Kluwer Patent Blog

Highlights of Swiss patent litigation in 2023: Swiss Federal Patent Court on SPC for sitagliptin and metformin

Simon Holzer (MLL Legal Ltd.) · Sunday, February 4th, 2024

From the potpourri of decisions that the Swiss Federal Supreme Court handed down last year, I have selected one in subjective hindsight that I consider to be particularly relevant regarding further cases. The outcome of most decisions of the Swiss Federal Patent Court in 2023 heavily depended on the specific circumstances and the effects of these rulings on other cases is therefore somewhat limited. A noteworthy exception is the dispute between Merck Sharp & Dohme LLC (MSD) versus Spirig HealthCare AG (Spirig, a Stada subsidiary).

Said case concerned MSD's Swiss SPC for the combination of sitagliptin and metformin. Although Swiss law on SPCs differs from EU law in some respects, Swiss courts are expected to follow the case law of the CJEU in the interpretation of the EU SPC Regulation.

SPCs for sitagliptin (concerning the monosubstance or combinations with other active ingredients) have led to several court rulings in various jurisdictions and have therefore attracted some comments by the Kluwer Patent Blog (see, for example, here and here).

Pharmaceutical products Januvia® and Janumet®

Sitagliptin is a successful treatment for type II diabetes. It is distributed in Switzerland by MSD under the brand name Januvia®. MSD obtained a Swiss marketing authorization for Januvia® on 18 April 2007. According to the SmPC of Januvia®, the drug can be combined with pharmaceutical products with the active ingredient metformin if patients do not achieve adequate glycemic control with metformin alone.

MSD also offers a fixed-dose combination product containing a combination of the active ingredients sitagliptin and metformin. This fixed-dose combination obtained its Swiss marketing authorization approximately one year later, i.e., on 8 April 2008. It is sold under the brand name Janumet®.

Basic patent and Swiss SPCs

Based on the basic patent EP 1 412 357 B1 (expired on 5 July 2022), MSD obtained two Swiss SPCs, namely C01412357/01 for the fixed-dose combination of sitagliptin and metformin (granted on 31 December 2009, expired on 7 April 2023) and C01412357/02 for monosubstance sitagliptin (granted on 23 November 2021 in the form of a pediatric SPC with a term of six months (pediatric SPCs are special SPCs under Swiss law that do not have a direct equivalent under EU law).

Because of its six-month term, the pediatric SPC for sitagliptin expired on 4 January 2023 already).

The basic patent EP 1 412 357 B1 relates to the treatment of diseases in which the activity of DP IV enzymes is involved, such as diabetes, characterized by elevated plasma glucose levels or hyperglycemia in the fasting state or after administration of glucose during an oral glucose tolerance test. The basic patent as granted includes 30 claims relating to ?-amino-substituted tetrahydrotriazolopyrazine anti-diabetic agents, including, but not limited to, sitagliptin.

Claim 15 of the basic patent mentions sitagliptin with 59 other compounds. It is also encompassed in the Markush formula of claim 1 of the basic patent. Furthermore, claim 18 as granted describes the use of, inter alia, sitagliptin or a pharmaceutically acceptable salt thereof for the manufacture of a medicament for the treatment, control, or prevention of diabetes, non-insulin-dependent (type 2) diabetes mellitus, hyperglycemia, obesity, insulin resistance or lipid disorders. Claim 25 refers to a composition according to claims 1 to 15 and an insulin sensitizer selected from 15 groups of compounds to which metformin belongs.

Facts of Swiss dispute

When Spirig obtained a Swiss marketing authorization for a generic fixed-dose combination for sitagliptin and metformin, MSD requested Spirig to confirm that they would respect MSD's two Swiss SPCs. Spirig announced that they would respect the pediatric SPC for sitagliptin but refused to confirm the same for the combination SPC. Spirig argued that the SPC for the combination of sitagliptin and metformin was invalid and referred to the ruling of the German Federal Patent Court of 23 June 2021 that held the German SPC for sitagliptin and metformin invalid (decision of the German Federal Patent Court 3 Ni 2/20 combined with 3 Ni 24/20 and 3 Ni 3/21 of 23 June 2021. The SPC holder in Germany appealed the ruling of the German Federal Patent Court (see case no. BGE X ZR 64/21 of the German Federal Court of Justice)).

In Switzerland, after a first unsuccessful attempt, MSD was able to demonstrate in an amended PI application that there was new evidence that Spirig had entered the market with a fixed-dose combination containing sitagliptin and metformin in January 2023. The President of the Swiss Federal Patent Court therefore issued an ex-parte PI on 16 January 2023 against Spirig based on MSD's Swiss SPC for the combination of sitagliptin and metformin. After having heard both parties, the Swiss Federal Patent Court confirmed the PI against Spirig in a judgment of 27 March 2023.

Turning back to the alleged invalidity of the combination SPC, the Swiss Federal Patent Court held that the 'infringement test' still applied to C01412357/01 in connection with the question of whether the combination of sitagliptin and metformin mentioned was protected by the basic patent (Art. 140b para. 1 lit. a Swiss Patent Act, Art. 3(a) EU SPC Regulation). The Swiss Federal Patent Court referred to the case law of the Swiss Federal Supreme Court. In a judgment of 11 June 2018, the Swiss Federal Supreme Court switched from the previously applicable infringement test to the test for combination products according to Art. 3(a) EU SPC Regulation advocated by the CJEU (see this blog here). However, the Swiss Federal Supreme Court stated at the same time that the new case law should not apply to Swiss SPCs granted before its judgment of 11 June 2018. SPCs that are older than 11 June 2018 should still be assessed according to the infringement test.

