt, bedeutet nicht automatisch im Umkehrschluss, dass die dritte Äquivalenz-Frage zu bejahen ist. Das greift zu kurz."

However, I believe that the German Court of Justice (and the Swiss Supreme Court) got it right: If the modified feature has the "same effect" (*first question of the equivalence infringement test*) as the claimed feature and complies with the "accessibility" requirement of the second question, the attacked embodiment normally infringes the patented claim if there is no exemption under *settled case law* that allows a court to deny the infringement in special circumstances, such as the German

Federal Court of Justice examined (but denied) by considering whether the pemetrexed case is similar to the "Okklusionsvorrichtung" ruling. The *burden of proof* with respect to such an exemption lies with the potential infringer of the patent.

Validity of SPCs for combination products

Another landmark decision that might have long-term effects is the Federal Patent Court's ruling concerning the validity of Gilead's SPC for tenofovir disoproxil fumarate plus emtricitabine of 3 October 2017 (please note that the law firm of Meyerlustenberger Lachenal AG has been involved in this case on behalf of the owner of the SPC).

Art. 140b para. 1 lit. a of the Swiss Patent Act requires that with respect to SPCs the product as such, a process for manufacturing it or a use of it must be protected by a basic patent. In a case regarding to this rule the Swiss Federal Patent Court issued a judgment in October 2017 confirming the validity of Gilead's SPC for a composition containing tenofovir disoproxil fumarate in combination with emtricitabine, based on the Swiss portion of EP 915 894 and the marketed pharmaceutical product Truvada®, a medicinal product used with other HIV-1 medicines to treat HIV-1 infection.

Mepha, a Swiss subsidiary of Teva, sought a declaration of invalidity of Gilead's Swiss SPC. It did not attack the validity of the basic patent EP 0 915 894. In addition, neither party disputed that Truvada® would infringe the (expired) basic patent and that Gilead's SPC was therefore valid under the so-called infringement test.

The basic patent explicitly mentions tenofovir disoproxil, but not emtricitabine. Mepha argued that Switzerland should abandon the infringement test traditionally employed (see the Swiss Supreme Court decision BGE 124 III 375 – Fosinopril of 10 July 1998) in favor of the ECJ's case law of Medeva and the following decisions concerning SPCs for combination products. If applied to the combination of tenofovir disoproxil and emtricitabine, this would, according to Mepha's point of view, lead to the nullity of Gilead's SPC.

The Swiss Federal Patent Court came to the conclusion that in light of the still unclear case law in the EU there is no reason to change the Swiss practice and move away from the infringement test when examining the validity of Swiss SPCs for combination products. Harmonization of Swiss law with EU law did not compel adopting the ECJ's case law of Medeva by Swiss courts. While it was correct that the Swiss SPC was introduced to harmonize Swiss law with the (then) relevant European legislation regarding SPCs, a complete harmonization was unnecessary according to the court because it would not lead to better market access of pharmaceutical products in Switzerland or in the EU. Switzerland is not part of the EU regulatory framework for the approval of pharmaceuticals. Drugs approved in the EU would still need separate authorization in the EU, and vice-versa.

The Swiss Federal Patent Court could have left it at this, but it went on to assess whether applying the ECJ's case law would benefit legal certainty. The court summarized the various decisions of the ECJ concerning SPCs and concluded that the ECJ's jurisprudence in this area of law was a "terminological mess" ("terminologisches Durcheinander"). Therefore, the Federal Patent Court did not feel seduced to move away from the infringement test.

Mepha filed an appeal against the ruling of the Federal Patent Court and we might expect a decision of the Federal Supreme Court in the summer of 2018.

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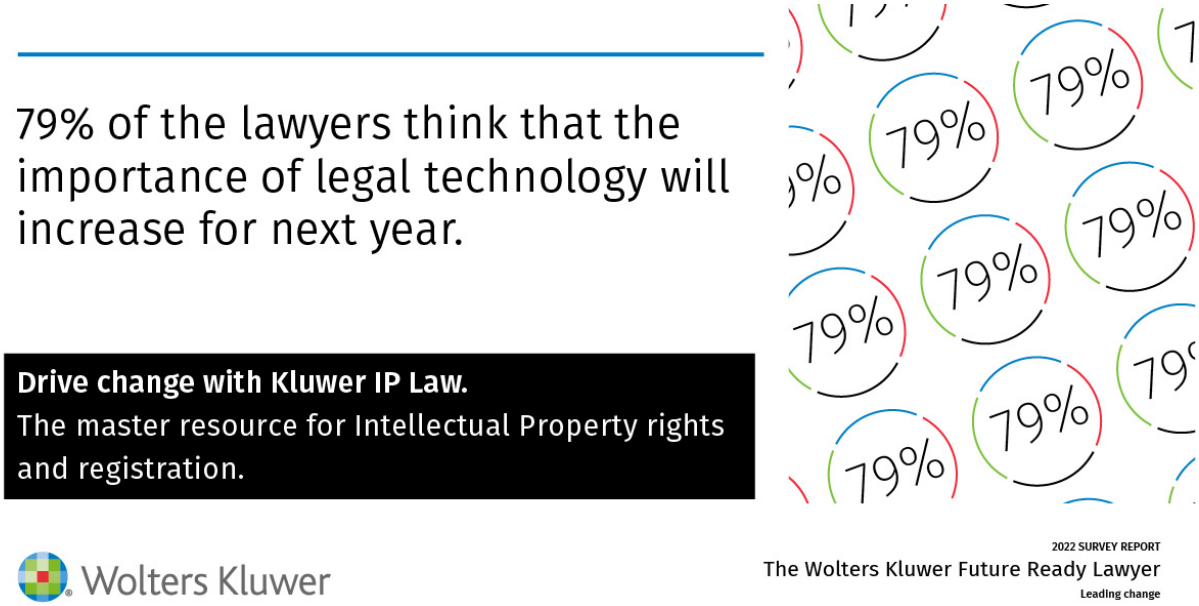

This entry was posted on Sunday, January 7th, 2018 at 9:47 pm and is filed under literally fulfil all features of the claim. The purpose of the doctrine is to prevent an infringer from stealing the benefit of an invention by changing minor or insubstantial details while retaining the same functionality. Internationally, the criteria for determining equivalents vary. For example, German courts apply a three-step test known as Schneidmesser's questions. In the UK, the equivalence doctrine was most recently discussed in Eli Lilly v Actavis UK in July 2017. In the US, the function-way-result test is used.">Equivalents, Litigation, Pharma, SPC, Switzerland
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