The immediate application of the new case law of the CJEU to existing SPCs would have violated the principle of trust and good faith according to the Swiss Federal Supreme Court. Since MSD's

SPC for the combination of sitagliptin and metformin was granted long before the judgment of the Swiss Supreme Court of 11 June 2018, the Federal Patent Court did not examine whether the requirements of Art. 140b para. 1 lit. a Swiss Patent Act and Art. 3(a) EU SPC Regulation according to the current case law of the CJEU were given, but simply referred to the requirements of the infringement test, which were obviously met.

Core of Swiss dispute: is SPC for sitagliptin and metformin based on the first marketing authorization according Art. 140b para. 2 Swiss Patent Act (Art. 3(d) EU SPC Regulation).

The core of the Swiss dispute revolved around the question whether the SPC for sitagliptin and metformin is based on the first marketing authorization or whether the earlier authorization for the monosubstance sitagliptin should be regarded as the first authorization in the sense of Art. 140b para. 2 Swiss Patent Act (Art. 3(d) EU SPC Regulation).

Spirig argued that the combination of the active ingredients sitagliptin and metformin would not lead to an additional “inventive advance” as requested by the German Federal Patent Court. The simultaneous administration of the monopreparation sitagliptin in combination with metformin had already been possible according to the marketing authorization for the monopreparation Januvia®.

According to Spirig, the identification of the composition of sitagliptin and metformin in the claims of the basic patent was not sufficient to qualify this composition as an independent (inventive) product. Spirig stated that the combination was neither based on an additional inventive concept nor could it be attributed an inventive advance over the monosubstance. According to Spirig, the first authorization pursuant to Art. 140b para. 2 Swiss Patent Act (Art. 3(d) EU SPC Regulation) was therefore the authorization granted for the monosubstance sitagliptin on 18 April 2007 and not the authorization subsequently granted for the combination in the fixed-dose formulation on 8 April 2008. Spirig therefore argued that the SPC for the combination should not have been granted because it was not based on the first marketing authorization for the product.

The Swiss Federal Patent Court was not convinced by this argument. The court stated that although the marketing authorization for the monopreparation Januvia® permitted the simultaneous administration of sitagliptin and metformin, it did not permit the marketing of a combination of sitagliptin and metformin in a fixed-dose product. A separate marketing authorization was required for this. The first authorization for the fixed-dose combination of sitagliptin and metformin was therefore the authorization for Janumet® of 8 April 2008 according to the Swiss Federal Patent Court.

The court did not agree with Spirig’s view that the combination product, which was authorized only after the monopreparation and is protected by the same basic patent as the first authorized product, must differ from the latter by an “inventive advance” for an SPC to be granted. The Swiss Federal Patent Court considered the corresponding understanding of the German Federal Patent Court to be incorrect and not supported by European case law.

Importance of principle of trust and good faith

Interestingly, the Swiss Federal Patent Court in an obiter dictum referred to the principle of trust and good faith in this context and stated that even if one were to follow the interpretation of European case law by the German Federal Patent Court, this would not lead to the revocation of the combination SPC for sitagliptin and metformin, which was granted more than twelve years ago, because of the principle of trust and good faith.

The Swiss Federal Patent Court pointed out that the combination SPC has been applied for on 17 September 2008 and had been granted on 31 December 2009. At that time, it was established Swiss practice to grant an SPC for a combination of active ingredients even if an SPC had already been granted for one of the individual active ingredients. If, following the German Federal Patent Court, one were to conclude from the case law of the CJEU that it was not sufficient for the concerned pharmaceutical products to be clearly different under pharmaceutical law but would additionally require that the products in question are to be regarded as "independent inventions", this change of practice would not apply retroactively to MSD's SPC granted around twelve years ago under a different regime in Switzerland.

The Federal Patent Court again referred to the leading case of the Federal Supreme Court in the Truvada SPC matter (combination of disoproxil fumarate plus emtricitabine) of 18 June 2018. As mentioned above, in said judgment, the Federal Supreme Court emphasized that the grant of an SPC was protected by the principle of trust and good faith, and that a revocation of an SPC because of a change of practice was only reasonable if the revocation was required by a particularly important public interest. According to the Federal Supreme Court, the retroactive application of new case law requires a significant public interest, which does normally not exist.

It is noteworthy that the Swiss Federal Patent Court applied the principle of trust and good faith established by the Federal Supreme Court not only in connection with the examination of the requirements pursuant to Art. 140b para. 1 lit. a Swiss Patent Act (Art. 3(a) EU SPC Regulation) (the Federal Supreme Court's judgment of 11 June 2018 in the Truvada SPC matter dealt with this question) but also extended this concept to the assessment of the validity of SPCs according to Art. 140b para. 2 Swiss Patent Act (Art. 3(d) EU SPC Regulation).

From a Swiss perspective, it will be interesting to follow the proceedings before the CJEU in the matter C-119/22 (initiated by the Finnish Market Court on 17 February 2022) and before the German Federal Court of Justice in the case no. X ZR 64/21. Both cases concern national SPCs for the combination of sitagliptin and metformin. However, the Swiss Federal Patent Court rightly pointed out that the situation in Germany and in Finland was slightly different from the facts of the Swiss case. In Germany and Finland, an SPC for the monopreparation sitagliptin had already been granted at the time when the SPC for the combination of sitagliptin and metformin was granted. In Switzerland, the SPC for the combination was the first SPC.

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